Time for a paradigm shift? Medical Law in Transition

Introduction

The dominant approach to medical law in this country has been a highly rational ethical consumerism. 1 It sees medical law as unified around ethical concepts such as respect for autonomy and self-determination, truth-telling, confidentiality, respect for people (including their dignity), and justice.² It sees one of its key tasks as redressing the imbalance of power that exists between expert medical practitioners and lay patients by establishing ground rules for the relationships between them.³ It also worries that important moral judgments are being clothed with the mystique of professional expertise and appropriated by medicine from their proper place as social and political problems. 4 In essence, this approach is based on a liberal account of law protecting independent rights-based principles. Medical law is a species of applied ethics, implying a staged process of applying ethical principles to a problem and deriving the necessary legal rules from that application. The social and political dynamics of health care are regarded either as a distracting distortion impeding the implementation of progressive law reform or as evidence of the need for such intervention. The roots of medical law on this model are external to medicine, and law is a mechanism for regulating the professions in the public interest.

I want to suggest that this approach has failed to account for the way in which the subject has actually developed. I have argued before that the focus on medicine is too limited and that there are important social and organisational issues raised by our National Health Service that should lead us to consider the law governing health care rather than just medicine as the natural focus of our activity. However, the work of doctors remains extremely important even within this subject area. This paper suggests that the approach I have described as liberal in its nature has fostered a paradigm for the discipline of medical law that now makes it hard to understand and explain the rules of law and outcome of cases involving the work of health professionals. I shall use the term medical law (and by extension medical lawyers) to describe the corpus of such rules and cases that are understood to constitute a discrete subject for study. In order to define a subject sufficiently precisely to enable further study, it is necessary to develop a working hypothesis, or paradigm, of its underlying coherence. Such a paradigm is useful so long as the data to be examined has a rough degree of 'fit'. However, when it begins to distort that data, consideration needs to be given to the need for a new way of conceptualising the subject. This paper suggests that such a transformation of the paradigm of medical law needs to occur in order to

¹ For this characterisation of the dominant approach, see J. Montgomery, 'Medical Law in the Shadow of Hippocrates' (1989) 52 MLR 566-576.

² I. Kennedy & A. Grubb, *Medical Law: Text with Materials* (London: Butterworths, 1994), 3. See also I. Kennedy, 'Emerging Problems of Medicine, Technology, and the Law' in I. Kennedy *Treat Me Right* (Oxford: Oxford University Press, 1988).

³ I. Kennedy, 'The doctor-patient relationship' in P. Byrne, *Rights and Wrongs in Medicine* (Oxford: Oxford University Press, 1986), 7-21, esp. 12-15.

⁴ I. Kennedy, *The Unmasking of Medicine* (St Albans, Granada 1983).

⁵ J. Montgomery, *Health Care Law* (Oxford: Oxford University Press, 1997) 1-4.

take account of the actual practice of lawmakers and the changing context in which the law operates.

I shall begin by outlining key issues that arise in relation to the generally accepted paradigm and then explore the tensions in maintaining it as a framework within which to analyse medical law. I shall suggest that an examination of the way in which the courts, the health professions, and the NHS have regulated standards of practice shows how the idea of externally driven scrutiny has been less effective than had been hoped by many commentators. Instead, a paradigm based on the development of values within the health care communities provides a more illuminating model for explaining the subject. Examples from the handling of malpractice, patients' rights and problems of medical ethics are used to make a series of points, but also to illustrate how the concerns of this paper can help explain the full compass of the subject. The exploration of malpractice suggests that litigation has done little to establish standards and attention should turn to the evaluation of the emerging quality assurance model to see whether it might be more effective. Consideration of key areas of patients' rights indicates that they have been given fuller attention by the institutions of health care than by the courts and that the current Government's modernisation agenda for the NHS requires a more corporate approach than the traditional legal models have indicated. Finally, an examination of the treatment of medical ethics by the courts suggests that they are less concerned than the traditional paradigm would lead us to expect with substantive rules and that other models of the role of the judiciary should be considered.

A paradigm under pressure

The widely accepted paradigm of medical law adopts positions on a number of issues that are becoming increasingly problematic. First, the conception of the rule of law and its requirement that medical practice be regulated by principles to govern conduct backed up by mechanisms for accountability. The instrinsic values of medicine and other health professions are to be subordinated to the values of the wider community. Yet, this is difficult to reconcile with the continuing dominance of the *Bolam* philosophy (to be explored later). Second, commentary has traditionally given relatively little weight to the fact that most health care in the UK is delivered within a state system, the National Health Service. This has led to insufficient attention being given to the institutional structure of health care and to an interest in foreign developments with too little regard to the difficulties in translating solutions to our domestic context. Third, a reliance on ethical principles as providing the foundations for a coherent discipline has served to obscure some of the aspects of legitimation that are raised by the fact that medical law regulates a public service.

(1) Medicine subject to law

Understanding the sociological nature of medical ethics involves more than the application of general ethical and legal principles to medicine. The health professions have their own normative values that are only partially developed from these sources. Law built on that understanding would hold that the regulation of the enterprise of medicine would require recognition and consideration of those specific norms. This

presents a challenge to positions that seek to analyse problems in medical decision-making by distinguishing those aspects that are strictly medical from those which are ethical, arguing that there is no medical expertise involved in the latter. Instead, medical law would need to draw on the values of the groups that come together in the enterprise of providing health care as well as those of the wider community. It would thus be more than merely the application of general principles of law in the medical context. It would have an intrinsic unity of its own.

It is not difficult to find statements that doctors are subject to the general rule of law. In *R v Arthur*, a criminal trial concerning allegations of medical murder of a disabled child, the jury was directed that

There is no special law in this country that places doctors in a separate category and gives them special protection over the rest of us.... It is because no doctor has special exemption, or a special right in this way, that this case comes before you. We have heard a good deal about medical ethics and it is a fact that in virtually every profession, or any trade were there is a guild of association of that kind, rules of conduct are set out.... But that does not mean that any profession can set out a code of ethics and say that the law must accept it. In this case it has been suggested that what Dr Arthur did here, whatever may be the medical ethics of the matter, has gone beyond what any doctor is entitled to do and has committed a crime.

In fact, however, the subjection of medicine to the general law is far from being a simple matter. Even if judges direct juries to disregard the medical context, there is no guarantee that they will do so. We can only speculate whether Dr Arthur's acquittal was because of or in spite of the direction that the jury received.

More importantly, it seems that English law does in fact treat doctors differently from others. A number of actions are legal if performed by doctors but illegal if done by others. They include the intentional termination of pregnancy, tattooing of minors, removal of tissue for transplant, female circumcision (for medical purposes only), and the prescription of certain drugs and the use of unlicensed medicines. Most significant, however is the way in which doctors have been permitted to care for the dying in a way prohibited to lay carers. Non-medical carers have been prosecuted for failing to provide proper nutrition for those they were looking after. Yet in *Airedale NHS Trust v Bland* it was held that professional carers could withhold food and water, even though it would lead to Tony Bland's death, because it was in accordance with professional ethics to do so in that case. ¹⁰ English law does recognise that the regulation of medical care requires special rules of substance and not merely extent.

⁶ See e.g. I. Kennedy, *The Unmasking of Medicine* (1983) ch 4.

⁷ R v Arthur (1981) 12 BMLR 1, per Farquarson J. See also R v Adams [1957] Crim LR 365, per Devlin J. For rejection of the suggestion that the law of negligence treats doctors differently see *Gold v Haringey* [1987] 2 All ER 888, 893-4, per Lloyd LJ.

⁸ Abortion Act 1967, Tattooing of Minors Act 1969, Human Tissue Act 1961, Prohibition of Female Circumcision Act 1985, Medicines Act 1968. Some of these monopolies are shared with other health professions. For discussion, see J. Montgomery, *Health Care Law* (1997) 141-2, 219-20.

⁹ R v Instan [1893] 1 QB 450, R v Stone [1977] 2 All ER 341, R v Gibbins & Proctor (1918) 13 Cr App R 134.

¹⁰ Airedale NHS Trust v Bland [1993] 1 FLR 1026

(2) The institutions of health care

Recognising the complexity of professional values, requires medical law to consider the corporate institutions of health care, the professions and the National Health Service within which most health professionals work. If medical law is to reflect the values of those groups and bodies, it also needs to address the processes by which those values are produced and developed. The traditional assumption of commentators has been that medical law should look for its governing principles outside medicine. However, this paper suggests that the source of the norms that seem most influential in practice may be found principally in the institutions of health care rather than those of the law. The sources of medical law would therefore go beyond legislation and judicial decision.¹¹

One implication of this is that law in a narrow sense has a limited place in the regulation of health care. This is not to say that we should reject the role of law, although the former health secretary, Frank Dobson, perhaps adopted such a view when he issued an invitation for consultation under the title 'Lawyers out of hospitals, doctors out of court'. It does, however, imply that an extensive legalism through the use of consumerist rights would not play a major role in regulating health care. These tend both to build on an atomistic conception of the experience of being a patient and to characterise the relationships between doctors and those they look after as confrontational in nature. The fact that the law has rejected such rights is hard to explain within the dominant model and provides tentative support for the suggestion that we should re-examine that paradigm if we wish to understand the dynamic of our subject. 13

If there is to be a move away from legalism in a narrow sense, one would expect to see greater weight being placed on improving forms of accountability and redress that rely on bureaucratic rather than legalistic processes. In the last five years of the twentieth century, the NHS has revamped its complaints procedures and extended the role of the Health Services Commissioner to raise the profile of less legalistic dispute resolution. Over the same period the medical profession has begun to rethink the role of its regulatory structures and become more proactive in its approach. Each of these developments supports the contention that an appreciation of the institutions of health is becoming increasingly important in understanding the area of medical law.

(3) A domestic or international concern?

A third characteristic that indicates that English medical law may need to be understood in new ways is the way that international comparisons are treated warily by the courts. This is less surprising if the values of medical law are to be drawn from those of the health care community, than from abstract moral principle. In a more parochial paradigm, the usefulness of overseas legal authorities will largely depend on the extent to which the practice of health care in those jurisdictions shares the values

¹¹ See J. Montgomery, *Health Care Law* (Oxford: Oxford University Press 1997) 4-20.

¹² Press Release 98/162, Wednesday 29th April 1998, 'Dobson to tackle rising levels of litigation in the health service'.

¹³ J. Montgomery, 'Patients first: the role of rights'. In: Fulford K, Ersser S & Hope T (eds.) *Patient Centred Health Care* (Oxford: Blackwell Scientific, 1996) 142-152.

of our own system. Transplanting legal cultures will only work if the health care cultures are comparable. There will not be space in this paper to draw out this feature in detail. However, it can quickly be illustrated. The disparaging comments on the transatlantic doctrine of informed consent in *Sidaway* and the failure to export the English approach to Australia serve as an illustration of the difficulties of giving medical law an international flavour even in legal jurisdictions that share the common law tradition. Although the leading Australian case was reported in an English series of reports, presumably in the belief that it would encourage the demise of Sidaway, it has not been cited in English judgments. The point can also be made when it is seen that the English courts had considered 'duty to warn' cases without discussion of the well-known US decision of Tarasoff. A quick survey of the Lloyds Medical Law Reports for 1998 shows that no overseas cases were cited in any of the thirty-five cases reported for that year. Citation of cases on the European Convention on Human Rights is becoming commonplace, but the medical law of other domestic jurisdictions has little impact on judicial reasoning.

(4) Legitimation

If English medical law displays these characteristics, it becomes necessary to address questions of legitimacy in a novel way. Traditional 'rule of law' thinking suggests that legitimacy comes from subjecting medicine to law, an enterprise that some doctors have criticised as little more than an inter-professional turf battle. ¹⁷ A more contextual approach would accept that medical law should grow out of the prevailing norms of health care practice. Legitimacy would be conferred by processes to make those professional norms accountable, but those processes need not themselves be legal processes. Nor need they necessarily relate to individual practitioners rather than to the profession or professions as communities.

This question of legitimacy brings us to the idea that medical law may be in a transitional phase. The regulation of health care is undergoing a process of radical change. The current National Health Service reforms constitute the most radical reorientation since its inception. The Government is looking to build a brand identity for the NHS based on a corporate culture. Quality assurance, under the banner of clinical governance, is now the legal responsibility of NHS Trust boards. Even general medical practitioners, never so far brought within the managerial boundaries of the NHS are being wooed to adopt corporate status through primary care trusts. Those who accept will become subject to the cultural hegemony of the NHS Executive in a way that has been resolutely resisted to date. National Service Frameworks are being established to provide nationwide benchmarks against which practice can be measured. The National Institute for Clinical Excellence will

¹⁴ See especially Lord Diplock's comments on *Canterbury v Spence* (1972) 464 F 2d 772 and *Reibl v Hughes* (1980) 114 DLR (3d) 1 in his speech in *Sidaway v Bethlem RHG* [1985] 1 All ER 643.

¹⁵ Rogers v Whittaker [1993] 4 Med LR 79.

¹⁶ There was passing mention of the case in *W v Egdell* [1990] 1 All ER 835 and in *Palmer v Tees HA* [1999] Lloyds Rep Med 359 (CA) but it was not regarded as requiring full consideration.

¹⁷ R.A. Hope, 'The Birth of Medical Law' (1991) 11 OJLS 247-53.

¹⁸ The New NHS: Modern and Dependable (London: Stationery Office 1997).

¹⁹ Health Act 1999, s 18.

²⁰ E.g. National Service Framework for Mental Health: Modern Standards and Service Models (London: DoH 1999).

gradually supplant the diversity of individual clinical judgment in assessing the effectiveness of care, as already indicated in the discussion of the flu drug Relenza.²¹ The Commission for Health Improvement will police standards and tackle failing services.

Professional regulation too has been radically restructured. From being an organisation largely concerned with securing the individual autonomy of doctors and resisting the encroachments of external regulation, the General Medical Council has redefined its role. ²² Its guidance on medical ethics to doctors has changed in nature from being advice on how to avoid falling foul of the disciplinary system to a statement of the values that doctors are expected to espouse. ²³ The transition is from a function based on the demarcation of occupational monopoly to one premised on the creation of a professional community with shared core values. The reasons for this transition are complex, but I have argued elsewhere that the driving force is a response to a crisis of confidence that threatens to undermine the status of medicine. Doctors now try, as nursing has done throughout the century, to use the regulatory system to convince the public that the profession can be trusted. ²⁴ This strategy is a deliberate attempt to build a new and powerful set of cultural norms that define the nature of medicine in our society. It aims to build a moral, not merely technical and scientific community of medicine.

This transformation is a response to the inability of the traditional regulatory mechanisms of the NHS and professions to prevent failures of care in some very public scandals, of which events at the Bristol Royal Infirmary provide the symbolic focus. It will be interesting to see whether the public inquiry into those events identifies as radical and extensive a revolution of accountability and quality control as the NHS and the medical profession are already putting into place. The control of standards is therefore an appropriate place to begin the analysis of where English law is going in its transformation.

Accounting for good practice

One of the key tasks of medical law is to ensure that the practice of doctors is of an acceptable standard and that they can be called to account if it fails to reach that standard. In most industries this task is carried out through a mixture of regulatory strategies and the deterrent effect of liability for mishaps. In relation to medicine, the direct effect of litigation on standards of practice has been marginal. Despite

²¹ Doh press release 1999/0604, Friday 8th October 1999, 'Dobson gives go ahead to NICE advice on relenza'.

²² For an account from the President of the GMC of this revolution, see D. Irvine, 'The performance of doctors I: professionalism in a changing world' (1997) 314 BMJ 1540-42, D. Irvine, 'The performance of doctors II: maintaining good practice, protecting patients from poor performance' (1997) 314 BMJ 1613-15, D. Irvine 'Dysfunctional doctors: the GMC's new approach' in M. Rosenthal, L. Mulcahy & S. Lloyd-Bostock (eds), *Medical Mishaps: pieces of the puzzle* (Buckingham: Open University Press 1999).

²³ Compare *Professional conduct and discipline: fitness to practice* (1992) with *Good Medical Practice* (1998, first version issued in 1995).

²⁴ J. Montgomery, 'Professional regulation: a gendered phenomenon?' in S. Sheldon & M. Thomson (eds) *Feminist Perspectives on Health Care Law* (London: Cavendish Publishing 1998).

widespread concern about defensive medicine, there is little evidence that doctors have fixed their standards by reference to what the courts might think of their work. In fact, both the profession and its principal employer, the National Health Service, have taken on the pursuit of improved standards of practice themselves. To understand why and how this has happened it is necessary to review the limitations of medical malpractice law.

(1) Malpractice law

It is hardly necessary to point out that the cornerstone of medical law in this jurisdiction has become the *Bolam* test. Expanding from its origins in the law of negligence, it has been used by the House of Lords to define the law on informed consent, the treatment of incapacitated patients, and to establish the limits of the obligation to sustain life. The philosophy of *Bolam*, by which I mean the regulation of health care practice through a filter of prevailing professional standards, is evident in many other areas of medical law. The definition of death is determined by medical standards. The legality of individual abortions depends on the honest belief of doctors that the grounds set out in the Abortion Act 1967 (as amended) are satisfied. The law makes no direct inquiry into the circumstances, but trusts two registered medical practitioners to do so on society's behalf.

My purpose requires a brief discussion of the *Bolam* test and its application. I shall make no attempt to explain the law in detail, ²⁷ but its key characteristics are an important context to the changes to which I wish to draw attention. The test, as set out by McNair J reads as follows

A doctor is not guilty of negligence if he has acted in accordance with a practice accepted as proper by a responsible body of medical men skilled in that particular art... Putting it the other way round, a doctor is not negligent, if he is acting in accordance with such a practice, merely because there is a body of opinion that takes a contrary view.²⁸

The essence of this test is that it measures the work of doctors against the practice of their peers rather than against a judicial assessment of acceptable practice. It is reinforced by the reluctance of the courts to determine conflicts of professional opinion. In *Maynard v W Midlands RHA*, the House of Lords held that judges should not choose between schools of thought. ²⁹ Once it was established that a responsible body of opinion accepted the practice that was followed, it was immaterial that other,

²⁵ Sidaway v Bethlem RHG [1985] 1 All ER 643, Re F [1989] 2 FLR 376, Airedale NHS Trust v Bland [1993] 1 FLR 1026.

^{[1993] 1} FLR 1026.

²⁶ Re A [1992] 3 Med LR 303; Human Tissue Act 1961 s 1(4), (4A); A code of practice for the diagnosis of brain stem death: including guidelines for the identification and management of potential organ and tissue donors (London: Department of Health, 1998)

²⁷ I have set out my account of this law in J. Montgomery, *Health Care Law* (1997) pp 169-176. This was written prior to the decision of the House of Lords in *Bolitho v City & Hackney HA* [1997] 4 All ER 771, although for reasons set out below I believe that the account remains substantially accurate after that decision. See also M. Jones 'Breach of Duty' in I. Kennedy & A. Grubb (eds) *Principles of Medical Law* (Oxford: Oxford University Press 1998) 340-48.

²⁸ Bolam v Friern HMC [1957] 2 All ER 118, 122.

²⁹ Maynard v W Midlands RHA [1985] 1 All ER 635.

even equally responsible, practitioners disagreed. It has further been held that even a very small group of doctors can constitute a 'responsible body of opinion' provided that they are appropriately skilled in the relevant area. 30 The general impact of the Bolam test has been that medical practice is judged by doctors rather than lawyers. At best, it reinforces prevailing professional standards, but it means that the courts do little to alter medical culture or practice.

The general dissatisfaction of lawyers with this approach can be seen in a series of short but trenchant articles in the New Law Journal written by an eminent personal injury lawyer claiming to explode the *Bolam* myth. ³¹ Iain S. Goldrein opens by observing that the *Bolam* test was nothing other than part of a summing up to a lay jury and that it deludes judges into thinking that they balance the reasonableness of risk and precautions as lawyers rather than lay people. Thus judgments that should be issues of fact are treated as resolved by a legal rule. Goldrein tries to show that the Bolam test can be sidelined as being incompatible with the general structure of the law of tort. The most startling thing about these articles is that the consistent adherence of the House of Lords to the application of *Bolam* is completely ignored. The leading case of Whitehouse v Jordan was not even cited. ³² The decision in Maynard v W Midlands RHA was quoted as if was a departure from rather than a retrenchment of the peer review standard. 33 An allusion to Sidaway v Bethlem RHG was made, but there was no recognition of the role played by the Bolam test in that decision.³⁴ The reality is that the *Bolam* test is at the heart of the legal doctrine of medical malpractice, and cannot be treated as an anomaly. Only by completely ignoring the approach upheld by the highest court of the land could Goldrein suggest that a different philosophy prevailed. The House of Lords has had ample opportunity to refine or reject the Bolam test and the fact that it has chosen not to do so needs to be explained not ignored.

The latest pronouncement from the House of Lords, Bolitho v City & Hackney HA has been seen by some as a step away from the dominance of the *Bolam* test. 35 I want to suggest that it offers little new, and that the limitations of malpractice litigation have now to be tackled outside the courts and indeed are being addressed vigorously. Bolitho is an unusual case in that the question of professional standards came to the fore not in relation to what the defendant's doctor had done, but in respect of the causal link between an accepted failure of care and the plaintiff's injuries. The Health Authority accepted that their doctor's failure to attend Patrick Bolitho fell below the required standard of care, but contended that even if the doctor had examined him she would not have intubated him. Only if she had intubated him would his death, due to respiratory failure leading to cardiac arrest, have been avoided. For that defence to succeed the health authority needed to show not only that the doctor would not have intubated but also that her failure to intubate would not itself have been negligent. The

³⁰ De Freitas v O'Brien[1995] 6 Med LR 108.

³¹ I. Goldrein, 'Bolam – problems arising out of "ancestor" worship' (1994) 144 NLJ 1237-39, 1248, 'Exploding the Bolam myth' (1994) 144 NLJ 1282-84, 'The interface of expert and jury' (1994) 144 NLJ 1315-6, 'Exploding the Bolam myth' (1994) 144 NLJ 1378, 'Exploding the Bolam myth' (1994) 144 NLJ 1415-16, 'Exploding the Bolam myth' (1994) 144 NLJ 1449-50, 'Exploding the Bolam myth' (1994) 144 NLJ 1480-81. ³² Whitehouse v Jordan [1981] 1 All ER 267.

³³ Maynard v W Midlands RHA [1985] 1 All ER 635.

³⁴ Sidaway v Bethlem RHG [1985] 1 All ER 643.

³⁵ *Bolitho v City & Hackney HA* [1997] 4 All ER 771.

Bolam test fell, therefore, to be considered in respect of a possible alternative course of events to that which actually happened.

The House of Lords reviewed the case law and argued that the *Bolam* test did not require the courts simply to defer to professional judgment. Lord Browne-Wilkinson noted that the words 'responsible' and 'reasonable' appeared in the test itself and that in Maynard Lord Scarman had referred to a body of opinion needing to be 'respectable'. He stated that where professional opinion is not capable of withstanding logical analysis, the judge is entitled to hold that the body of opinion is not reasonable or responsible. He emphasised that it would 'very seldom' be right for a judge to reach such a conclusion about the genuine views of a competent medical expert, but he reserved to the courts the right to do so. Expert opinion, he said, would provide the bench mark unless it could not logically be supported at all.

The crucial point to be made about these statements is that they are really nothing new. As Lord Browne-Wilkinson himself pointed out, the opportunity to impose judicial standards has always been stressed by the courts. In Hills v Potter, reported in 1983, the judge said that he must satisfy himself that medical opinion was 'both respectable and responsible. '36 In Sidaway Lord Bridge rejected the suggestion that standards were merely a question for the medical profession (although Lord Scarman took a different view of the effect of applying *Bolam*). ³⁷ The actual decision in Bolitho went against the plaintiff precisely because the court accepted the expert evidence that a competent body of opinion supported refraining from intubation. This was despite the fact that the judge indicated that from a lay person's perspective he would have expected intubation to be the right course.

The impact of the *Bolitho* decision is still difficult to assess. There are examples of courts appearing to use it to justify a more interventionist role. In Sharpe v Southend HA, Creswell J seemed to reserve right to judge professional standards in a radiology case, relying on the Bolitho decision in the Court of Appeal, although his approach is still a little ambiguous.³⁸ In *Ian Leslie Marriott v W Midlands HA* the Court of Appeal was split on the application of *Bolitho*. ³⁹ Beldam LJ held that the judge was entitled to subject medical evidence to her own analysis. 40 However, he also held that the evidence in question in the case was only of a personal view and not indicative of whether a responsible body of opinion would agree. It would not, therefore have satisfied the requirements of the *Bolam* test even without judicial scrutiny of its substance. Pill LJ held that this was not a Bolitho case at all because there was only one view on what should have been done on the findings of fact actually made.⁴¹

However, there is still ample evidence of the judiciary continuing to decide cases on the basis of the Bolam approach. In Briody v St Helen's & Knowsley AHA the judge

³⁶ Hills v Potter [1983] 3 All ER 716, 728.

³⁷ Sidaway v Bethlem RHG [1985] 1 All ER 643, 663 (Bridge), 649 (Scarman); Scarman, 'Law & Medical Practice' in P. Byrne (ed.) Medicine in Contemporary Society (London King Edward's Hospital Fund for London 1987) 131-39, 134.

³⁸ [1997] Medical Law Reports 299, esp. 303 (QBD).

³⁹ [1999] Lloyds Medical Law Reports 23.

⁴¹ Swinton Thomas said 'I agree'. The reporter places his concurring speech with that of Beldam LJ, but there is no indication of why it should be agreement with one rather than the other of his colleagues.

had sought to go beyond unchallenged medical evidence that a respectable body of medical opinion would have acted as consultant did. This was held to make the decision unsustainable on appeal. In *Hallatt v NW Anglia HA* the *Bolitho* approach was distinguished when looking at conflict of evidence between experts because their opinions (based in part on reference to medical textbooks) were rational and justifiable. In *Rhodes v W Surrey & NE Hampshire HA* the defendant was supported by eminent expert evidence representing a responsible professional body of opinion and was found therefore not to be negligent despite opposing experts.

Some cases indicate that the judiciary strives to maintain the non-interventionist stance exemplified by Bolam even where it is satisfied that the health service should be held liable for injuries suffered by patients. In Wisniewski v Central Manchester HA a Bolitho style problem arose on the facts. 45 The doctor had negligently not attended, but the defence claimed that there was no causal link with the plaintiff's injuries because he would not have acted so as to avoid mishap. The judge had found that all reasonable doctors would have avoided the danger and that any other approach was unacceptable, rejecting the contrary opinion of some of the experts. The Court of Appeal criticised the judge's rejection of the defence evidence. While criticisms could be made of it, it was logically supportable and therefore satisfied the *Bolam* test (as interpreted in Bolitho). Interestingly, although application of Bolitho was rejected, 46 the Court of Appeal found a different route to sustain liability. They held that the failure of the doctor to give evidence permitted inferences to be drawn against him. The court was, therefore, entitled to conclude that he might in fact have done what the plaintiff suggested (and would therefore have avoided mishap). Even though it would not have been negligent to have acted differently at a later stage in the care, the doctor's own admitted error had on those facts caused the injury.

A similar pattern of reaffirming the primacy of *Bolam* while upholding liability on the facts was seen in *Penney, Palmer & Cannon v East Kent HA*. ⁴⁷ The case concerned errors in a cervical smear programme whereby abnormal slides had not been identified as such. In the High Court there was a direct attack on the application of the *Bolam* test. His Honour Judge Pepitt QC rejected evidence that competent screeners could have made the errors that were made. He argued that the *Bolam* test did not really come into question because mistakes had been made and therefore the practice was not acceptable. The expert evidence related to whether the error was excusable, seen to be a different point. Further, he held that if the *Bolam* test was relevant, *Bolitho* applied to allow a finding that the evidence did not stand up to logical analysis. In the Court of Appeal, it was held that the *Bolam* test did apply to ascertaining the appropriate standard of care. However, the differences between the parties were found to be matters of evidence in relation to what was apparent from the specific slides. This was a different matter from the required standard of competence in reading them. It was proper for the court to resolve a conflict of evidence on what

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⁴⁷ [1999] Lloyds Medical Law Reports 123 (QBD), (1999) Times November 25 (CA).

⁴² [1999] Lloyds Medical Law Reports 185, esp. 191 (CA)

⁴³ [1998] Lloyds Medical Reports 197, esp. 203 (CA).

⁴⁴ [1998] Lloyds Medical Reports 256 (Aldershot & Farnham County Court). See similarly *Bancroft v Harrogate HA* [1997] Medical Law Reports 398 (CA).

⁴⁵ [1998] Lloyds Medical Reports 223 (CA).

⁴⁶ NB The High Court argument considered the application of *Hucks v Cole* [1994] Med LR 393 as that stage of the hearing predated the *Bolitho* decision. The arguments in the two cases are similar.

the slides contained, which determined the case in favour of the plaintiffs. The Court of Appeal was therefore able to uphold liability without departing from the peer review standard of care in negligence. Even if the *Bolitho* decision represents a stronger affirmation of the judicial right to set standards for medicine, it seems clear that the courts prefer to avoid doing so.

The key question to understand is why the judiciary has not seized the opportunity to move away from the non-interventionist interpretation of the *Bolam* test. While there may be some change in attitude, the *Bolitho* decision has not led to judges balancing risks on their own assessment as Goldrein's approach would expect. As I have argued elsewhere, the most plausible explanation of this lies in the acceptance by the judiciary that doctors are altruistic, working under considerable pressure in the public interest and generally undeserving of liability. In a sense, they are seen as on our side, part of our community. Taken with self-doubt about the courts' ability to comprehend the technical nature of medical knowledge and the interpretative skills required to apply it, this ideological paradigm has led the courts to be wary of departing from the assumption that peer review is the appropriate way to determine liability. 48 Unless those assumptions are displaced, it seems unlikely that the test for malpractice will be developed. This review of the case law has shown that the failure of the law to promote good practice is directly related to its central conceptual tool – the Bolam test and that there seems little prospect at this time of the courts altering their approach. Medical lawyers need, therefore, to consider different strategies to improve standards of care.

(2) Institutional Responses

Equally importantly, both the NHS and the medical profession have good reasons to avoid complacency. Despite the relative friendliness of the test for negligence, the NHS spends considerable amounts of money, time and human resource on dealing with litigation, even litigation that is successfully defended. It is therefore keen to ensure that its exposure is reduced. For the medical profession, the maintenance of a favourable malpractice regime depends on the continued respect of the judiciary. At a time when confidence in medicine has been severely shaken, acting to reassure us that the profession can be trusted is a key strategy in staving off external regulation. Accountability through open and robust self-regulation is preferred to the imposition of judicial standards.

The response to a perceived 'malpractice crisis' has taken a number of forms, a diversity of approaches that probably reflects the lack of reliable knowledge about the incidence and impact of litigation. Even information on the cost of litigation is of dubious value. In a single month, Parliament was given different figures on the cost of clinical negligence litigation for the year 1995-6 by the then Health Minister, Alan Milburn. On July 14 the cost of clinical litigation in England was said to be £149.1 million. On the 24th of that month it was £173 million.

⁴⁹ Hansard, House of Commons, 14 July Written Answers Col 75, 24 July 1997 Written Answers Col 726.

⁴⁸ J. Montgomery, 'Medicine, accountability and professionalism' (1989) 16 JLS 319-39.

One series of measures aims to contain the costs of litigation. One of these is the new clinical negligence protocols, introduced under the civil procedure reforms to streamline the process of litigation, making it faster and cheaper. Other changes have been internal to the NHS. In 1989, NHS indemnity was introduced to replace reimbursement of insurance premiums in the hope that it would prove a cheaper option. Once they became directly responsible for the costs of litigation, NHS bodies introduced risk management strategies aimed to reduce exposure. These have been reinforced by the establishment of the Clinical Negligence Scheme for Trusts (CNST), with elaborate standards for the management of risks and claims. Some of these standards have substantive impact on promoting good practice and go some way to mitigating the failures of the common law to set standards (see further below).

The handling of clinical negligence litigation within the Health Service has also been streamlined in order to reduce costs and promote efficiency. NHS Trusts are no longer left to determine how to manage claims in independent isolation. The NHS Litigation Authority is now responsible for overseeing and giving advice on structured settlements, novel, contentious or repercussive claims, big claims (i.e. those worth more that £1 million) and on developments in law and legal practice. A prescribed panel of solicitors' firms for CNST work will reintroduce a system that will ensure that defence work in clinical negligence litigation is concentrated on relatively few experienced firms (reversing the fragmentary effect of the decentralisation that resulted from the creation of NHS Trusts in the early 1990s). The intention is that the normally unpredictable development of malpractice law, dependent on the desire of particular plaintiffs and defendants to have their day in court rather than settle, should become more controlled. Perhaps enabling a more comprehensive and rational approach to moving legal doctrine forward.

It is too early to be clear whether this desire will be matched by achievement. The defence of litigation against the NHS in respect of Haemophilia and Hepatitis C infection is being co-ordinated by the NHS Litigation Authority under its powers to call in and manage claims which are 'novel, contentious or repercussive.' They will be handled through a single firm of solicitors. This will also enable expert evidence to be co-ordinated. Similarly claims in relation to negligent prescription of AZT have been identified for co-ordination in the same way. 55

The principal points to be made about the NHSLA at this point are concerned with the institutional nature of the response. These developments show a corporatist, centralist, conception of how the litigation game should be played. Cases are now brought against NHS bodies because they fund damages. This sweeps away some interesting

⁵⁵ NHSLA 'AZT (Retrovir/Zidovudine) Claims' 97/C9, 6 November 1997.

⁵⁰ Claims of Medical Negligence against NHS Hospital and Community Dentists, HC(89)34. For commentary, see R. Bowles and P. Jones, 'Better Safe than Sorry' (1991) HSJ 21 Mar., 18–19; P. Reeves, 'National Health Service Indemnity' (1990) 87/18 LSG 24–5; P. Fenn and R. Dingwall, 'Medical Negligence and Crown Indemnity' in J. Gretton (ed.), Health Care United Kingdom 1989 (Birmingham: Policy Journals, 1990), 39–46; R. Dingwall and P. Fenn, 'Is NHS Indemnity Working and is There a Better Way?' (1994) 73 British J Anæsthesia 69–77.

⁵¹ Clinical Negligence Scheme for Trusts, *Risk Management Standards and Procedures: Manual of Guidance* (London: NHS Litigation Authority 1997) Risk Management Standard No. 7.

⁵² NHSE, The National Health Service Litigation Authority: Framework Document (NHSE 1996).

⁵³ NHSLA, 'Haemophilia and Hepatitis C' 97/C3 25 February 1997.

⁵⁴ NHSLA, 'Re Hepatitis C Claims' letter of 27th May 1997

areas of debate. The old system has gone by which individual doctors were sued as well as health authorities but apportionment of damages was arranged by the NHS and the medical defence organisations. This prevented the courts considering the attribution of responsibility within health care teams, leaving it to the NHS and medical professions to reach an extra-legal accommodation. Now, as it is NHS bodies who are sued, the NHSLA will be able to exercise a degree of control that was formerly lacking in previous fragmented systems. Anecdotal indications that the medical defence societies sometimes selected cases to fight with an eye to tactical advantage in the development of legal doctrine provide a precursor to a real possibility in the new corporate NHS. Thus, the NHSLA, rather than the local health authority, was responsible for deciding that the Canterbury screening case proceeded to the Court of Appeal in order to seek to overturn the apparent disregard for the ascendancy of the *Bolam* test in the High Court. Had the High Court reasoning been sustained, the implications for the NHS as a whole might have been considerable. See

In addition to measures designed to reduce the cost of litigation, there has also been concern to divert grievances away from the courts into administrative procedures. Comprehensive complaints procedures were finally introduced into the NHS in 1996. After long negotiation with the medical profession, the complaints procedures for general and clinical complaints were integrated. A semi-independent review system was established for cases where local resolution had not proved satisfactory. The jurisdiction of the Health Service Commissioners was extended to clinical matters. While the emerging evidence suggests that the new system has satisfied few of those experienced in its operation, one of the key functions of the new system is to keep disputes out of the courts where possible. An understanding of the way in which adverse incidents are raised and examined in the current medical law cannot be obtained without recognition of this corporate quasi-legal dimension to NHS dispute resolution.

(3) Clinical governance

The most significant response to the supposed 'malpractice crisis' can be found in attempts to assure the standard of clinical services. The central plank in the Blair Government's approach to this issue of quality control is the introduction of 'clinical governance' into the NHS. This is defined as

A framework through which NHS organisations are accountable for continuously improving the quality of their services and safeguarding high

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⁵⁶ HM 54(32).

⁵⁷ Penney, Palmer & Cannon v East Kent HA [1999] Lloyds Medical Law Reports 123 (QBD), (1999) Times November 25 (CA).

⁵⁸ The fact that a move away from the *Bolam* test might be regarded as desirable does not detract from the point being made here, which is that a corporate attempt is being made to influence the doctrinal development of the common law. For a single health authority fighting a single case, this would not be an economic use of funds, but for the NHS as a whole it is seen as an appropriate consideration.

⁵⁹ See J. Montgomery, *Health Care Law* (1997) ch 5.

⁶⁰ H. Wallace & L. Mulcahy, Cause for Complaint? An evaluation of the effectiveness of the NHS complaints procedure (London: Public Law Project 1999).

standards of care by creating an environment in which excellence in clinical care will flourish. ⁶¹

The Government wishes to see the culture of 'blame' replaced by one of learning. A comprehensive programme of quality improvement is intended to ensure systematic clinical audit programmes (no longer on a voluntary basis), the extension of evidence based practice, the implementation of national standards and guidance, effective monitoring of standards of clinical care, continuing professional development and research and development programmes. Risk management is to be extended to clinical risks, with systematic programmes to reduce risks. Adverse incidents should be identified through complaints and reporting procedures. The NHS should learn from them and act promptly to avoid their recurrence. Poor professional performance should be addressed early through clear reporting procedures and steps to help staff improve their standard of work. NHS bodies are currently undertaking baseline assessments of their ability to meet these quality control standards and drawing up development plans to move the agenda forward.

This local culture of quality improvement is to be supplemented by a national framework to establish and assure standards. National Service Frameworks are to set benchmarks against which services can be assessed. Thus, the National Framework for Mental Health promises that people who contact their primary health care team with a common mental health problem should have their mental health needs assessed and should be offered effective treatments including referral to specialist services if necessary. They should be able to make contact with local services round the clock to meet their needs and receive adequate care. A duty doctor approved under the Mental Health Act must be available 24 hours a day. Every primary care group will need to work to develop resources within each general practice to assess mental health needs, to manage common mental health problems, and to support agreed care plans for those with severe mental illness. These care plans should be written and users should have a copy.

Two new NHS bodies have been created as part of this quality assurance system. Standards will be identified by the National Institute of Clinical Excellence. This body will review evidence and recommend good practice in service delivery. This will include assessing the effectiveness of drugs and advising on how they should best be used. Policing performance on clinical governance will fall into the remit of the Commission for Health Improvement. It will give advice on the implementation of clinical governance and carry out a rolling review of inspections. Ultimately, the Commission will have the power to take over the management of failing bodies.

⁶⁷ Health Act 1999, ss 19-22, Sched 2.

⁶¹ NHS Executive, *Clinical Governance: Quality in the new NHS* (DoH 1999) para. 6. See Annex 2 for the components summarised in this paragraph. A dedicated site has also been created on the NHSWeb, an intranet for the Service.

⁶² See also GMC Maintaining Good Professional Practice (London: GMC 1998).

⁶³ NHS Executive, National Service Framework for Mental Health: Modern Standards & Service Models (1999).

⁶⁴ *Ibid.* pp. 33, 41.

⁶⁵ *Ibid.* p. 35.

⁶⁶ National Institute for Clinical Excellence (Establishment and Constitution) Order 1999, SI 1999 No 220; National Institute for Clinical Excellence Regulations 1999, SI 1999 No 260.

It is far too early to test whether clinical governance will make a positive contribution to raising standards in the National Health Service. However, medical lawyers need to pay attention to assessing and testing that contribution. The new corporate approach to assuring standards has a number of implications for their subject. First, it creates a powerful and prescriptive system for defining service standards that is politically rather than legally accountable. There seems no obvious route by which those who believe that their access to particular treatments is being restricted by the imposition of corporate NHS standards could seek redress in the courts. Following national standards would provide a complete defence to malpractice allegations and be entirely reasonable for judicial review purposes. It is also unclear how doctors could raise a claim that their clinical freedom was being compromised if they did not agree with the standards being set. The model of individual clinical freedom, with the possibility of significant variations of practice, that the *Bolam* test protects is being supplanted by a corporatist version. The NHS does not share the reticence of the House of Lords in choosing between schools of thought.

The Government has made great play of the introduction of a statutory duty of quality for NHS Trusts, ⁶⁹ supplementing the earlier limited focus on financial duties. ⁷⁰ This new duty is not, however, a duty to provide high quality services but to have quality assurance processes in place. It will not give rise to new rights of redress on the part of individuals. The purpose of the reform is to foster a particular culture of quality assurance and performance, not to extend legal grounds for review. Clinical governance leads to a corporatist approach to service development rather than individual clinical freedom. It seeks to build a particular sort of professional community built on institutional loyalty rather than personal freedom. This throws up a challenge to lawyers to consider whether clinical negligence litigation will become increasingly seen as a species of public authorities' liability. In the past litigation against the health service has rarely been seen in these terms because most cases have taken the form of allegations of negligence against individual professionals.⁷¹ The newly corporatised NHS may need to be examined in a different light. The leading House of Lords cases on public service liability may need to be examined more carefully with an eye to their application to the NHS. 72

Patients' Rights

The law on patients' rights within health care provides a crucial test of the ideological foundations of English medical law. It is here that one would expect to see most clearly that standards are set for the medical profession establishing the respective obligations and rights of the players. An examination of the law on consent and confidentiality soon shows, however, that the dominant theme is the creation of moral values within the professional and NHS communities and their reinforcement through

⁶⁸ See *R v Derbyshire HA*, *ex p Fisher* [1997] Medical Law Reports 327 (QBD).

⁶⁹ Health Act 1999, s 18.

⁷⁰ NHS and Community Care Act 1990, s 10, Sched 2 para 6.

⁷¹ For discussion of cases that depart from this norm, see J. Montgomery, *Health Care Law* (1997) 70-74.

⁷² See *X v Bedfordshire CC*, *M v Newham LBC*, *E v Dorset CC* [1995] 3 All ER 353 and *Barrett v Enfield LBC* [1999] 3 WLR 79.

the law. It also becomes clear that the traditional approaches to studying, defining and evaluating the law may need to be reconsidered.

(1) Access to health care

Historically, attempts to use the law to enforce rights to health care have been mostly frustrated by the English courts' willingness to accept clinical and managerial discretion in the allocation of scarce resources. 73 The traditional position can perhaps be most clearly illustrated by the case of Jaymee Bowen, whose father's court action failed to secure NHS funding for the treatment he believed to be in Jaymee's best interests. 74 The Court of Appeal rejected the suggestion that her right to life could override the fact that Parliament had delegated the responsibility to allocate health resources to health authorities relying on clinical advice. Such attempts have been handicapped by the vagueness of legal definitions of the duties on the NHS to provide services. Thus general medical practitioners are obliged to provide 'all necessary and appropriate personal medical services of the type usually provided by general medical practitioners' – an essentially circular definition that reinforces professional practice rather than defines patients' rights. 75 The Secretary of State for Health has duties under the NHS Act 1977 to provide a comprehensive health service, but these duties are limited by reference to 'such extent as he considers necessary to meet all reasonable requirements.'76

Disputes over the scope of patients' rights will remain. The However, the main legal disputes over access to health care will increasingly take a new form. As more decisions about the way in which the NHS delivers its care are taken centrally the focus of disputes will become less individualised and more a matter of challenging corporate practice. An early taste of the work of the National Institute for Clinical Excellence was its refusal to recommend the influenza drug Relenza for NHS use with the elderly. This sort of decision will be the principal form of rationing in the 'New NHS'. The clearest indication of the legal route down which this development will take us is the litigation instigated by Pfizer when the Secretary of State for Health, Frank Dobson, sought to discourage doctors from prescribing Viagra, its new drug for the treatment of male impotence.

The form of the litigation was judicial review of a NHS Circular in which doctors were advised not to prescribe Sildenafil (marketed as Viagra). The ruling was that, while the Secretary of State had the power to limit doctors' power to prescribe, this could not be done through the administrative route of an advisory circular. Most interesting, however, is the way in which the legal arguments were cast. European community law, guaranteeing free movement of goods provided one of the strands. It was found that restricting the use of particular drugs for reasons of public finance was

⁷³ See generally J. Montgomery, *Health Care Law* (1997) 63-70.

⁷⁴ R v Cambridge HA, ex p B [1995] 2 All ER 129.

⁷⁵ NHS (General Medical Services) Regulations 1992, SI 1992 No 625 (as amended), Sched 2 para. 12(1).

⁷⁶ Ss 1-5.

⁷⁷ E.g. *R v N Lancashire HA*, ex p A (1999) Times 24 August.

⁷⁸ HSC 1998/158

⁷⁹ R v Secretary of State for Health, ex p Pfizer [1999] Lloyds Medical Law Reports 289 (QBD).

acceptable within that law. This strand of argument concerns the relationship between two great industries, health services and pharmaceuticals, rather than the interests of patients. A second strand concerned the degree of clinical freedom of doctors within the service. Collins J held that the circular was unlawful because it required doctors to refrain from prescribing Viagra independently of whether their patient needed it according to their professional judgement. This line of argument is about the degree to which the NHS is entitled, under current regulations, to instruct doctors how to exercise their clinical judgement.

What the Viagra litigation exposes, although it does not resolve it, is a clash between the traditional culture of individual clinical freedom and the new modernised NHS in which consistency of practice has become an important goal. With the emergence of the National Service Frameworks and the gradual extension the work of the National Institute for Clinical Excellence, legal disputes about the degree of flexibility individual practitioners should have are likely to become more commonplace. They are likely to be fought not between patients and doctors or health authorities, but between industries and the central NHS institutions. The key battleground will be the extent to which the NHS is entitled to insist on conformity to its nationally determined priorities and values. In the past, this has largely been a matter for internal politics. With the creation of new institutions of control, it will become a matter for legal determination. Our understanding of the nature of medical law needs to incorporate this newly important dimension.

(2) Consent issues

It is widely accepted that the law of consent is a fundamental building block of medical law. It is this area of law that establishes the balance of power between patients and the health professionals who care for them. ⁸⁰ The legal requirement of consent is usually portrayed by commentators as reinforcing the ethical principle that we should have control over what happens to our bodies by providing a veto on unwanted intrusions. Thus, it has been said in the House of Lords that it is a 'fundamental principle, now long established, that every person's body is inviolate'. ⁸¹ Without consent, medical intervention on a competent person is unlawful.

The same judge, Lord Goff, re-emphasised the principle in the *Bland* case:

[I]t is established that the principle of self-determination requires that respect must be given to the wishes of the patient, so that if an adult patient of sound mind refuses, however unreasonably, to consent to treatment or care by which his life would or might be prolonged, the doctors responsible for his care must give effect to his wishes, even though they do not consider it to be in his best interests to do so ... To this extent, the principle of the sanctity of human life must yield to the principle of self-determination ... and, for present purposes

⁸⁰ I. Kennedy, 'The doctor-patient relationship' in P. Byrne, *Rights and Wrongs in Medicine* (Oxford: Oxford University Press, 1986), 7-21, esp. 12-15

⁸¹ Re F [1989] 2 FLR 376, 435 per Lord Goff.

perhaps more important, the doctor's duty to act in the best interests of his patient must likewise be qualified. 82

In fact, this rights based explanation of the foundation of the law of consent is not the only strand of judicial thinking. Lord Donaldson put forward a very different approach in which he distinguished between the legal and clinical purposes of consent. He explained the purpose of consent as follows.

There seems to be some confusion in the minds of some as to the purpose of seeking consent from a patient (whether adult or child) or from someone with authority to give that consent on behalf of the patient. It has two purposes, the one clinical and the other legal. The clinical purpose stems from the fact that in many instances the co-operation of the patient and the patient's faith or at least confidence in the efficiency of the treatment is a major factor contributing to the treatment's success. Failure to obtain such consent will not only deprive the patient and the medical staff of this advantage, but will usually make it much more difficult to administer the treatment. I appreciate that this purpose may not be served if consent is given on behalf of, rather than by, the patient. However, in the case of young children knowledge of the fact that the parent has consented may help. The legal purpose is quite different. It is to provide those concerned in the treatment with a defence to a criminal charge of assault or battery or a civil claim for damages for trespass to the person. It does not, however, provide them with any defence to a claim that they negligently advised a particular treatment or negligently carried it out. 83

The difference between these approaches is in part one of perspective. Lord Goff formulates his proposition from the point of view of the patient. Lord Donaldson explains the situation from the vantage point of a doctor. However, approaching the issue from these different sides of the doctor-patient relationship leads to variations of substance. The divergent strands can be identified in the leading consent case, Sidaway v Bethlem RHG.84 Lord Scarman's speech begins with the assertion of patients' rights to self-determination and constructs a framework based on the right to receive material information, subject to a therapeutic privilege enabling doctors to keep information back when they deem it necessary to do so in the patient's best interests. Lord Diplock's speech exemplifies the alternative approach. He argued that doctors had a single legal duty to exercise their skill and judgement in order to improve the patient's health. 85 Consent issues did not invite a distinctive approach in the way that Lord Scarman had suggested. Instead, Lord Diplock found, it was as much a matter of clinical judgment to decide how much to tell a patient about the treatment as it was to diagnose the problem or administer care. Although the other two speeches adopt slightly different stances, they broadly adopt the perspective of Lord Diplock by seeing the issue as one of medical duty rather than patient right. 86

⁸² Airedale NHS Trust v Bland [1993] 1 FLR 1026, 1035-1036 per Lord Goff.

⁸³ Re J [1992] 2 FCR 785, 799-800.

⁸⁴ Sidaway v Bethlem RHG [1985] 2 All ER 643.

^{85 (1985) 1} BMLR 132, 149

⁸⁶ I have discussed the interpretation of *Sidaway* in J. Montgomery *Health Care Law* (1997) 241-245. For an account with a rather different emphasis, see I. Kennedy, *Treat Me Right: Essays in Medical Law and Ethics* (Oxford: Oxford University Press 1988) pp 193-212.

Immediately after *Sidaway* some commentators took the view that the door was open to the development of the law of consent. Simon Lee wrote that he suspected

That medical law and ethics [was] getting ahead of the field.... I have little doubt that *Sidaway* will come to be seen as a significant expansion of the ambit of informed consent.... I imagine that ever since *Sidaway* plaintiffs have been tacking on to claims of negligent treatment a claim that they were not in a position to give informed consent. Once these cases come to court, if not before, medical practice will alter to cover against such actions in the future. ⁸⁷

Ian Kennedy offered a similarly confident summary after a detailed analysis of the speeches: 'The message of *Sidaway* is clear. Those who advise doctors already know it. Medical paternalism has had its day.' 88

In fact, history suggests that this confidence has proved unfounded. The Court of Appeal has consistently regarded the *Sidaway* decision as requiring a professional standard of disclosure to be applied rather than developing the doctrine of informed consent. Although the occasional high court decision has been more adventurous, the overall picture remains a non-interventionist one. In the only post-*Bolitho* Court of appeal decision the plaintiff's claim that she should have been told more was rejected because the court accepted medical evidence that the risk that she alleged she had not been told was insignificant. Although the Court of Appeal suggested that patients should be told of significant risks, it recognised that this was no more than had been suggested in *Sidaway* and that it reflected the normal position that could be supplanted where circumstances were unusual. In *Sidaway* such circumstances seemed to import clinical discretion.

It is implausible to suggest that the English courts' refusal to adopt informed consent ideals is inadvertent. ⁹² In *Sidaway* itself, there was extensive discussion of the doctrine as developed in Canada and the USA. Since then, the approach in *Sidaway* has been rejected by the Australian courts in the decision of *Rogers v Whittaker*. ⁹³ This case was seen as sufficiently relevant to be reported in the English series of medical law reports but has been buried without trace before the English judges. No citation of it appears from a lexis search. Medical lawyers seem strangely disconnected from the judiciary. The opportunities have been there, but the courts have not taken them.

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 ⁸⁷ S. Lee, 'Towards a Jurisprudence of Consent' in J. Eekelaar & J. Bell (eds) Oxford Essays in Jurisprudence. Third Series (Oxford, Oxford University Press 1987) 199-220 at p. 216.
 ⁸⁸ I. Kennedy, Treat Ma Right: Essays in Medical Law and Ethics (Oxford: Oxford University Press 1987)

⁸⁸ I. Kennedy, *Treat Me Right: Essays in Medical Law and Ethics* (Oxford: Oxford University Press 1988) p 210.

⁸⁹ Gold v Haringey HA [1987] 2 All ER 888, Blyth v Bloomsbury HA [1993] 4 Med LR 151, Palmer v Eadie (unreported, 18 May 1987), O'Keefe v Harvey-Kemble (1998) 45 BMLR 74, Pearce v United Bristol Healthcare NHS Trust (1998) 48 BMLR 118. I have discussed the implications of the first two of these cases in J. Montgomery, 'Power/Knowledge/Consent: Medical Decisonmaking' (1988) 51 MLR 245. See also the Scottish case of Moyes v Lothian HB [1990] 1 Med LR 463. Michael Jones makes a similar assessment of the case law, although the conclusions he draws are different, in 'Informed consent and other fairy stories' (1999) 7 Med Law Rev 103-134.

⁹⁰ Smith v Tunbridge Wells HA [1994] 5 Med LR 334.

⁹¹ Pearce v United Bristol Healthcare NHS Trust (1998) 48 BMLR 118 (CA).

⁹² For a comprehensive review, see M. Jones, 'Informed consent and other fairy stories' (1999) 7 Med Law Rev 103-134.

^{93 [1993] 4} Med LR 79.

Although the common law has failed to develop a law of informed consent, statutory interventions have sometimes moved things forward in that direction. Examination of regulations governing specific areas of health care identifies a number of examples of provisions likely to enhance higher standards of informed consent. Opticians are obliged to provide written diagnoses. 94 Taken in context, however, this is probably related more to the desire to increase their exposure to market forces than to promote greater understanding of the care required. The main purpose of the requirement is to prevent patients being forced to buy their spectacles or contact lenses from the person who does their eye test. Armed with a written prescription they can shop around for the best fashion or financial deal. 95 Dentists too are required to provide written treatment plans for their patients, giving them information to take away while they decide whether to accept a course of treatment. ⁹⁶ Where an organ is to be provided for transplantation by a live donor, statutory consent requirements supersede the common law. The Unrelated Live Transplant Authority has to be satisfied that a registered medical practitioner has given the donor an explanation of the nature and risks involved in the procedure, that the donor understands that explanation and that they have consented without coercion or the offer of an inducement.⁹⁷

None of these specific interventions really addresses the issues of substance. Most reflect rather than extend the limitations of the common law. The same is generally true of the activities of the Department of Health. General guidance has been issued on consent matters and on the court rulings, but it has done little to encourage practitioners to go beyond the minimal standards required by the courts. ⁹⁸ Although the Human Fertilisation and Embryology Authority has issued model consent forms, these are aimed to facilitate recording of specific consents required by the legislation and the Code of Practice merely cross-refers to the general Department of Health guidance on consent issues. ⁹⁹ The Mental Health Act Code of Practice is similarly limited in its general treatment of informed consent. ¹⁰⁰

Just occasionally, the Department of Health has been prepared to go further. One such area is informed consent in relation to testing for HIV. This has been the subject of much debate amongst legal commentators. Some have argued that testing for HIV without explicit and full explanation might be unlawful under the law of trespass to the person. Although it is as yet untested in court, ¹⁰¹ it seems unlikely that the courts would adopt that approach given their resistance to the use of battery as a form of

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⁹⁴ Opticians Act 1989, s 26; Sight Testing (Examination and Prescription) (No 2) Regulations 1989, SI 1989 No. 1230.

 ⁹⁵ See J. Montgomery, 'Patients First: The Role of Rights' in K.W.M. Fulford, S. Ersser, and T. Hope (eds.), *Essential Practice in Patient-centred Care* (Oxford: Blackwell Science, 1996), 142-52.
 ⁹⁶ NHS (General) Dental Services) Regulations 1973, SI 1973 No 1468 as amended, Sch.1, paras. 4(1)(b), 5(1)(b).

Human Organ (Unrelated Persons) Transplant Regulations 1989, SI 1989 No 2480, art. 3.

⁹⁸ See *A guide to consent for examination or treatment* NHS Executive (London. Department of Health, 1990) issued with HC (90)22; *Consent to treatment : summary of legal rulings* HSC 1999/031.

⁹⁹ HFEA *Code of Practice* (4th Edition 1998) , especially Annex D 'Model Form for Consent to Egg Retrieval and/or Egg or Embryo Replacement. Model Form for Consent to Donor Insemination'. ¹⁰⁰ 3rd ed 1999 ch 15.

¹⁰¹ M. Sherrard and I. Gatt, 'HIV Antibody Testing' (1987) 295 *BMJ* 911–12; I. Kennedy and A. Grubb, 'Testing for HIV Infection: The Legal Framework' (1989) 86/7 *LSG* 30–5, 86/9 *LSG* 30–1; A. Grubb, and D. Pearl, *Blood Testing*, *AIDS and DNA Profiling* (Bristol: Family Law, 1990), ch. 1.

action in informed consent. However, the Department of Health has dealt with the matter by issuing its own guidance on the way in which informed consent should be obtained to HIV testing, following consultation with an expert advisory group. 103

Counselling should follow four steps before obtaining a decision on testing. The first is to ensure that the individual understands the nature of HIV infection, transmission, and risk reduction. The second is to discuss risk activities the individual may have been involved in with respect to HIV infection including the date of the last risk activity and the perception of the need for a test. The third is to discuss the benefits and difficulties to the individual, his or her family and associates of having a test and knowing the result whether positive or negative. Finally the individual should be given details of the test and how the result will be provided. Only after this should the professionals seek an informed decision about whether or not to proceed with the test. The guidance provides further suggestions on what might be included in discussion to assist professionals engaged in counselling and reports on survey work on what clients have been found to want.

It may be that the key here is that expert advisory groups have become reluctant to display the traditional deference to the law and are demonstrating professional frustration with the timid approach of the common law. The General Medical Council has now issued guidance on securing consent that goes far beyond the limited observations of the courts. It advises that patients have a right to information and sets out guidance on what patients may wish to know. These include

- Details of diagnosis and prognosis;
- Uncertainties about diagnosis, including options for further investigation prior to treatment;
- Options for treatment and management, including the option not to treat;
- Likely benefits, probabilities of success, discussion of any serious or frequently occurring risks, lifestyle changes that may be caused or necessitated by treatment.

The substance of this advice will not be unfamiliar to commentators and lawyers. The point is not that there is some radical shift occurring within the profession. It is that the doctrine of informed consent proposed by Lord Scarman is becoming established within the professional community despite its rejection by the courts.

The Guidance issued by the Royal Surgical Colleges on ethical and legal issues has effectively rejected the ruling in *Sidaway*, giving content to the obligation to counsel patients in terms of the doctrine of informed consent. Patients should be told about common side effects, significant risks, alternative treatment options in the detail required by a reasonable person in the circumstances of the patient so as to make a

Medical Defence Union, AIDS: Medico-legal Advice (London: MDU, 1988); J. Montgomery, 'Victims or Threats?—The Framing of HIV' (1990) 12 Liverpool LR 25, 44–8; J. Keown 'The Ashes of AIDS and the Phoenix of Informed Consent' (1989) 52 MLR 790-800; J. Montgomery, Health Care Law (1997) 234-5.

¹⁰³ Guidelines for pre-test discussion on HIV testing March 1996 (London: Department of Health, reissued with amendments June 1997).

¹⁰⁴ General Medical Council, Seeking patients' consent: the ethical considerations paras. 4-5.

relevant and informed judgment. ¹⁰⁵ This can be seen as a victory for the rejected speech of Lord Scarman in *Sidaway*, but it has come via the internal normative work of the medical profession not through the courts. It probably goes too far to suggest that departing from this guidance will be *Bolam* negligent, as one commentator has suggested. ¹⁰⁶ However, as a step towards enshrining the values of informed consent in the culture of UK health care, professional guidance seems to be providing more than the courts have been prepared to offer.

There is, however, another important dimension to developments in the position of the patient that points to a further pressure on the individualistic models on which the law is based. The current Government's vision for the 'New NHS: Modern and Dependable' envisages that the assumption that the principal source of information on medical care will be communication from the treating physician will quickly become unfounded. Part of the Government's programme for improving the nation's health is to construct a new social contract for health in which citizens take responsibility for being active partners in health promotion. Those with chronic health problems are to be encouraged to become 'expert patients', knowledgeable in their condition. The Information Strategy for the NHS aims to provide electronic access to general information.

The fundamental and radical development here is that the position of patient is being detached from a relationship with an individual doctor and becoming a relationship with an organisation. Lawyers will know that the NHS has issued standard consent forms, ¹¹⁰ but in fact the impact of the NHS on consent issues has already been more significant than this and is likely to become even more so. The NHS Executive has indicated that the system for review of the effectiveness of treatment under the auspices of the National Institute for Clinical Excellence will probably generate advice on what patients should be told to secure informed consent to particular treatments. ¹¹¹ There may thus become NHS norms for information giving, building a culture of informed consent within the service.

Another example of service developments generating more far reaching expectations than the common law can be seen within the risk management processes being adopted to deal with perceptions of escalating litigation. It is a requirement of membership of the Clinical Negligence Scheme for Trusts that patient information sheets are produced for common elective procedures showing risks and benefits. To obtain level 1 of the risk management standards, these must be available for at least 10 common elective treatments. To obtain level 2, there must be information leaflets for at least 20 such treatments across a range of specialties. To obtain level 3

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¹⁰⁵ Senate of Surgery of Great Britain and Ireland, *The Surgeon's Duty of Care – Guidelines for surgeons on ethical and legal issues* (1998).

¹⁰⁶ C Foster, 'Surgeons side-line Sidaway' (1998) 138 SJ 228.

¹⁰⁷ The New NHS: Modern and Dependable.

¹⁰⁸ Saving Lives: Our Healthier Nation (London TSO 1999) Cm 4386, paras 3.47-3.50.

¹⁰⁹ Information for Health (Leeds: NHSE 1998)

¹¹⁰ See Department of Health, *A Guide to Consent for Examination or Treatment* (London DoH 1990) and HSG (92)32 substituting two of the model forms from the original guidance.

¹¹¹ Faster access to modern treatment: how NICE appraisal will work (Leeds: NHS Executive 1999) para. 39. ¹¹² Clinical Negligence Scheme for Trusts, Risk Management Standards and Procedures: Manual of

¹¹² Clinical Negligence Scheme for Trusts, *Risk Management Standards and Procedures: Manual of Guidance* (London: NHS Litigation Authority 1997) Risk Management Standard No. 7.

there must be a clear mechanism for patients to obtain additional information about their condition.

Our traditional paradigms are based on a relationship between individuals, but we need to move towards models recognising the importance of institutions. In fact, of course, we can see once again that this is not really new. It has long been the case that the responsibility for securing consent has rested with the health care system rather than the individual doctor. In the NHS consent to surgery will often not be obtained by the person actually performing the procedure. This has been made explicit in the standard consent forms for the avoidance of doubt. 113

Meeting the demands of patients for information and autonomy requires that the cultural resources of the NHS community be harnessed. Protecting patients' rights is being done through the values of the NHS and professional communities not as an imposition from outside. Our understanding of the role of law needs to be developed to reflect this strengthening of the importance of corporate values.

(3) Confidentiality and data protection

Perhaps the clearest illustration of this move towards the corporatisation of patients' rights can be found in the area of confidentiality. The traditional model of what it means to be a patient envisages an intimate relationship in a private consulting room. So far as confidentiality is concerned, the implication is that patients confide in the doctor on the understanding that the information will go no further. In reality, health care is delivered by a multi-disciplinary team which needs to share information to be effective. Considering the importance attached to confidentiality by patients and health professionals, the law is surprisingly undeveloped. 114 What we do have, however, displays many of the tensions that have been explored in this paper.

The issues can be illustrated by reference to two important health confidentiality cases. The first is the decision in W v Egdell where a mental health patient claimed that the release of a privately commissioned medical report to his psychiatrist and to the Home Office constituted a breach of confidentiality. 115 The Court of Appeal explored the basis of medical confidentiality and found that it was a matter of public more than private interest. This public interest rests in the fact that confidentiality is a pre-requisite for effective health services. Doctors cannot effectively diagnose and treat without accurate information and they will not receive that from patients without the promise of confidentiality. The importance of confidentiality is therefore derived from the nature and values of the organisations and professions within which the enterprise of health care is carried out. This insight is reinforced by the way in which the Court of Appeal in Egdell relied heavily on the professional guidance given by the General Medical Council when seeking to define the limits of confidentiality.

¹¹³ Department of Health, A Guide to Consent for Examination or Treatment (London DoH 1990) Appendix A and HSG (92)32.

See J. Montgomery, *Health Care Law* (1997) ch 11.
 [1990] 1 All ER 835.

This public interest approach was called into question in the other key health confidentiality case, *R v Department of Health, ex p Source Informatics.*¹¹⁶ The case, concerned the legitimacy of using anonymised data on the prescribing habits of GPs. As with the Viagra litigation, the form that the action took was a challenge to the lawfulness of advice from the Department of Health by a commercial organisation. That advice suggested that data on prescribing could not be used without breaching confidentiality because the patient would not have consented to such use, either explicitly or implicitly.

The case raised arguments that demonstrate the tensions that arise in a system of socialised health care. In the High Court, Latham J, took the view that the key question was patient agreement to the use of the information (and therefore legitimate use was limited by the scope of that consent). ¹¹⁷ He held that patient consent was essential before the information could be used and therefore that the Department of Health's Guidance was sound. However, this strong support for the individualist foundation of confidentiality was tempered by allusions to the possibility that there might be a special regime for the NHS. Latham emphasised the commercial context of the applicant's business and the risks that the pharmacists, from whom the applicants wished to collect data, might benefit from that business (placing them in a conflict of interest). Latham J noted the possibility that the public interest might justify disclosure where the information was to be used for NHS purposes.

The Court of Appeal took a rather different approach. It found a solution to the case by looking at the value that underpinned the legal protection of medical confidences. It identified this as lying in the protection of privacy and reasoned that only uses of confidential information that compromised the privacy of patients were unlawful. As the data would only be used in an anonymised form, it would not be traceable to any individual and consequently would not threaten their privacy. The wider arguments of public policy were not discussed in detail, but Simon Brown LJ indicated that he anticipated that the scope of the legal protection for confidentiality would be 'circumscribed' so as to recognise the need for audit, research and management within the NHS. 118 He declined to pursue arguments about implicit consent on the basis that they were likely to lead to the same conclusion as arguments based on the public interest. Yet disentangling these approaches is fundamental to clarifying whether English law is more concerned with protecting patients' rights or providing the foundations for an effective health service. The two approaches are not contradictory and steps have been taken to encourage improved patient understanding of how information is shared within the NHS in order to enhance the plausibility of arguments based on implicit consent. 119 However, whether they go far enough remains to meet the legitimate concerns of patients' rights remains a matter for debate.

These tensions in the law of confidentiality indicate how important it is to examine how the law incorporates the values of the NHS in order to understand the

¹¹⁶ [2000] 1 All ER 786.

¹¹⁷ [1999] 3 All ER 185.

¹¹⁸ [2000] 1 All ER 786, 800-801.

¹¹⁹ See the sample information leaflets in DoH, *The Protection and use of Patient Information* (London: DoH 1996) Annex A; Caldicott, F, *Report on the Review of Patient-identifiable Information* (London: Department of Health 1997) Appendix 10.

development of medical law. However, there is another even more important dimension of our conceptualisation of confidentiality that needs to be recognised as requiring a new appreciation of the area. The traditional image of confidentiality is of a cosy relationship between a patient and their doctor. On this model, confidentiality ensures that people outside that relationship do not get to hear the intimate details of the conversation. The reality in modern health care is rather different. Effective care depends on the sharing of information within professional teams. There is a circle of confidentiality within which information circulates and confidentiality is preserved against those outside the circle rather than within it. 120

The modernisation of the NHS, particularly the embracing of information technology through the electronic health record, requires us to see the problems of confidentiality in a different way. ¹²¹ Guarantees of confidentiality are increasingly only deliverable through effective service management because no individual can control the flow of information. The NHS has responded by appointing 'Caldicott' guardians in each organisation to oversee the proper protection of personal information. ¹²² The key aspects of this concern restriction of access to records, because it is the records in which information is contained (rather than the information itself) that can be most easily protected. Records will become accessible by a wider range of people, remote from the person who drew them up. It will no longer be possible to expect the person making the record to preserve their confidentiality. The paradigm is therefore shifting from one of confidentiality to one of data protection. The extension of data protection principles to all records, whether held manually or electronically is the natural consequence of these developments. ¹²³

(4) Conclusion

This brief review of patients rights in the area of access to services, consent and confidentiality shows three trends that are key to the transition of medical law towards its new paradigm. First, there is the failure of the common law to deliver the rights that commentators support. This has led in some areas to professional and political intervention to foster a more patient focussed system of values. This second trend of collegiate responsibility requires a broader vision of the way in which norms are set if medical lawyers are to fully understand their subject. Thirdly, the Government's vision for a modernised NHS will bring new challenges that fit uncomfortably with the idea that the lynchpin of medical law is the doctor-patient relationship. The expectation of more fully informed patients is to be met as much by corporate activity as by disclosure by the treating doctor. Protecting privacy will be mainly a task for organisations. Medical law is becoming more and more a matter of corporate governance.

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¹²⁰ There is some recognition of this aspect of confidentiality in $Re\ W$ [1998] 2 FCR 405.

¹²¹ The argument summarised in this paragraph is elaborated in J. Montgomery, 'Confidentiality in the modernised NHS: the challenge of data protection' (1999) 146 Bulletin of Medical Ethics 18-20. ¹²² 'Caldicott Guardians' HSC 99/012.

¹²³ Data Protection Act 1998.

Medical Ethics

Traditionally, medical lawyers have seen the relationship between ethics, law and medicine as a hierarchy. The purest discipline is ethics, the substance of which should be reflected in the law, which in turn should use its coercive aspects to bring medicine into line. Medical law is thus a species of applied medical ethics. This paradigm implies that the law should lead the medical profession towards more ethical practice. In fact however, the picture is much more complex. To a great extent, the courts have followed rather than led the profession. I want to suggest that this flows deliberately from the judicial understanding of the nature of the task with which the courts are required to grapple.

(1) Caesarian section cases

The literature on court authorised caesarian sections is now extensive and this section does not seek to provide an account of the issues and merits of the string of legal cases. Rather, I hope to consider what can be learnt from the flurry of activity in the High Court about the way in which medical law develops and draw some conclusions about confidence, or lack of it, in the ability of the judiciary to take medical law forward. I want to suggest that those cases demonstrate substantial technical failures of law making that call into question the effectiveness of relying of litigation to develop the principles of medical law. This in turn forces us to consider whether actively promoting the development of professional values is a more promising strategy.

The story starts not at the beginning but with the decision of the then President of the Family Division in $Re\ S$. ¹²⁴ This was a decision that had to be taken in circumstances of some urgency in an emergency hearing during a lunchtime recess. It is a tribute to the accessibility of the courts that a judicial hearing could have been arranged, held and concluded within 50 minutes of the matter being brought to the attention of officials. However, considerable reservations have to be expressed about the impact of that decision.

First, the President authorised the surgical delivery of the woman without giving reasons. One can extrapolate from the arguments presented to him that that two factors were regarded as significant, although his judgment gives little clue as to whether it was those that persuaded him. First, that the pregnancy was at term (six days overdue, although that is well within the margins of normal variation). Second, that there would be no adverse effects on the mother (presumably overriding her wishes was not an adverse effect for these purposes). There is no indication in the judgment that questions of the woman's competence were addressed. Nor is there any account of the legal status of the child. Two legal authorities were referred to. One, an American decision was in fact erroneously interpreted. The second merely left the question open. The most direct authority, which was substantially against a nonconsensual operation, was not cited. 125

¹²⁴ Re S [1992] 2 FCR 893 ¹²⁵ Re F [1998] 2 All ER 193.

The lessons to be learnt from this stage in the history are not about the merits of the decision so much as the nature of the process of law making. If one of the functions of the law is to establish canons of acceptable conduct, the consequence of an unexplained decision such as this is unwelcome uncertainty. Following *Re S* widely different interpretations were made within the medical profession of its implications. On anecdotal evidence, it has been said that obstetricians in one hospital in the South of England (not Southampton, for the avoidance of doubt) were telling women that they had better accept their advice about caesarians because the court would override any refusal if asked to do so. Thus, the President's decision was used as a powerful bargaining counter to coerce women. In contrast, the Royal College of Obstetricians and Gynaecologists used the lack of reasoning to issue robust guidance that effectively advised that it would never be ethical to impose a caesarian section on an unwilling woman. ¹²⁶

The string of High Court cases that followed suggested that the line taken by the doctors from my anecdotal source was the more accurate. Even when they recognised the fact that the decision in *Re S* was incompatible with earlier Court of Appeal authority the judiciary persisted in authorising non-consensual sections on the basis of the interests of the unborn child. In *Norwich and Norfolk NHS Trust v W* Johnson J authorised a caesarian section on the basis of an account of a telephone discussion with a psychiatrist who had interviewed the woman. That psychiatrist believed that the woman could have instructed a solicitor and understood the treatment options. However, he told the Official Solicitor's representative that she was not able to balance the various factors involved. On this basis, the woman was found to be incompetent and the operation was authorised.

In the middle of the hearing of the *Norwich* case, Johnson J broke off to deal with another similar case. The consultant obstetrician was clear that the woman was competent, yet the judge felt able to override that judgment without further evidence. He said that

a patient who could, in those circumstances, speak in terms which seemed to accept the inevitability of her own death, was not a patient who was able properly to weigh-up the considerations that arose so as to make any valid decision, about anything of even the most trivial kind, surely still less one which involved her own life. ¹²⁸

Such a judgment, considering the decision reached rather than the capacity for and the process of reasoning is incompatible with the established approach to assessing capacity as was clearly pointed out by the Court of Appeal in *Re MB*. ¹²⁹ The judge seemed to feel vindicated by the fact that the woman in fact changed her mind (presumably suddenly becoming competent in the process) and that the procedure was carried out by consent. That this indicated that she could have been persuaded rather than coerced was not commented upon.

129 Re MB [1997] 2 FCR 541.

¹²⁶ A Consideration of the Law and Ethics in Relation to Court-Authorised Obstetric Intervention (London: RCOG 1994).

¹²⁷ Norwich and Norfolk NHS Trust v W [1997] 1 FCR 269.

¹²⁸ Rochdale Healthcare (NHS) Trust v C [1997] 1 FCR 274.

If the task of the courts is to establish rules for ethical practice, these early cases indicate a series of failures of law making. Without reasons, no principles can be discerned. Where earlier authorities are ignored there can be no confidence that the law is consistently applied. Further, where judicial decisions were taken on what later proved to be wholly inaccurate accounts of the facts there can be little confidence in the objectivity of the legal system. Thus, in the St George's case the court proceeded on the basis that the woman was in labour when in fact this was not the case. ¹³¹

The Court of Appeal has now provided us with a clear account of the law based on the fundamental principles that competent women are free to decide what treatment to accept and that fetal interests cannot prevail over their right to this autonomy. This explanation of the task in terms of legal principle fits well with the traditional paradigm of law as applied ethics. However, the practice of the courts of first instance suggests that such law making may not be how they understand their role. Lord Justice Thorpe has suggested that it is unrealistic to expect judges to disregard the human reality of cases in favour of cold legal principles. ¹³² In many ways his view is more characteristic of the approach of the courts in medical law cases than the more traditional view. I want to suggest that the apparent failures of law making may highlight the need to see the courts as fulfilling a slightly different role.

(2) Withdrawing treatment

The cases on withdrawal of life sustaining treatment provide an informative insight into the problems. What they suggest is a conscious resistance to the idea that the courts should establish rules from which the proper steps can be derived, rather than reinforcing processes for good practice.

In the early 1980s it seemed that the courts were seeking to reach a rough and ready conception of the quality of life that was thought to require medical intervention even when the doctors and family were not sure. In the Baby Alexandra case, ¹³³ the Court of Appeal authorised an operation to be performed to remove an intestinal blockage from a child with Down's Syndrome. Lord Justice Templeman suggested that this was because her life would not be 'intolerable' or 'so awful that in effect the child must be condemned to die.' For those who look to the courts to establish boundaries, this looked like an attempt to move towards a formulation of quality of life factors. The task for the courts would therefore be to refine the approach until it became more workable.

This was tried in 1990 where James Munby QC for the Official Solicitor invited the Court of Appeal to consider where the line should be drawn. He initially proposed a sanctity of life principle, under which the possibility of prolonging life would

¹³⁰ For discussion of the idea of failures of law making, see L. Fuller, *The Morality of Law* (New Haven, Yale University Press revised ed. 1969) 33-41.

¹³¹ St George's Healthcare NHS Trust v S; R v Collins, ex parte S [1998] 2 FCR 685

¹³² 'The Caesarean Section Debate' [1997] Fam Law 663.

¹³³ Re B [1990] 3 All ER 927.

outweigh any question of the quality of existence that could be secured. When this was rejected, on the basis that it introduced a principle to compete with the child's best interests, he offered a less absolute formulation. This was that 'a court is only justified in withholding consent to such treatment if it is certain that the quality of the child's subsequent life would be "intolerable" to the child, "bound to be so full of pain and suffering" and "demonstrably so awful that the child must be condemned to die"." The Court of Appeal rejected that offer too.

Rather than identifying rules or principles, the Court of Appeal preferred to examine the processes for decision making. Lord Donaldson described the way in which the law sought to ensure a partnership between parents and professionals. The law created, he argued, a sort of stand off in which neither can determine what happens without securing the consent of the other. Doctors could not impose treatment without parental consent, but parents could not demand particular types of care. Their lordships were seeking to foster and promote a particular culture rather than to influence outcomes. Ultimately, as the cases consistently show, the courts almost universally side with the medical profession when this partnership breaks down, ¹³⁵ but this does nothing to undermine the judicial encouragement to work together.

The fact that this resistance to rule making is conscious rather than inadvertent makes some sense of the decision of the House of Lords in the *Bland* case. Despite the many arguments that were raised and debated, in the end the legal logic of the decision is simple and straightforward. Withdrawing life-sustaining care from Tony Bland was to be classed in law as an omission to keep him alive (which could in certain circumstances be permissible) rather than an act that caused his death (which would be illegal). As it was an omission, the doctors were at liberty to withdraw the care providing that they had no legal duty to keep him alive. Their legal obligation to keep him alive was determined by professional opinion. So long as a responsible body of relevant professional opinion supported the doctors' view that it was in Tony Bland's best interests to be allowed to die, then it was lawful to do so. Categorical distinctions between medical treatment and providing nourishment and water were rejected in favour of an extension of the *Bolam* test. While the judges sought to emphasise the seriousness of the decision it is hard to discern any real move away from the peer review that *Bolam* implies. 137

Considerable weight, however, was placed on the fact that the profession had itself created guidance on the way in which patients in persistent vegetative state should be cared for. The House of Lords was in a position to accept a non-interventionist position even in the context of decisions about life and death because they were satisfied that medical ethics provided a safeguard against abuse. This safeguard is not, however, provided by a set of quasi-legal rules. It quickly became apparent that departure from the letter of the guidance on diagnosis and management of patients in permanent vegetative state did not make practice unacceptable. In *Frenchay NHS Trust v S* there was no independent clinical assessment and not all the diagnostic criteria were established. It was still legitimate to withhold a life sustaining

¹³⁵ See J. Montgomery, *Health Care Law* (1997) 414-420.

¹³⁴ Re J [1990] 3 All ER 930.

¹³⁶ Airedale NHS Trust v Bland [1993] 1 All ER 821.

¹³⁷ See J. Montgomery, *Health Care Law* (1997) 438-39.

intervention. 138 In $Re\ H$ the patient showed some visual tracking and was therefore outside the Royal College of Physicians criteria (although not an international consensus document). 139 Discontinuation of artificial life support was authorised. In Re D the patient had two further reactions in addition to visual tracking that took her outside the scope of the PVS diagnosis, but it was still permissible to withdraw lifesustaining treatment. 140 The courts are not taking comfort in the fact that the medical profession has established law-like rules. Rather, the existence of guidance reassures the judiciary that medicine is a moral activity that will respond appropriately to the dilemmas. Once satisfied that there is a strong moral community of this sort, the courts are happy to regulate medical ethics through the filter of peer review.

This reliance on professional ethics can be seen quite explicitly in comments of Balcombe LJ in Re W. 141 It was suggested that there was a disturbing consequence of holding that parents could consent even where their children were *Gillick* competent. This was that an abortion could be forced upon a 17 year old girl who wished to keep her baby. Balcombe LJ deflected the force of that objection by saying that he could not conceive of a case in which a doctor would collude with such a parental decision. The law was developed on the specific assumption that the medical profession has an established ethical approach to dilemmas raised by their work.

(3) Judicial roles

Medical lawyers would do well to re-examine their expectations of the courts. The development of standards to guide health professions in grappling with issues of medical ethics is by no means the most common approach taken by the judiciary. Even when standards are set, the courts are as likely to affirm the work already done by the professions as to examine the matter independently. In general adherence to professional standards provides a shield against criticism. However, the post-Bland PVS cases show that those standards will not usually furnish litigants with a sword with which to coerce doctors.

There are, in fact, a number of other ways in which the judiciary has explained its contribution. As medical law moves forwards it will need to consider these more carefully. One such approach sees the involvement of the courts as a mechanism for validating the work of the medical community. It is hard to see the exhortation from the House of Lords in Bland to bring PVS case to court as resulting in the development of legal principles. Their lordships explained their suggestion of court involvement as responding to the uncertainty over the nature of PVS and the consequent scope for disagreement between relatives and between professionals. Further cases have brought those issues before the judges, but have done little to resolve the uncertainty.

Nevertheless, the courts have offered reassurance over the careful way in which decisions are taken. Judicial scrutiny can be seen as a way of ensuring that decisions

¹³⁹ [1998] 3 FCR 174.

¹³⁸ [1994] 2 All ER 403.

^{140 [1998] 1} FCR 498. 141 Re W (1992) 9 BMLR 22, 41.

are properly thought through. Once exposed to public debate, there is the scope for others to engineer changes in approach even if the judges are reluctant to do so. This may explain the insistence that cases are heard in public. ¹⁴² It explains the desire of the courts to allow public discussion of the issues raised in wardship cases, while trying to protect the privacy of the individual children. ¹⁴³ The courts also sometimes see themselves as providing a forum for airing scientific controversy. This was highlighted by Wilson J as being a feature of litigation over whether a child's HIV status should be tested despite the parents' opposition. ¹⁴⁴ The role of the courts here is as a sort of safety valve to ensure public awareness of the way in which medical ethics works. This approach assumes that the medical community is fundamentally sound ethically and provides a form of quality assurance.

A different sort of role can be seen in relation to the therapeutic value of litigation. Judges suggest that court involvement can demonstrate respect for the gravity of decisions. Thus, it has been suggested that cases in which it is proposed to override the sincerely held views of Jehovah's Witness parents and order that their children should receive blood transfusions should be heard in the High Court. ¹⁴⁵ It is thought that this make the decision more palatable than it being taken merely by doctors. Judges also see themselves as lifting the burden of decisions by taking responsibility for them. ¹⁴⁶ Whether these sentiments are shared by the families and doctors is unknown. However, they suggest that there may be other ways of understanding the contribution that the law can make than those adopted by the traditional paradigm of medical law. If the courts are seen as part of the overall framework of decision-making, integrated within the broader health care community rather than imposed upon it, then some of the decisions become easier to understand. Different issues then become apparent, such as whether courts are in fact able to build public confidence and reassure them, or whether they are a cost-effective mechanism for such tasks.

Conclusions

This analysis of an illustrative range of areas of health care law has demonstrated the apparent failure of medical law as generally conceived by commentators. Judged against the idea that it is a mechanism for setting standards for health professionals on behalf of society, medical law has failed to deliver. The dominance of the 'Bolam' philosophy has prevented the courts playing a leading role in raising professional standards and enhancing patients' rights. This failure has led to the health professions and the NHS seeking to create their own mechanisms for meeting these challenges. It has been suggested that those responses have been more effective in pursuing the agendas that medical lawyers have traditionally set out and that consideration should be given to the potential for consolidating these achievements.

Recognising this transformation requires us to focus our activity in different ways. The materials on which lawyers should be working will increasingly be those

¹⁴³ e.g. *Re C (No 2)* [1989] 2 All ER 791.

¹⁴² Re G [1996] 1 FCR 413.

¹⁴⁴ Re C (a child) (HIV test) [1999] 2 FLR 1004 (FD & CA).

¹⁴⁵ Re O [1993] 1 FCR 925.

¹⁴⁶ Re C [1996] 2 FLR 43.

produced within the various communities of the health care system. Looking at the way in which institutional norms are created, and most importantly challenged, will be crucial tasks for those looking to influence practice. The concept of law with which we work has to become more complex. The force of 'law' and 'guidance' needs to be evaluated. The sources of those norms need to be identified and analysed. Our understanding of who are the lawmakers, and how their authority can be legitimated for the wider public, needs to be reformed. In short, the traditional paradigm that sees the health professions and the institution of the NHS as the principal problem, forces to be constrained, needs be replaced by a broader paradigm that sees them as part of the solution.

This is both a descriptive and a normative project. Without regard to the complexity of medical law and its current reliance on organisational and professional norms, we cannot properly understand why we have the laws that we do. However, when the changing nature of health care is considered, it can be seen that the new focus of medical law on its institutional context can offers considerable opportunity for influence and progress. Seen in this perspective, the judicial approach can be seen as an attempt to exploit the fact that the professions have a strong culture of values rather than to establish an independent system of law. The 'New NHS', with its corporate and technological focus, will force a more institutionalised approach upon us. The traditional cornerstones of medical ethics, consent and confidentiality, now require the strengthening of corporate rather than individual ethics.

These insights are not necessarily novel, but the attempt to incorporate them into the traditional paradigm of medical law has tended to marginalise the regulatory techniques that have proved most effective. Medical law will need to draw more on the acceptance of health care as a public service; on public law rather than private law. Patients are now primarily the responsibility of the NHS not individual professionals, and this transition would reflect that reality. In its emerging manifestation, medical law will become geared to generating particular values and standards, consciously aiming to create the sort of morality that we want for our health services. It will seek to make the transition from an ambitious project that has collapsed into protecting professionals at work from outside scrutiny into a force for progress.