Saturday 27 June 1998

BMJ

All changed, changed utterly

British medicine will be transformed by the Bristol case

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"The Bristol case," in which judgment was passed last week[1] will probably prove much more important to the future of health care in Britain than the reforms suggested in the white papers. Reorganisations of the NHS come round with monotonous regularity, but changes on the wards and in surgeries are slow and often unrelated to the passing political rhetoric.[2 3] In contrast, the Bristol case is a once in a lifetime drama that has held the attention of doctors and patients in a way that a white paper can never hope to match. The case has thrown up a long list of important issues (see box) that British medicine will take years to address. At the heart of the tragedy, which has been Shakespearean in its scale and structure, is, as the GMC said, "the trust that patients place in their doctors." That trust will never be the same again, but that will be a good thing if we move to an active rather than a passive trust, where doctors share uncertainty.

The trust between doctors and patients works on two main levels: between individual patients and doctors and between society and doctors' organisations. The Bristol case will affect both. The most profound—but least easily measured—effect may well be on the relationship between individual doctors and patients. In the past two weeks the case must have been in the minds of many patients consulting doctors, particularly those about to undergo operations. Worldwide, the doctor-patient relationship is changing.[4–6] For instance, the main theme of last week's world conference of general practitioners in Dublin was the change from patients being passive recipients of care to being active partners in all decisions; it was also the theme of the first conference to celebrate the 50th anniversary of the NHS. Evidence is growing that as patients become equal partners in the doctor-patient relationship then outcomes and satisfaction improve and costs fall.[4 7] If the Bristol case hastens the move to patients being treated as equals it will have produced real benefit.

The Bristol case has already accelerated the move to provide patients with data on the performance of doctors and hospitals,[8–10] and this has to be a good outcome. Cardiothoracic surgeons have already taken impressive steps,[10] but they are way ahead of the pack. Doctors in other specialties, particularly non-surgical ones, are going to have to think hard and fast about how to gather and present data on their performance.[11] Neither gathering nor interpreting the data is easy,[12] and experts on improvement emphasise that such data are best used as a source of knowledge for improvement rather than for judgment.[13 14] If the Bristol case leads to an environment where we concentrate on removing bad apples rather than improving the whole system then both patients and doctors will suffer. There must be mechanisms for responding to doctors whose performance has deteriorated to an unacceptable level, but such mechanisms will never bring about the systemic improvements that we need.

Although dramas like the Bristol case are powerful levers for change, they tend to lead to key protagonists overreacting. Frank Dobson, the secretary of state for health, made a serious mistake last week when he announced on television that all three of the doctors in the Bristol case should have been struck off (only two were[1]). He has met several times with parents of the Bristol children, and it is understandable that he has been affected by their grief and outrage. Less understandably, he may also have been influenced by Labour spin doctors' interpretation of public opinion.

Issues raised by the Bristol case

The GMC identified several issues that arose during the course of its inquiry that concern the practice of medicine and surgery generally and that need to be addressed by the medical professsion.

- The need for clearly understood clinical standards
- How clinical competence and technical expertise are assessed and evaluated
- Who carries the responsibility in team based care
- The training of doctors in advanced procedures
- How to approach the so called learning curve of doctors undertaking established procedures
- The reliability and validity of the data used to monitor doctors' personal performance
- The use of medical and clinical audit
- The appreciation of the importance of factors, other than purely clinical ones, that can affect clinical judgment, performance, and outcome
- The responsibility of a consultant to take appropriate actions in responses to concerns about his or her performance
- The factors which seem to discourage openness and frankness about doctors' personal performance
- How doctors explain risks to patients
- The ways in which people concerned about patients' safety can make their concerns known
- The need for doctors to take prompt action at an early stage when a colleague is in difficulty, in order to offer the best chance of avoiding damage to patients and the colleague and of putting things right

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Even the strongest supporters of the Labour government bemoan its excessive concern with media opinion. Mr Dobson cannot possibly have read the evidence produced over more than 60 days at the GMC, and in a calmer moment he surely would not advocate judgment by public opinion rather than a judicial process that operates under act of parliament.

Mr Dobson will inevitably confer with his spin doctors and consider whether the time has come to end self regulation for doctors. The GMC, the keystone of self regulation, has long been criticised,[15 16] and the whole notion of self regulation—not least for members of parliament—is suspect in this age of increased accountability. My judgment is that the government will decide against wholesale reform of the GMC. Firstly, although previous presidents may have been slow to read the signs that self regulation was under threat, the current president, Sir Donald Irvine, has committed himself to substantial reform.[17 18] Secondly, the government won't want to waste its time fighting with doctors while trying to modernise the NHS: the rhetoric is all about partnership. Thirdly, the Treasury will not want to pick up the cost of trying errant doctors. Fourthly, a system run by non-doctors would inevitably depend on doctors for judgments on what was acceptable, and doctors (clever people still) would probably prove adept at subverting a system that they didn't own. Fifthly, the government will want to try out the many systems it has proposed in its white paper for raising performance.

Moreover, reforming the GMC misses the point: regulation of doctors is not all about the GMC. Innumerable groups influence the practice of doctors, and some of them, I have argued elsewhere, have much more influence than the GMC.[3] The council may control the ultimate sanction of removing a doctor's licence to practise, but its influence is not felt every day: to the average doctor it feels distant. In contrast, teachers and colleagues have both power and everyday influence. Royal colleges and postgraduate deans also have great influence, and they must recognise their role in self regulation. It is this local, everyday self regulation that has been especially weak, but there are now signs that it is being taken seriously.[19] The challenge is to maintain the impetus for improvement created by the Bristol case and turn fine words into effective actions.

The consequence for the British medical profession of failing to act effectively could be serious. The *BMJ* and other journals publish many studies showing that doctors fail to practise in line with the best evidence and continue to provide poor service: just last week the *BMJ* published the results of a confidential inquiry showing poor care of many patients before admission to intensive care units.[20] The government has proposed in its white paper the concept of clinical governance, which means that trust boards will be responsible not only for financial and legal affairs but also for ensuring a high standard of clinical care. It remains ambivalent over how much clinical governance is management of or management by clinicians. Failure of doctors' organisations to implement much better mechanisms for ensuring high quality of care may lead to the micromanagement of doctors that is routine in the United States.

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Central venous catheters—time for a change?

If you put them in properly you don't need to change them routinely

It is often difficult to ascertain exactly where a particular medical practice or policy originates. Thus it is with routine scheduled changes of central venous catheters in patients requiring prolonged intensive care. If we are to believe the telephone survey by Cyna et al in this week's issue (p 1944),[1] the policy of routinely replacing central venous catheters to reduce a perceived high incidence of catheter related sepsis appears to be ingrained in many British intensive care units. That this policy continues is surprising, since it is impossible to find a published randomised trial in the past 12 years supporting the contention that the incidence of catheter related sepsis increases with duration of catheterisation.

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Indeed, there are now several randomised controlled trials comparing routine catheter change with change when clinically indicated, and these have been the subject of a recent meta-analysis.[2] Although routine exchange over a guidewire is associated with fewer technical complications but a higher incidence of catheter colonisation and infection than routine replacement at a new site, neither approach confers any

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benefit when compared with changes only when clinically indicated. How recently had those units stating that their routine change policy was based on published evidence actually reviewed the literature, or are they confused with the evidence on pulmonary artery catheters—which should be removed within 72 hours of insertion?[3] A recent study has shown that the incidence of systemic infection associated with pulmonary artery catheterisation can be reduced to zero if the catheter is removed within 4 days.[4]

Routine change of central venous catheters is expensive and has appreciable morbidity and, in critically ill patients, potential mortality. Clearly, intensive care physicians supporting such a policy must perceive that there is a risk-benefit advantage. Is such a view justified? Published studies suggest that the risk of catheter colonisation is around 25% and of infection 5%[5–6]—levels far lower than most of us might have expected. Why is there this inaccurate perception of the size of the problem? Is it because outside trials, in routine clinical practice, the incidence of infection is far higher? Maybe it is because this nosocomial infection is by definition iatrogenic and leads to feelings of responsibility and guilt. The latter seems unlikely since many doctors have failed to accept the convincing evidence that use of maximal aseptic technique (sterile surgical field, surgical mask, gown, and gloves) at insertion significantly reduces infective complications.[7]

As multilumen catheters are no more likely to become infected than single lumen devices and have the additional benefit of reducing the need for peripheral venous access (just as susceptible to infection),[8] the days of the "no touch, no glove" insertion of single lumen internal jugular lines so beloved of cardiothoracic anaesthetists should be long past. Finally, it should be remembered that, although a patient with catheter related sepsis may present seriously ill with severe haemodynamic disturbance, removal of the catheter is often the only treatment needed, and these infections generally run a relatively benign course.[9]

It appears that many British intensive care units need to review their policies on inserting and changing central venous catheters. As well as improving insertion technique and abandoning the routine change, doctors should also consider other changes supported by evidence from randomised clinical trials: the use of povidone-iodine ointment and cotton gauze dressings at insertion[6] and of catheters impregnated with antibiotics or antiseptics. One study has shown a reduction in the incidence of colonisation to 13.5% and of infection to 1% with a catheter impregnated with chlorhexidine and silver sulphadiazine.[5] Once the catheter is inserted, the environmental factors shown to reduce colonisation and infection are provision of adequate nursing and medical staffing levels,[10] use of special teams for catheter care, and avoiding excessive manipulation of the catheter.[6] It might be interesting if Cyna and colleagues were to repeat their study in, say, a year's time so that we can see if the message has finally filtered through. More likely, the intensive care community will be so fed up of answering these time consuming telephone calls that we shall never know.

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Controversy in managing patients with prostate cancer

Banish dogma, get more data

Life is uncertain, and never more so than when a serious illness like prostate cancer strikes and a decision must be made about how to proceed. Ideally, the clinician would find (or remember) the relevant research, interpret the findings as they apply to the patient at hand, estimate prognosis, and discuss treatment options objectively and with compassion and support. Even then, life remains uncertain; for any particular patient, no matter how good the evidence and precise the probability estimates, there can be no guarantee.

This irreducible uncertainty is confronted routinely by doctors and patients and is rarely a source of clinical controversy. Trouble begins when experts reach different conclusions from the same piece of evidence. The poorer the evidence, the more discretionary the interpretation, and the more controversial the conclusion. When available evidence is totally inadequate to inform decisions that must be made, then clinical controversy may border on chaos. Savage and others have shown that in Britain and elsewhere controversy and chaos reign in the management of prostate cancer.[1-3]

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For early prostate cancer, there have been no controlled trials good enough to show whether survival is increased by active intervention with radical prostatectomy, radiation, or hormonal therapy. For men with early disease, any benefit is likely to be realised long after treatment and the immediate side effects of incontinence and impotence have been well documented.[4] In light of uncertain, delayed survival benefits and known, immediate harm, it is no wonder that clinicians' recommendations vary.

In the survey conducted by Savage and colleagues among 274 British urologists, nine out of 10 favoured active intervention for men aged under 70 years with poorly differentiated early prostate cancer—five recommended radiation, three radical prostatectomy, and one immediate hormone treatment. For men aged over 70, three out of 10 urologists would recommend some form of active treatment, most often radiation. The authors did not ask about moderately differentiated disease, by far the most common type of prostate cancer now being detected and for which prognostic uncertainty is greatest. For patients with well differentiated early disease, who probably have a good prognosis regardless of treatment, four out of 10 British urologists would still recommend radical surgery and three would recommend radiation for those aged under 70. For men over 70, seven out of 10 would favour observational management.

The inclination toward active management for younger men reported by a majority of urologists is at odds with their views about screening. Only a quarter thought that early detection of prostate cancer conferred a survival advantage. The survey also found divergent recommendations for treating locally advanced and metastatic prostate cancer and relapsed prostate cancer. The recent publication of the Medical Research Council trial showing improved outcomes for patients with early prostate cancer treated with androgen deprivation may (or may not) increase consensus.[5]

The controversy and chaos are not limited to Britain. Similar variability in treatment choices have been described in the Nordic countries.[2] In the United States there is stronger consensus and greater enthusiasm for surgery among urologists, who, in recent years, have performed more than 100 000 radical prostatectomies annually.[3] But the enthusiasm is not universal. Rates of radical prostatectomy vary widely among American states.[3] American radiation oncologists generally favour radiation treatment. With no evidence for long term effectiveness, brachytherapy and cryotherapy now compete with external beam radiation and radical prostatectomy as the preferred treatment for early cancer.

What can be done to bring reason and order to the management of prostate cancer? Savage and colleagues recommend establishing standards of practice.[1] But standards or guidelines can inform decisions only when the evidence on which they are based is adequate. For the foreseeable future, recommendations for managing prostate cancer, especially clinically localised disease, will rely more on dogma than data.

This is the conclusion reached by the Prostate Cancer Clinical Guidelines Panel of the American Urological Association.[6] Rather than offer recommendations for patients with different clinical characteristics, the panel concluded that treatment alternatives should be presented as options, each with its advantages and disadvantages. Its only recommended standard was that patients with newly diagnosed cancer should be informed of all commonly accepted treatments.[6] Programmes to support communication of options, leading to treatment choices that reflect the preferences and attitudes towards risk of the individual patients who will live with the consequences, have been shown to be feasible in busy urology practices.[7] Decisions would be supported with access to the best available information, with candour about what existing evidence does not allow us to know, and with compassion for the patient facing an uncertain future. Well supported decisions would lead some men to opt for possible future survival benefits, with one or another active treatment depending on their own assessment of the impact of side effects on quality of life. Some might not be willing to accept any compromise in quality of life and choose expectant management. But for others, perhaps many, the benefits and harms would balance, such that the best choice might well be participation in a randomised trial. Trials of treatment for localised prostate cancer are under way.[8] But they will involve a mere fraction of the men who are eligible and, we believe, a mere fraction of the men who would choose participation if well informed.[9] Undoubtedly, we could reduce our collective ignorance more quickly if we redoubled efforts to bring men who found themselves at "effective equipoise" into controlled trials.[10] We could also learn from registries, or preference trials, of men whose preferences and attitudes led them to a clear choice among standard or evolving treatments.[11]

The constructive professional response to the controversy and chaos in the management of patients with prostate cancer is not to develop standards of practice that include treatment recommendations unsupported by currently available evidence. The men we care for now and in the future will be better served if the new standard is to promote patient choice with compassion and care, and then learn from their experiences.

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Taking precautions with ACE inhibitors

A theoretical risk exists in patients with unilateral renal artery stenosis

Angiotensin converting enzyme inhibitors have revolutionised the treatment of congestive heart failure,[1] hypertension,[2] and diabetic nephropathy.[3] After myocardial infarction, treatment with angiotensin converting enzyme inhibitors decreases the incidence of life threatening left ventricular failure and improves survival.[4] Yet, despite appearing to be a panacea for vascular diseases, angiotensin converting enzyme inhibitors may present a hazard for patients with unsuspected atherosclerotic renovascular disease,[5] and the size of that risk may be growing.

Convention dictates that if the serum creatinine concentration is unchanged several days after starting an angiotensin converting enzyme inhibitor there is no haemodynamically important renal artery stenosis. But this scenario applies only in bilateral renovascular disease: in unilateral disease these drugs may cause ischaemic damage and loss of function of the affected kidney while the serum creatinine concentration remains stable. Not all cases of acute renal failure induced by angiotensin converting enzyme inhibitors are reversible.[6]

The prevalence of renovascular disease, once quoted as 1-5% in unselected hypertensive patients,[7] is now thought to be higher.[6 8] Increasingly, atherosclerotic renal artery stenoses are being identified in the presence of atherosclerosis elsewhere. In one study over 40% of patients with peripheral vascular disease had angiographic evidence of significant renovascular disease.[5] Similarly, serious coexisting renal artery stenosis was present in about a fifth of patients with coronary artery disease, confirmed by coronary angiography.[9] Renal artery stenosis may be more common in people with diabetes than had been assumed: a necropsy study showed clinically silent disease in nearly 10% of patients with type 2 diabetes mellitus.[10]

Ischaemic nephropathy is a major cause of end stage renal failure and may be more common than realised.[6 11] In a prospective study of all patients starting renal replacement therapy in one unit over 18 months renal angiography revealed atherosclerotic renal artery stenosis in 14%,[11] an incidence which may increase as many older patients are accepted on to programmes for end stage renal failure.

We do not know whether treatment with angiotensin converting enzyme inhibitors hastens the loss of renal function in the long term when given to people with unsuspected unilateral renovascular disease. Since clinical trials have shown overall benefit in preserving renal function in patients with diabetes—a group at high risk of renal artery stenosis—then either the theoretical potential for inducing ischaemic nephropathy has been exaggerated or angiotensin converting enzyme inhibitors can preserve function in the remaining healthy kidney. Alternatively, the results of these trials might have been even more impressive had patients with renovascular disease been excluded.

Atherosclerotic renal artery stenosis is a progressive disease: in a prospective study the incidence of progression from less than 60% stenosis to over 60% was 30%, 44%, and 48% at 1, 2, and 3 years respectively.[12] With the continued increase in the prescription of angiotensin converting enzyme inhibitors, caution must be exercised to prevent iatrogenic loss of the renal mass. Renal angiography remains the gold standard for diagnosis,[13] but renal duplex scanning offers a rapid, non-invasive test for screening for critical renal artery stenosis before starting treatment.[12-14] Comparative studies show that duplex ultrasound scanning can reliably predict the presence or absence of significant renal artery stenosis,[12 13] and colour Doppler ultrasonography may be even more sensitive.[14]

The success of angiotensin converting enzyme inhibitors in preventing and treating vascular disorders is undeniable. However, screening for unilateral renal artery stenosis might be wise before treatment is started in patients at high risk. These include hypertensive patients over 50 and those with peripheral vascular disease, diabetes, or coronary artery disease. When renovascular disease is identified the benefits of angiotensin converting enzyme inhibitors may still be available if treatment is started after percutaneous transluminal renal angioplasty and stent placement.

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Improving doctor-patient communication

Not an option, but a necessity

In most Western countries healthcare systems are changing; political and economic forces are behind the growth of profit driven medicine, managed care, and an increasingly technological focus. Paradoxically, at a time of global communication and the "Net generation," we are faced with a breakdown in communication between patients and doctors, increasing patient dissatisfaction, rising numbers of complaints and claims for malpractice, and abandonment of conventional medicine for alternatives that are often unproved.[1]

What do patients want? Most complaints by patients and the public about doctors deal with problems of communication not with clinical competency.[2] The commonest complaint is that doctors do not listen to them. Patients want more and better information about their problem and the outcome, more openness about the side effects of treatment, relief of pain and emotional distress, and advice on what they can do for themselves. Several studies have clearly shown that doctors and patients have different views on what makes good and effective communication.[3–5] These differences influence the quality of interactions between doctors and patients, as well as compliance, patient education, and health outcomes.

Why should doctors change the way they communicate? In the past decade responsibility for an individual's health care has shifted. Patients today are health consumers and want to be active participants in medical decision making. Kaplan et al showed that patients tended to leave doctors who failed to involve them in decisions.[6] In this observational study of 7730 patients and their doctors, a third of those rating doctors in the lowest participatory quartile changed doctors the following year. Furthermore, doctors who had training in interviewing skills scored higher than those without such training. Under pressure to contain costs, doctors respond by increasing their practice volume, with a corresponding decrease in time spent per patient.[7] This is a false economy if, as Kaplan suggests, it results in patients abandoning that doctor.

Good doctor-patient communication offers patients tangible benefits. Many studies have found significant positive associations between doctors' communication skills and patients' satisfaction.[8] Does good communication improve physical health too? Several studies and reviews clearly show a correlation between effective communication and improved health outcomes.[9] The outcomes affected were emotional health, resolution of symptoms, function, pain control, and physiological measures such as blood pressure and blood sugar concentration.

How can we overcome the difficulties doctors have in learning new communication skills? Firstly, there is plenty of good evidence that changing doctors' behaviour and communication skills can be achieved quite easily with proper teaching and that it will last.[8 10 11] Secondly, despite the changes in the structure and practice of medicine, it is still more than just a job. Doctors have a moral and social responsibility as well as a medical one and must preserve their patients' trust. Thirdly, communication is an interactive process. Patients will also need skills and support to take part in decision making and raise questions about quality. Efforts to improve quality increasingly incorporate patients' perspectives, and providers who know what services patients value can work to meet expectations or counsel patients so that expectations become more realistic. There is encouraging evidence that some of the issues addressed in the Toronto consensus statement on doctor-patient communication have already begun to change awareness.[12] The Toronto consensus statement published in 1991 clearly showed that communication problems in clinical practice are important and common. It also showed that quality of communication is related to health outcomes for patients, but that traditional medical education is ineffective at teaching communication. New teaching methods and media have been developed since then, but current knowledge has yet to achieve broad implementation in practice.

Learning communication skills in times of change and uncertainty depends on an emotional openness to self and others. Medical educators should use knowledge of patients' perceptions of care to focus teaching on areas that will help trainees to meet patients' expectations.[4] Teaching communication skills should be included at all levels of medical education and, even more importantly, should be a mandatory element of the medical school curriculum and programmes of continuing medical education. This can be achieved only with the support of all grades of doctors in all specialties.

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