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Lessons from the Bristol case

More openness—on risks and on individual surgeons' performance

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Cardiac surgery has changed within living memory from desperate attempts to achieve miracles for a few to the present situation where there is high expectation of a good result for tens of thousands of patients each year. It is easy to recall the surgeons who performed the first heart operations, who used cardiopulmonary bypass while it was still in its infancy, or who started transplantation—all undertaken with a high initial mortality. They worked on doggedly, in the face of doubt, scepticism, and often widely publicised criticism. They are now remembered with respect as having had "the courage to fail." Many others, equally determined, did fail and are not remembered.[1]

Some of that determination, in the face of possible failure, is necessary in every surgeon. But the congenital heart surgery undertaken in Bristol in the past 10 years—the subject of the General Medical Council's most recent, and arguably most important, disciplinary case (p 1691, 1740)[2,3]—was within the realms of routine practice, for which there are known and well established standards. In heart surgery accountability supplemented doggedness a long time ago. The present arrangements, however—which rely on local monitoring of results, clinician based judgments about acceptable standards, and continuing referrals—failed to avert the situation in Bristol, which we have seen spelt out in distressing detail before the General Medical Council and the nation's media (p 1757).[4]

Irrespective of the long awaited conclusions of the GMC in the Bristol case, it was already abundantly clear that British cardiac surgeons, themselves well in advance of other surgical specialties in keeping a record of their results, would have to be audited in a more explicit way. The United Kingdom Cardiac Surgery Register, to which cardiac surgeons voluntarily submit their annual figures, has been run by the Society of Cardiothoracic Surgeons of Great Britain and Ireland since 1977.[5] It has provided a useful benchmark against which to discuss variations in the provision of services and for individual surgeons to monitor their own mortality figures against a national average. At the time it was set up, and until recently—when there have been two high profile cases of unacceptable mortality for cardiac surgery[6,7]—there was a tacit assumption that the patients and surgeons in the dataset were anonymous and would remain so. Furthermore, the use of that benchmark to assess one's own practice was a matter of honour and personal reflection.

The first steps in changing that have already been undertaken. All cardiac and thoracic surgeons will now have to submit for inspection their individual figures in specified areas of practice. These will be coded, but any unsatisfactory results can be easily traced back to the surgeon and poor performance investigated. Before long central recording of full data on all cases, with appropriate risk stratification, is likely to be the norm. The anonymity offered by coding is notional and may be the last vestige of a belief in confidentiality for surgical results that for years was held to be sacrosanct.

The arterial switch operation for transposition of the great arteries, central to the Bristol case, has presented a particular dilemma for surgeons in balancing risk and benefit. "The switch" replaced well established operations (those devised by Senning in 1959 and Mustard in 1963) which provided very effective palliation by redirecting the blood flow in the atria, so that the physiology was corrected. The ventricles continued to do each other's work but only for as long as the right ventricle could withstand the systemic load. During the 1980s more and more surgeons turned to the technically exacting, but in the long term more satisfactory, arterial switch operation, with the objective of restoring normal expectation of life and function, rather than providing palliation of uncertain duration. The transition entailed the possibility of an increase in operative mortality for this condition during the "learning curve." The operation became the standard of care, but precise preoperative assessment, impeccable surgical technique, and skilled perioperative care are needed for consistently good results. An analysis of a cluster of deaths for this operation in an otherwise excellent series at Great Ormond Street is an exemplar of honest self appraisal.[8] Well in advance of the conclusions reached by the GMC in the Bristol case, a meticulous national registry for this operation has been established. We already know that for all 23 surgeons performing the operation (in 15 units) the mortality in just over 200 operations performed within the past two years is 6.5% (DeLeval M, British Cardiac Society meeting, May 1998).

A major issue in the Bristol case has been the nature of the information given to the parents. The estimates of risk of death were substantially less than the true risk of surgery in that unit. There may be a place for giving an optimistic outlook to a patient judged to have no choice but to undergo high risk emergency surgery to save life, but the circumstances where that approach is justified are limited. There was

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no justification for a rosy glow in this case, where the operations were elective, could be performed elsewhere, and the difference between success and failure was potentially many years of life. It appears to be self evident that parents have a right to know the truth from both referring cardiologist and the surgeon.[9] Why are doctors ever economical with it? Is truth thought to contaminate the trust in a relationship? A frank presentation of the risks and benefits to the family should include sympathy and compassion, but this should not supplant frankness.

The hearings and deliberations at the GMC into the Bristol paediatric surgery case have stretched over many months and explored complex issues. It is often the case with a disaster (and this has been a disaster not only for these families but for many others who work in and around heart surgery) that there is no one isolated gross and culpable error. Instead a sequence of more minor faults, errors, omissions, poor procedures, failure to follow protocol, and unheard warnings together lead to the eventual tragedy. In this case the unheard warnings are particularly worrying. In 1989 Professor David Hamilton's paediatric cardiac surgery working party, exploring the provision of supraregional services, included data which might have raised questions about Bristol's continuation as a centre for paediatric cardiac surgery. Quite separately, a consultant anaesthetist in Bristol "blew the whistle" but was disregarded (p 1739).[10] The UK register, to which Bristol contributed data, was available for comparison throughout this time. We have to ask why these warnings, and the questions and doubts that clearly must have surrounded the practice of paediatric cardiac surgery in Bristol for several years, were not heard.

It has now been agreed that the Royal College of Surgeons of England and the Society of Cardiothoracic Surgeons will provide a "rapid response group" so that a member of the council of the college and a senior cardiac surgeon can be on site within 48 hours, to listen and advise on action. This is an attempt by the profession to protect patients from continuing poor performance—and also to safeguard surgeons from inappropriate fault finding (since cardiac surgeons now feel very much under scrutiny and vulnerable in a climate of criticism and blame). It remains to be seen whether this initiative by the college and the surgeons' own society can be implemented effectively and whether it will be seen to be open enough to allay anxieties about the profession supposedly monitoring itself, but not doing it well enough. If we do not monitor ourselves effectively there is little doubt that it will be imposed upon us.[11]

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The need for a national body for research misconduct

Nothing less will reassure the public

The British medical research community is busy assembling its response to research misconduct. The question is no longer, "Do we have a problem?" but rather, "How can we best respond?" The *BMJ* has thus commissioned five answers to the question (p 1726),[1] two from people outside Britain with extensive experience of research misconduct. One recurrent theme is that Britain needs a central body to lead on this difficult issue.

The answers are published in a week when we have to retract yet another article because of probable fraud (p 1700).[2] One of the authors of the retracted paper was recently struck off by the General Medical Council for research misconduct.[3 4] He had also lied about his qualifications. Cameron Bowie, his coauthor, then started from the inevitable assumption that all of the rest of his work was fraudulent until proved otherwise and found that he could not satisfy himself that his coauthor had completed the work he said he had. Bowie describes his miserable experience in a personal view and has retracted a paper that has gained wide attention and been influential in developing policy (p 1755).[5]

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This week also sees the publication of the first annual report from the Committee on Publication Ethics (COPE),[6] a body set up by medical editors to support each other in tackling suspected research misconduct and considering the ethical problems that arise all the time in scientific publishing.[7–9] The group has considered 25 cases, many of them minor, but in the past year—as a result of COPE—I personally have referred an author to the General Medical Council (to discover that he had already been struck off) and made a complaint to a chief executive of a trust. It's a terrible thing to refer an author to such authorities, but editors have decided that we can no longer ignore misconduct. Nor can we investigate and punish, which is why we must refer authors to their employers or other authorities. Our experience with COPE makes it clear that

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once editors begin to pay serious attention to misconduct it is there before their eyes.

In the introduction to the annual report Mike Farthing, the chairman of COPE, argues that Britain needs a national agency to manage research misconduct.[10] The same message comes from Povl Riis, one of the founders of the Danish committee,[1] and from Drummond Rennie, deputy editor (west) of *JAMA* and a member of the United States Commission on Research Integrity.[1] Rennie pleads with Britons to learn from the United States' experience, which goes back 20 years. In the early days in the US each institution created its own rules for dealing with research misconduct. "The results," writes Rennie, "were frequently slow, bungled, idiosyncratic, and unfair to almost everybody." So was born the Office of Research Integrity to oversee and enforce institutions' compliance with federal regulations governing research.

Another important message from the US is that a legal rather than a scientific method is needed for managing cases of misconduct. "Scientists," writes Rennie, "are not trained in conflict resolution; their intuitive response is usually wrong and they tend to set up shaky ad hoc procedures that do not guarantee the accused notice of all the charges, the opportunity to respond to all the charges, and a decision based on rigorous standards."[1] COPE has been lucky to receive the help of Ian Kennedy, a professor of law.

The president of the GMC, Sir Donald Irvine, has set up a committee chaired by George Alberti, president of the Royal College of Physicians, to consider a better response to research misconduct. The committee includes the secretary of the Medical Research Council, which has now produced excellent advice on how allegations of misconduct should be investigated in its own units.[1 11] Crucially, it offers a procedure to follow in that very first and awkward stage when misconduct is suspected but far from proved. This is the stage that editors find so difficult: they have strong suspicions but no more—and no means to investigate. One problem with the emerging British response is that it doesn't cover all scientific research, but the National Academies Policy Advisory Group (a group that covers the bodies representing scientists, engineers, doctors, and the humanities) has also been studying research misconduct. It unfortunately is still at the stage of deciding whether there is a problem.

There is an understandable reluctance to create a national body to lead on research misconduct. Nobody wants more quangos than are absolutely necessary, and everybody would like to think that local bodies—universities or research institutions—can keep their own houses in order. Unfortunately the experience from the United States and from other countries that have acted on research misconduct and from Britain so far is that local responses are often inadequate. The institutions don't have enough experience and face a terrible conflict of interest in exposing one of their staff as a fraudster. A national body should take the lead in defining research misconduct, developing procedures for dealing with accusations, and ensuring that institutions comply with them. In addition—and ultimately more importantly—the national body could also lead in studying and preventing the problem.

The British public—stunned by the revelations from the Bristol case of surgeons continuing to operate when they knew their results were poor (p 1685)[12]—needs reassurance that everything possible is being done to ensure the purity of the research record. A national body is needed to provide that reassurance.

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Primary care and the NHS white papers

The right principles but bedevilled by the detail

Before last year's election the Labour Party made much of its intention to move away from the fragmentation allegedly caused by the previous government's NHS reforms and to return to a truly national health service. However, as the new government's proposals have been revealed, it is all too apparent that its commitment to devolution exceeds its commitment to the recreation of a national service. The differences in the organisation and nature of the service between the four parts of the United Kingdom are to be increased, and in particular health care in Scotland will diverge, with complete exclusion of general practitioners from the process of commissioning care.

Over the past six months a succession of white and green papers have spelt out the proposals for NHS reform[1–4] and strategic improvements in public health.[5–7] These have emphasised a service that is fairer, distributes resources more equitably, eliminates two tierism, is needs led, better integrates health and social services, is based on cooperation rather than competition, reinstates strategic planning, emphasises quality, addresses health inequalities, promotes better health, and involves the public. Thus, at the headline level, the proposals have secured wide endorsement, from both the public and health professions.

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However, it has been all too apparent that the detail has either been missing or contains threats to patient care and to those working for the NHS, and that the necessary resources required to make the strategies effective have not yet been delivered. Indeed, general practitioners worry that they may be blamed for service shortcomings and rationing in an underfunded NHS through no fault of their own.

General practitioners have thus become increasingly fearful and anxious about the ways in which the proposed primary care groups in England, and the similar local health groups in Wales and proposed primary care groups or partnerships in Northern Ireland, will threaten them and the care of their patients. (In Scotland quite different structures have been proposed.) Nevertheless, if those fears can be allayed there are real opportunities for the development of primary care. Some guidance has already been published,[8 9] including a highly ambitious timetable intended to implement the reforms by 1 April 1999. However, while the groups are to be formed by the end of July, the current lack of the reassurances that general practitioners are seeking threatens to prejudice their involvement in the government's reforms.

English primary care groups will be responsible for commissioning health services for the local population; managing a unified budget, including funds for hospital and community health services; managing general practice infrastructure and prescribing; contributing to local health improvement programmes and their implementation; working more closely with social services; developing primary care and ensuring its quality through arrangements for clinical governance and local self regulation; monitoring performance, both in primary and secondary care; involving the public; and maintaining effective management and financial arrangements. The task of clinical governance, which will include pressure on health professionals to conform with best practice, is daunting, if necessary.

Primary care groups are intended to develop around natural communities (although taking into account the benefits of coterminosity with social services), represent and involve all general practices, and typically serve about 100 000 patients. There have been some anxieties about this proposed size, with pressures for both significantly smaller and much larger groupings. Economies of scale and easier risk management at larger sizes must be weighed against the potential for easier working relationships and greater involvement at the smaller end of the scale.

Four levels of responsibility for primary care groups have been proposed. At level one the group will advise the health authority; at level two it will take devolved responsibility for managing the healthcare budget; at level three it will be a freestanding body, but accountable to the authority for commissioning care; and at level four it will also take on responsibility for providing community health services, as a primary care trust. Primary care groups are expected to progress through the levels and take on more responsibilities, although the legislation needed for levels three and four will not be in place until the end of this year at the earliest.

The governing bodies of primary care groups must contain representatives of general practitioners, community nurses, and social services, and there are strong arguments for also including representatives of the health authority, public health, and the public—not least to spread understanding of and accountability for the difficult priority setting decisions the groups will need to take.

The key outstanding issues for general practitioners include protecting their status as independent contractors; maintaining their freedom to prescribe and refer in the best interests of their patients; establishing governing boards that are led by general practitioners; ensuring adequate financial support and training for the preparatory work required before next April and adequate continuing resourcing thereafter; protecting the budget for the infrastructure of general practice; and securing recognition of the role of local medical committees as representing all NHS general practitioners.

Doctors fear that patient care will be damaged if their clinical freedom is undermined; if primary care groups inherit the debts of health authorities; if groups run out of money before the end of a financial year; if general practitioners are forced to ration because resources are inadequate; and if they are compelled to erode the infrastructure of primary care to fund prescribing or hospital services.

The paramount issues are control and investment. General practitioners will not have confidence in primary care groups if they do not have the ability to exercise effective control. They are understandably fearful that when the money runs out, they will be placed under moral pressure to fund direct patient care out of their own pockets and at the expense of the fabric of general practice—the environment where 90% of all episodes of health care take place. They foresee a threat to the resources available for their premises, staff, and computers unless at least the present level of funding is guaranteed.

The General Medical Services Committee, which represents all NHS general practitioners, has been striving to clarify and modify the government's plans and is currently involved in urgent negotiations with the Minister for Health to secure the reassurances that general practitioners need before they will be willing to play their full part in implementing the English white paper. We hope an acceptable outcome will result and that the government will not embark on unnecessary confrontation with the profession.

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Hydroxyurea therapy for sickle cell disease in Britain

Disappointing recruitment despite promising results

Sickle cell disease is the commonest inherited haemoglobinopathy in Britain and affects over 9000 people.[1] Clinical severity varies considerably, but patients with the most severe disease have a life expectancy of just over 40 years. Conventional management of the disease is largely supportive, highlighting a pressing need for approaches that can alter the course of the disease. Trials in America have suggested that hydroxyurea can have a significant impact on the course of the disease, but in Britain it is proving virtually impossible to recruit patients into trials to confirm these results in a British population.

The fact that the clinical severity of the sickle cell disease varies even within groups of patients with the same β globin genotype[2] has led to the concept that the disease is a multigene disorder, with inheritance of α thalassemia and genes controlling the concentration of fetal haemoglobin, among others, modulating disease expression.[2,3] In those severely affected debilitating bone pain crisis is responsible for 60-90% of sickle related admissions in Britain,[3] while the chest syndrome contributes another 15-30%. The adverse effects of these acute events on life expectancy is borne out by results from the cooperative study of sickle cell disease.[4,5] This showed a median survival of just over 40 years in adults with HbSS who have three or more pain crises a year and about 53 years in those who had fewer than three. The risk of severely symptomatic disease and early death is correlated with the fetal haemoglobin concentration.[5] For years effort has been directed into the investigation of pharmacological agents which may raise concentrations of fetal haemoglobin.

Hydroxyurea is the first widely available and affordable agent that appears to have a real impact on the course of sickle cell disease. Its precise mechanism of action is unknown but it causes an increase in fetal hameoglobin concentrations in most subjects, which physically interferes with the polymerisation process of deoxyhaemoglobin S. In 1994 a large multicentre, randomised, double blind placebo study in America of 299 subjects showed that the drug significantly reduced the frequency and severity of painful crises, the incidence of acute chest syndrome, and blood transfusion requirements.[6] These results were communicated as a "clinical alert" by the National Institutes of Health.

With appropriate monitoring, side effects are few, and pilot schemes using hydroxyurea in children with sickle cell disease have now been reported from America and Belgium.[7] A theoretical risk exists that hydroxyurea may transform chronic granulocytic leukaemia and myeloproliferative disorders into acute leukaemia,[8] although these are themselves premalignant conditions. The increased risk of leukaemogenesis in non-malignant conditions is unquantified but appears to be low. No evidence of malignant transformation was seen in 64 patients with secondary polycythaemia reported by Triadou et al.[9]

British haematologists think that the single American study should be repeated in Britain. We need to study the reproducibility of the results in a British population. Also, we do not yet know which patients are likely to respond nor do we have a full understanding of the best regimen, whether by daily or intermittent administration. Combination therapy with hydroxyurea and other agents acting on fetal haemoglobin concentrations may provide optimum therapy. For the 20% of people who do not respond alternative strategies will be required. However, several studies started in Britain have not been completed because many patients are unwilling to take the drug.

Studies at the North Middlesex, Whittington, and King's College hospitals and Manchester Royal Infirmary have failed to recruit enough patients to be continued. Although patients' spoken fears are about the possibility of secondary malignancies, reasons for their reluctance to try new drugs such as this are probably complex and include wariness in patient-doctor relationships, peer group criticism, and anxiety about change. Support groups have campaigned openly against the use of hydroxyurea. As a result only a few severely affected patients are taking hydroxyurea, in a variety of different regimens. It will not be possible to make clinical decisions from the results of this unstandardised approach.

Hydroxurea is not a cure for sickle cell disease and it should at present be offered only to severely affected patients who are fully informed about the treatment, its potential benefits, and possible side effects. However, for selected patients it is likely to be the best we have to offer in the near future, and it may transform the life of patients who respond to it. It is therefore regrettable that so few patients in Britain currently feel able to avail themselves of it.

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Community acquired pneumonia in elderly people

Current British guidelines need revision

Community acquired pneumonia is the most common reason for acute admission to hospital, with an estimated 50 000 cases occurring each year in the United Kingdom.[1] Over 90% of these patients are aged over 65 years and the associated mortality is 16-40%.[2] *Streptococcus pneumoniae* is still the most common causative organism, probably responsible for up to 40% of cases; *Mycoplasma pneumoniae* (3-23%), *Haemophilus influenzae* (5-8%), and *Legionella pneumophila* (3-6%) are the next commonest.[2] "Atypical" pathogens are, however, becoming more prominent in old people, and current guidelines on antibiotic treatment may not be appropriate in this age group.

Until recently pneumonia due to atypical pathogens has been considered uncommon in old people: a review of 11 studies of pneumonia identified *Chlamydia* and *Coxiella* spp as the cause in only 2% of patients aged over 65.[2] However, recent studies have documented *Chlamydia pneumoniae* in up to 26% of cases, which suggest it is the second commonest cause of pneumonia in this age group.[3] Increased recognition of its role is probably due to improved methods of detection, although these are not widely available in diagnostic microbiology laboratories.

C pneumoniae was first described as a cause of pneumonia in 1985. Most infections due to this organism are believed to occur early in life and result in mild disease, although reinfection in elderly people can cause more severe disease.[4] Pneumonia caused by *C pneumoniae* is often difficult to diagnose, with an insidious course and absence of leucocytosis.[4] It seems to be a common cause of pneumonia in long term institutions,[5] suggesting nosocomial transmission.

For uncomplicated pneumonia of unknown cause, of mild to moderate severity, the British Thoracic Society guidelines recommend an aminopenicillin—for example, amoxycillin or ampicillin—or benzylpenicillin.[1] For severe pneumonia a second or third generation cephalosporin plus high dose erythromycin is recommended. These guidelines may not, however, be wholly appropriate in elderly people.

Firstly, the use of cephalosporins in hospital, including in elderly people, has increased greatly, although some of this may have been due to misinterpretation of the guidelines. Excessive use of these antibiotics has been implicated in the increased incidence of diarrhoea and colitis due to *Clostridium difficile*.[6 7] Although most antibiotics can promote *Cl difficile* diarrhoea, this is greater with cephalosporins.[6] In addition, they are likely to select for other antibiotic resistant hospital pathogens such as vancomycin resistant enterococci. Either cefotaxime or cefuroxime has been recommended by the British Thoracic Society because of concern about penicillin resistance in *S pneumoniae*. However, the current rate of resistance (penicillin minimum inhibitory concentration >0.1 mg/l) for England and Wales is estimated to be only 3.8%,[8] although regional variations exist. Furthermore, little evidence exists that such levels of resistance are clinically relevant in pneumococcal pneumonia providing adequate doses of penicillin are given.[9] Thus there is little need to use a cephalosporin as first line treatment for community acquired pneumonia, although the local epidemiology of penicillin resistance should be considered. Amoxycillin or ampicillin remains first choice oral treatment[10] with co-amoxiclav as an alternative for better activity against *H influenzae;* intravenous penicillin is recommended for more severe cases unless local resistance patterns preclude it, and only then should a cephalosporin be used.

Secondly, in view of the role of *C pneumoniae* and its resistance to β lactam antibiotics, the addition of erythromycin should always be considered unless the laboratory can rapidly exclude it. Finally, evidence is growing that newer macrolides, such as clarithromycin, are better than erythromycin in their extended antibacterial range of action and increased activity against *C pneumoniae*. They cause fewer gastrointestinal side effects and can be given in twice or even single daily regimens.[11] Several fluoroquinolones also have a similar range of activity. Of these, sparfloxacin has been shown to be as effective as more established antibiotics, although photosensitivity was a problem.[12] Clinical trials are under way to evaluate these and other new fluoroquinolones as monotherapy in community acquired pneumonia. The results may be relevant to future guidelines.

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