Florence Nightingale’s statement that ‘the very first requirement in a Hospital that it should do the sick no harm’\(^1\) would seem to be self-evident. Unfortunately, the fact is that for many the hospital is not a safe place; not the haven that the sick crave but a place fraught with potential dangers ranging from the careless and/or negligent activities of those who staff the ‘hallowed’ halls and also a potential cesspit alive with the modern day ‘super bugs’. Although medicine is now high powered, complex and operates in a high pressure environment, it is paramount to appreciate that health care is reliant on people more often than on machines. It is the ‘human factor’ that accounts for errors made and they must be addressed.

It is clear that the number of cases finding clinical negligence has increased dramatically \(^2\) and continues to rise at an alarming rate despite procedures implemented to ensure that safeguards with regard to clinical practice are built into the system. Improved risk management and regular audits of a clinician’s work in conjunction with the requirement of annual validation with regard to an individual’s clinical work are now mandatory but still the ‘bad apples’ are slipping through the net as it were. It would appear that the odds are stacked in a physician’s favour at least partly because the profession can employ the ‘Bolam Test’ to avoid the attachment of any blame for injuries or death that may have resulted from nonchalant clinical practice.

Mr Justice McNair enunciated the *locus classicus* of the test with respect to clinical negligence in *Bolam*\(^3\) when in directing the jury he stated that ‘…a doctor is not guilty of negligence in a medical claim 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’.\(^4\) Thus the ‘Bolam Test’ entered the annals of medico-legal law and has for over 50 years allowed medical practitioners to avoid the consequences of their actions or inactions.\(^5\) Therein lies the rub for it is patently obvious that simply by concurring with the actions of another the legal repercussions pertaining to remiss clinical practices are avoided, perhaps wrongly so as all should be held accountable for injury done to others.

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1 Florence Nightingale, *Notes on Hospitals* (John W Parker and Sons 1859).
2 Sir Liam Donaldson (Chief Medical Officer) ‘Making Amends’. A Report commissioned and published in 2003 cited an increase of 1200% in reported cases of clinical negligence over the 30 years preceding publication. This is a consultation paper setting out government proposals for reforming the approach to clinical negligence in the NHS.
3 *Bolam v Friern Hospital Management Committee* [1957] 1 WLR 582.
4 The direction given to the jury by McNair J in *Bolam V Friern Hospital management Committee* [1957] 2 All ER 118 at 122, [1957] 1 WLR 583 at 587.
5 Kim Castle ‘Medical negligence: The Pathology of The Responsible Man’; Dissertation produced in April 2010 at The School of Law, Bangor University, North Wales.
It could be contended that the Bolam test is no longer tenable in this modern world given that the realms of cyberspace are ever expanding such that there is now a wealth of information available to the enquiring mind with the consequence that the mystique which has characterised the medical profession is becoming more transparent. Consequently, ‘Joe Public’ no longer accepts that a physician’s word is gospel and irrefutable; they are fallible and should be made to answer for their poor performance, particularly when the consequences can be devastating for both the afflicted and their families. All have the right to expect the best from their clinician but the problem for both parties, the aggrieved and the clinician with regard to allegations of clinical negligence, is how to prove or disprove the charge as levelled?

When considering the Bolam test it must be remembered that medicine, like law, is in evolution. The two often run in tandem; developments in medicine can beget changes in the law as evidenced most dramatically by the major advances that have been made in the province of human infertility such that the Human Fertilisation and Embryology Act came onto the statute books in 1990. Thus, regulating the application of new technology and guarding against unscrupulous, unethical and immoral practice.

New discoveries are being made every day and, as knowledge expands into previously uncharted territory, the potential for mishaps is an ever present threat. Sir Alexander Fleming’s discovery of Penicillin in 1947 heralded a new era in the treatment of infection but few could have envisaged its import nor the potential for severe adverse reactions sometimes resulting in death. It must be appreciated that there are risks associated with all forms of treatment; that which is acceptable must be balanced against that which is patently not and it is oft a question of ensuring that the former outweigh the latter. Coupled with this balancing act is the competency or otherwise of the treating clinician which can quite literally mean the difference between life, death or severe iatrogenic injury.

There is no doubt that the Bolam test is inadequate in this litigious age. It could be argued that the continued use of Bolam has resulted in a ‘time warp’ with regard to

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6 ibid.
7 ibid.
8 The Human Embryology and Fertilisation Act was first entered into the Statute books in 1990 but due to the rapid advances in medical technology amendments have had to be applied, the most recent in 2008. The principal purpose of the Act is to protect the human embryo and any subsequent developments relating to an embryo such that those who would seek to exploit the vulnerable are prevented by law from doing so.
9 Penicillin causes a generalised allergy in 0.7%-10% of cases and acute anaphylaxis, which is characterised by bronchospasm and sudden death in 0.004-0.015%. It is impossible to predict who will suffer an adverse reaction until the event occurs. Of course once the allergy is discovered it is incumbent upon a physician to ensure that the individual never receives the antibiotic again; to prescribe again would be both negligent and inexcusable. See Nicholas Boon, Nicki R. Colledge, Brian R. Walker (eds) (Churchill Livingstone Elsevier, 20th ed, 2006).
10 ibid, page 2.
11 ibid, page 2. Iatrogenic is defined as that which is caused by the actions of physicians. In this modern age of hospital acquired infections it is of particular relevance but can apply to any procedure or therapeutic regimen.
this area of medical law; there is in effect a glaring lacuna in the law which is worthy of both consideration and modification in the 21st century. Challenge has been mounted by several high profile cases, the most notable of which is Bolitho12 but there is still much that the law can do to clarify this legal minefield which has the potential to exacerbate harm sustained by all concerned and is indeed deserving of a satisfactory form of resolution. The reader must appreciate that the Bolam test has also been applied to other professions including auctioneers and the designers of double-glazed windows.13

I – The Tale of a Snail: To Whom do I Owe a Duty of Care?
A gastropod with a predilection for ginger beer and a penchant for cloudy bottles slithered out of a bottle and into the annals of legal history when it sought refuge in a bottle of ginger beer. The snail contributed much to the development of the law of tort with regard to a manufacturer’s liability and the duty of care owed to any potential customer if it can be proven that there was no opportunity for tampering of the product between point of origin and use. The tale of the snail pertains to Donoghue v Stevenson14 which concerned the appellant and a friend who purchased a bottle of ginger beer for the former. The unfortunate woman having already consumed half the drink discovered a partially decomposed snail in the remainder of the drink which slipped into her glass thereby altering the law of Tort forever. Unsurprisingly the appellant developed gastroenteritis. She successfully sued the manufacturer for negligence

That infamous snail not only promoted the development of the law with regard to the rights of a consumer but also led to Lord Atkin invoking the ‘neighbour principle’ when he stated that: ‘The rule that you are to love your neighbour becomes in law, you must not injure your neighbour...Who is my neighbour?...Who,...in law is my neighbour? The answer seems to be persons who are so closely and directly affected by my act that I ought reasonably have them in contemplation as being so affected that when I am directing my mind to the acts or omissions which are called into question.’15 That a relationship exists between healthcare staff and patient is self-evident such that the duty of care is well established but problems arise when this duty can be called into question.

The relationship between the major players is paramount in this area of law. It cannot be ‘acquired’ by another. This means that a physician who prescribes medication which is then taken by another other than the individual for whom it was meant, cannot generally be held responsible should an adverse event occur to the person who consumed it. Likewise, the principle of a duty of care owed is not extended to future contacts of the single patient as was held in Goodwill v BPAS16. Duty of care would

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12 Bolitho v City and Hackney Health Authority [1997] 4 All ER 771.
16 [1996] 2 All ER 161. This case concerned a man, M, who underwent a vasectomy whilst still married and was subsequently informed that the operation had been successful and that contraception
extend to only a current partner because although the medical profession are credited with much that is laudable, they are not clairvoyant. The cases of *West Bromwich Albion v El-Safty*\(^\text{17}\) and *Farraj v King’s Healthcare NHS Trust*\(^\text{18}\) serve to further exemplify this point with regard to the law of tort. Lastly, the position of the doctor who encounters an accident victim must be considered; does a passing doctor owe a duty of care to the injured? The law recognises that a doctor may act in the best interests of someone who lacks the capacity to grant consent to treatment\(^\text{19}\) but it also mandates that the doctor must not inflict harm. The latter would indeed incur a charge of clinical negligence which would be incontestable; however, the provision of necessary treatment which should have been provided has\(^\text{20, 21}\) also been acknowledged. It is of course incumbent upon a general practitioner to treat any of his patients should he encounter them injured and also upon both ambulance crews and ‘Accident and Emergency’ staff to treat those seeking help.\(^\text{22}\)

In the context of clinical negligence it is readily apparent that ‘closeness’ exists between a physician and his patient but when exactly does this relationship arise? At exactly what point does the transition between ‘stranger’ and ‘patient’ occur? Is it when a patient registers at a particular surgery or is it when any treatment is initiated? It is obvious that such a relationship is generated between a patient and medical institution when advice and help are sought. Recognition of the need for treatment has already been acknowledged but what if there is a failure to appreciate a said need\(^\text{23}\) or

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\(^\text{17}\) [2006] EWCA Civ 1299. A doctor was not held liable for the negligent treatment of a footballer which resulted in financial loss for the club. The physician was not employed by the club; his duty of care was owed solely to the player.

\(^\text{18}\) [2006] EWHC 1228(QB). An NHS hospital was held to owe a patient a duty of care after having commissioned some tests to be performed at a laboratory but subsequently failed to inform the patient of the results which needed to be acted upon.

\(^\text{19}\) *F v Berkshire HA* [1989] 2 All ER 545, 567 which concerned the sterilisation of a severely mentally incapacitated female patient who had started a sexual relationship with a fellow male patient. Given her mental incapacity she would not cope with any of the means of contraception available so the hospital sought sterilisation which was allowed on appeal, her mother having contested the action.

\(^\text{20}\) *Powell v Boldaz* (1997) 39 BMLR 35. This tragic case concerned the unexpected death of a child from Addison’s disease which is difficult to diagnose. His parents attempted to claim for psychiatric injury but it was held that the duty of care was owed to the child not the parents; it did not transfer to the latter upon receipt of the news of his death.

\(^\text{21}\) Longmore, Murray et al *Oxford Handbook of Clinical Medicine* (Oxford University Press, 5th Edn., China, 2001) Page 302. Primary adrenocortical insufficiency, Addison’s disease, is rare, with an incidence of about 8/1,000,000. It can have a myriad of clinical presentations such that diagnosis is often only made at autopsy. Accordingly it is a diagnosis that can very easily be overlooked even by the most experienced of medical practitioners with tragic consequences.

\(^\text{22}\) *Barnett v Chelsea and Kensington Hospital Management Committee* [1969] 1QB 428. Three workmen fell ill after having drunk some tea and presented in the A&E department of the hospital at which they were working with acute vomiting. The casualty doctor on-call declined to see them, advising them to see the General Practitioner with whom they were registered. Sadly one died and it was subsequently discovered that the tea had been laced with arsenic.

\(^\text{23}\) *ibid.*

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what if the need had been recognised and there was no remedy? Could the unfortunate physician who chose not to examine a patient be considered negligent in the course of his duties when there was naught that he could do to avert inevitable death?24

Does a physician owe a duty of care to the patient who chooses to ignore advice and either neglect to take medication as advised or simply refuse to do so?25 Much has been made of autonomy in a modern world and the duty owed to a patient but surely it is incumbent upon the patient to recognise that a professional is also owed a duty which recognises the physician’s right to practise without compromise to their professional integrity? Responsibility must be assumed by both parties when a relationship is established; a contract has in effect been formulated between the parties involved.

With respect to the duty of care owed by a physician or a health institution, could there ever be a public policy reason for non-prosecution? It may be that an institution is at fault rather than a particular individual, for example due to poor staffing levels or lack of suitable equipment; indeed this was recognised in *A(A Child) v The Ministry of Defence*26 wherein a neonate suffered irreversible brain damage at the hands of a negligent German obstetrician during childbirth. It was held that the NHS had a duty to provide a safe and satisfactory service to a patient in the aftermath of the closure of all the British military hospitals in Germany.27

II – The Tort Trilogy and the Reasonable Man

‘Duty of care’, ‘breach of that duty’ and ‘causation’ constitute the basic tenets with regard to the law of tort. All were established by reference to the ‘neighbour principle’ and elaborated upon by Lord Wilberforce in *Ann v Merton LBC*28 when he formulated the concept of proximity with regard to the law of tort when considering the relationship between the parties concerned; could any acts or omissions be reasonably expected to result in injury or death? Again the ‘closeness’ that exists between patient and physician must be emphasised.

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24 ibid. There is no cure for arsenic poisoning: once a sufficient amount of the poison has been ingested death is inevitable.

25 John Griffiths and others, ‘Euthanasia and Law in Europe’ (Hart Publishing 2008) 379-380. Garnier, *Conseil d’Etat*, 29 July 1994, Rec p 407. Dr Garnier diagnosed breast cancer in a woman who declined both chemotherapy and radiotherapy against his advice. Instead she opted to undergo homeopathic treatment which Garnier discussed with her. Two years later she presented with advanced disease and the admitting doctor reported Garnier to the French regional disciplinary board who found that the unfortunate doctor had failed to comply with the professional standards expected of him and he was suspended from his clinical duties for the prescribing of ‘illusory treatments’, therefore depriving the patient any hope of cure.

26 [2004] EWCA 641. The unfortunate infant was born to the wife of a British serviceman who was stationed in Germany at the time. The brain damage sustained at birth resulted in cerebral palsy.

27 See also *Bull v Devon AHA* [1998] QB 730. The hospital operated on 2 sites resulting in the late arrival of the obstetric registrar which culminated in the delivery of a severely handicapped twin; his sibling was healthy. The Court of Appeal found that the hospital had failed to provide an acceptable level of care.

28 [1978] AC 728. The local authority neglected to check that building work commissioned failed to comply with plans submitted with such that inadequate foundations resulted in structural problems.
The test of the ‘reasonable man’ is that which is applied in the determination of negligence; how would the ‘reasonable man’ have acted in the same circumstances which resulted in the detrimental act/s? The defendant’s actions are viewed objectively with regard to the harm that ensued but who is the ‘reasonable man’? He is the ‘man’ who would not perform a negligent act but would be guided by ‘those considerations which ordinarily regulate human affairs’. Simplistic perhaps, Greer LJ proffered a definition when he stated that ‘the person concerned is sometimes described as ‘the man on the street’ or…’the man on the Clapham Omnibus’, or…’the man who takes the magazines at home and in the evening pushes the lawnmower in his shirt sleeves.’ It is for the judge to determine if a defendant has behaved as the ‘reasonable man’. The aim of the law of tort is not only to compensate but also to deter; subsequent medical practice must be influenced by experience, adverse or otherwise. Importantly, that which is considered negligent relates to available knowledge at the time of the alleged incident, the ‘retrospectoscope’ cannot be employed in the determination of negligence.

III – Leading Cases Relating to the Common Law Approach on Medical Negligence

III(a) – Bolam

The case of Bolam is both interesting and horrifying. The claimant suffered from a bipolar disorder which it was deemed would be greatly alleviated by electro-convulsive therapy (ECT). Unfortunately the treatment is not without side-effects.

29 Kim Castle ‘Medical negligence: The Pathology of The Responsible Man’; Dissertation produced in April 2010 at The school of Law, Bangor University, North Wales. Page 5.


31 Hall v Brooklands Auto Racing Club [1933] 1KB 205. The case pertained to the killing of two spectators and the injuring of several others at a racetrack. The owners were accused of failing to provide adequate safety precautions but they could not have foreseen the accident.

32 ibid Lord Greer at 224.


34 Clare Dyer Doctors, Patients and the Law (Blackwell Scientific publications Ltd, 1992, Bodmin) Chapter one: ‘Medical Negligence’, page 9. The classic case with regard to this area of law is that of Roe v Ministry of Health [1954]2 QB 66. An anaesthetic agent was stored in glass ampoules which in turn were immersed in disinfectant. The ampoules developed cracks so allowing the disinfectant to seep into the drug, thereby contaminating it and resulted in the permanent paralysis when administered to the plaintiff at operation. This risk was not known in 1947 when the operation was performed. Accordingly, the risk could not have been foreseen and therefore the defendant was found not guilty of negligence. Lord Denning commented further by adding that the court ‘must not look at the 1947 accident with 1954 spectacles’.

35 Nicholas A Boon, Nicki R Colledge, Brian R Walker Davidson’s Principles &Practice of Medicine (Churchill Livingstone Elsevier Limited, 20th Edn., India 2006) Page 242. A ‘bipolar disorder’, also known as Manic Depression is one characterised by periods of alternate depressed and elevated moods. Unfortunately, it is a relapsing disorder and is associated with an increased lifetime risk of suicide.

36 Electro-convulsive therapy is an archaic form of treatment which has aroused much controversy in the medical world. Opinion is divided as to its efficacy and the manner in which should be administered; with or without general anaesthesia, plus or minus muscle relaxants. The treatment developed in the 1930s and initially was used widely in the 1950s and 1960s but has now been mostly
In the short term, convulsions can occur; in the long term, memory loss. Powerful, sustained convulsions can result in fractures, occurring in 1 in 10,000 treatments. The procedure is therefore not without risk. Accordingly, some clinicians, when obtaining consent from the patient, will inform them of these possibilities; however, not all are of the opinion that the patient should be informed of the potential for fracture injuries. Clinicians were also divided as to whether or not the patient should simply be restrained or muscle relaxants administered. Some felt that the latter were associated with the possibility of death and were to be avoided.

Bolam was not informed of the fracture risk at consent and the only form of restraint applied during ECT was support to the lower jaw. Muscle relaxants were not administered. Unfortunately he convulsed violently resulting in bilateral upward trajectory forces applied to both femora culminating in concomitant bilateral fractures to the acetabulae with attendant severe pain. Medical opinion was divided as to whether the treatment fell short of those standards that a physician owes to the patient or did it conform to ‘sound medical practice’? Some would have used muscle relaxants and perhaps anaesthetic agents whereas others would have only applied restraints, and yet both methods have been considered recognised forms of adjunct treatment when administering ECT. To the lay person such differing ‘recognised’ modes of treatment must make the medical profession seem even more incomprehensible than their language already does. It is a sobering thought that treatment methods with the potential for such different outcomes can be considered acceptable.

III(b) – Dissecting Bolam

Given the impact that this case has had on the issue of medical negligence, it is worthy of analysis. The essential question to be addressed was whether or not a health professional had breached the duty of care owed to a patient; seemingly straightforward, given the assumption that such a relationship always exists between a doctor and/or nurse and their patient. If one accepts this presumption, the next question to be answered is what series of events or acts of omission led to the mishap? The first question is easy to answer but what about the second? The premise as established in Bolam is that, as long as other ‘reasonable, respectable and responsible’ medical men would have acted in such a manner that could have resulted in injury, no breach in the duty of care owed had occurred. Fundamental to the law of tort is that the breach must be proven to have caused the injury and yet this would seem at odds with the tenet established in Bolam that recognised therapies, despite being associated with acknowledged side effects, are in effect excusable if others would have done the replaced by both more modern and humane methods, particularly pharmacological and psychological; the latter are of a talkative nature! It involves the application of electrodes to the skull and passing an electric current either across the whole brain or only half of the organ. The procedure is thought to cause the release of neurotransmitters which are thought to be involved in the aetiology of depressive disorders. It is of dubious efficacy and can be associated with distressing side-effects both in the short and long term; hence its fall from grace.

37 Put simply, both thigh bones broke free of his pelvis and pierced his abdomen.

38--Times Law Report, 27 November 1997. *Bolitho v City and Hackney Health Authority.* ‘ A court was not bound to hold that a defendant doctor escaped liability for negligent treatment or diagnosis just he led evidence from a number of medical experts who were genuinely of the opinion that his treatment or diagnosis accorded with sound medical practice.’
same. It is to be understood that Bolam did not address the question of causation, only that of the preferential treatment afforded to the patient.

The court accepted that two conflicting opinions as to treatment regimes could still be regarded as valid if a responsible body agreed that either was acceptable, but what defines ‘the responsible body’? The medical profession who were to be judged? Importantly, it meant that the judges were not permitted to choose between competing, perhaps diametrically opposed, expert views. In effect the judges, being bound by ‘medical judgements’, had their options limited from the outset. It could be argued that a decision as to whether or not a doctor was guilty of medical negligence was a \textit{fait accompli} even before the case went to court; the decision in court had little to do with the law and perhaps more to do with society’s perception of those who care for its health.

\textbf{III(c) – Treatment options}

Medicine is not an exact science and there are often several treatment options available to clinicians. In \textit{Bolam} there were two options, both of which had the potential for injury. The ruling in \textit{Bolam} meant that even if the least popular and possibly most injurious was chosen, a medical practitioner could not be deemed negligent even if a potentially life threatening event occurred. As long as a ‘competent body of medical opinion’\textsuperscript{39} accepts that a practice can be regarded as the norm, it will be acceptable. This is the main tenet upon which \textit{Bolam} rests.

It is to be appreciated that although several treatment options may be available to the clinician, it is incumbent upon him/her to choose the most appropriate and administer accordingly; to simply disagree with new advances is not sufficient reason to choose an outmoded regime. Another avenue to be explored is that often, in medicine, it is the terminally ill who are offered new and perhaps untested treatments. After all, they have nothing to lose and might be more accepting of adverse events; in effect they are ‘human guinea pigs’.

With regard to the incapacitated, the courts had rigidly applied \textit{Bolam}, asking if the administration of a treatment came within its remit. Was it in the best interests of the patient to receive the treatment and could the treatment be carried out in the NHS?\textsuperscript{40} Criticism was levelled at the courts for their universality in the use of the test as the defining mechanism of choice in later cases establishing that \textit{Bolam} should be used as a ‘filtering mechanism’ rather than the sole determinant,\textsuperscript{41} thereby enabling the clinicians to weigh up the advantages and disadvantages of a proposed treatment; an element of rationality was introduced as opposed to a simple acceptance of one expert’s views versus another’s.

Experimental therapies and the application of \textit{Bolam} were considered by Dame Elizabeth Butler-Sloss in \textit{Simms v Simms, A v A (a child)}\textsuperscript{42}, concerning the tragic case of two teenagers both severely disabled and bedridden with no discernible quality of

\textsuperscript{39} Chris Turner, Susan Hodge \textit{Unlocking Torts} (Hodder Education, 2\textsuperscript{nd} Edn, Malta, 2007) Page 109.

\textsuperscript{40} Phil Fennell ‘Medical law’ 19.15.

\textsuperscript{41} ibid at 19.15.

\textsuperscript{42} [2002] EWHC 2734 (Fam), [2003] 1 All ER 669.
life due to a severe degenerative form of variant Creutzfeldt-Jakob disease (vCJD)\textsuperscript{43}, from which there was no hope of recovery. An experimental treatment had become available and the question was whether it was in the patients’ best interests to administer the untested treatment. It was defined as untested, because it had not been tested on humans. On laboratory animals, however, it had produced good results. It was felt in applying Bolam in a permissive manner to allow the use of an untried therapy, both the interests of society as a whole and that of the patients should be considered; the test should not be allowed to hinder medical developments. Dame Elizabeth stated: ‘...the medical evidence...consistent with the philosophy that underpinned the test, it would not in itself have been irresponsible or unethical to give the treatment to the patients...’\textsuperscript{44} Thus her opinion was that Bolam should not hinder medical advances but, rather, its use could promote the development of the ‘new’, particularly if society as a whole could benefit. She further elaborated on this issue with regard to vCJD in that apparent futility in treatment may in fact be beneficial to all.

\textbf{III(d) – The standards applicable}

The ruling in Bolam effectively allowed the medical profession to determine the standard of care and the conditions which decided such. The doctors were ‘policing’ their own profession, akin to the police investigating complaints against serving officers before the inception of the Independent Police Complaints Commission.\textsuperscript{45} Clearly, this was unsatisfactory, yet the test was applied and endorsed by the House of Lords in \textit{Whitehouse v Jordan}\textsuperscript{46}, \textit{Sidaway v Bethlehem Royal Hospital Governors}\textsuperscript{47}, and \textit{Maynard v West Midlands Regional Health Authority}\textsuperscript{48}, although in each case the Bolam test was applied in a different context. In \textit{Whitehouse}, the House of Lords considered its application to treatment; in \textit{Sidaway} to disclosure of risk and in \textit{Maynard} to diagnosis. The multiplicity of application illustrates the extent to which Bolam was utilised by the courts when considering allegations of medical negligence and demonstrates the authority that was accorded to the ruling in Bolam. It was a judgement that coloured generations of cases and impeded the advancement of the law with regard to clinical negligence.

\textsuperscript{43} Creutzfeldt-Jakob disease is one of a group of neuro-degenerative disorders characterised by a rapidly progressive dementia leading to death. The variant form is seen in young people and is associated with eating contaminated beef. It progresses inexorably to death at a slower rate than the classic form. There is no cure available.

\textsuperscript{44} Phil Fennell ‘Medical Law’ All England Annual Review/2003/Medical Law at 19.17

\textsuperscript{45} Established by the Police Reform Act which came into force in April 2004.

\textsuperscript{46} [1981] 1 All ER 267. As a result of a traumatic forceps delivery, a baby sustained brain damage. The obstetrician was sued for medical negligence but he had made a clinical judgement which unfortunately was flawed, but he had not acted negligently.

\textsuperscript{47} [1985] AC 871. A patient underwent spinal surgery but was not informed of the 1% risk of paralysis and permanent damage; unfortunately she sustained both. The doctors involved were found not guilty of being negligent in their duty to inform of all risks involved.

\textsuperscript{48} [1985] 1 All ER 635. Two surgeons operated on a woman in order to determine a diagnosis. Unfortunately the patient sustained permanent damage to her vocal cords which resulted in speech impairment. Held that the doctors had acted in a reasonable manner.
Differences in medical opinions generally define the other problem inherent in the application of the Bolam test. A doctor’s alleged negligence is to be judged by ‘a competent body of medical opinion’ but in ever-changing spheres of excellence who can be defined as an expert in any particular field? It may well be that a procedure is so new that none can be considered ‘experts in the field’. If so, who is competent to judge the doctor of dubious ability? Consider also that there may be scope for a new procedure to be performed in a variety of ways with the same objective in mind; a cholecystectomy can be performed by key-hole surgery or by a classic incision. The removal of the gall bladder is the achieved aim in both, but the risks associated with each procedure differ.

Factored into the equation must be the possibility that a ‘so-called expert’ in a new realm of medicine may have played a part in the development of either a new drug or procedure and may be very unwilling to concede that perhaps his research methodology is at fault. Medical researchers have also been known to falsify results in their pursuit of recognition in what can be a highly lucrative field of medicine; innovation and research with the possibility of entering medicine’s hall of fame.

In addition, there are those in the medical profession who assume the mantle of ‘expert’ despite there being no scientific evidence to back up their supposed superior knowledge. Several high profile cases recently have highlighted this problem. The Cleveland case, which occurred in the late 1980’s resulted in 121 young children being placed in care as the result of the erroneous diagnosis of sexual abuse made on the basis of very dubious physical evidence determined to be pathognomonic of such maltreatment. Two paediatricians, Drs Marietta Higgs and Geoffrey Wyatt, had determined that, when examining the children, reflex anal dilatation proved the diagnosis of abuse; in fact it is relatively common amongst unabused children as research has revealed. Their controversial diagnoses resulted in the children being taken into care, contributing to the emotional trauma they had already experienced as a result of the examination and the manner in which they were treated by the doctors who in most cases failed to call the children by their first names or explain what they were doing. Perhaps most distressing is the manner in which the children were taken from their homes, sometimes in the middle of the night. A total of 2007 people were affected by the scandal that dominated the news and media; the doctors continued in clinical practice and the children are still suffering the long term consequences. Many describe their treatment at the hands of the so-called medical experts as sexual abuse.

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50 A cholecystectomy involves the removal of the diseased gall bladder. The classic adage is that it is a complaint common to those of the female sex who are ‘fair, fat and forty’!

51 Reshma Jagsi, Nathan Sheets, Aleksandra Jankovic, Amy R. Motomura, Sudha Amarnath, and Peter A. Ubel, "Frequency, nature, effects, and correlates of conflicts of interest in published clinical cancer research" (15 June 2009) Cancer 2783.

52 A Stanton, R Sutherland, ‘Prevalence of reflex anal dilatation in 200 children’ British Medical Journal vol 298, 802, 25 March 1998. This study revealed that reflex anal dilatation is not pathognomonic of sexual abuse.

And many are still suffering the long term effects of such treatment; reminiscent of Bolam? Yet neither of the doctors has ever been questioned in a criminal investigation.

Considering also the case of Sally Clark, another who suffered tragic consequences at the hands of the medical profession. The unfortunate woman was convicted of the murder of her two young sons on the basis of medical evidence submitted to court by self-proclaimed expert medical witnesses. Her first son died suddenly at the age of 12 weeks in 1996; her second son died at the age of 8 weeks just 2 years later. ‘Sudden Infant Death Syndrome’ or, colloquially, ‘cot death’ is a well-recognised clinical entity and thankfully comparatively rare, resulting in the death of about 300 babies every year. There are several risk factors associated with the syndrome, namely prematurity, low birth weight and male sex; Harry was premature thereby qualifying for two of the risk factors.

The medical profession held the view that ‘lightning could not strike twice’ in the same family and, apparently lacking sufficient evidence to ascertain the causes of death, decided that the children must have been smothered. Principally the paediatrician, Professor Meadow, was of the latter opinion; he attributed the chances of two children succumbing to cot death in the same well-to-do family as 1:73,000,000. The true figure is actually around 1:200 but the jury was swayed by the professor’s apparent authority. It is small comfort that he was subsequently discredited as his belief in his own expertise destroyed families; units not easily ‘mended’.

As a result of this somewhat flawed medical evidence, Sally Clark was tried for murder, convicted and jailed. She spent 4 years behind bars before her case came before the Court of Appeal. A similar case was that of Trupti Patel who was convicted of the murder of her three young children, but she too was subsequently acquitted on appeal. A lot of cases involved Professor Meadows whose firmly held beliefs caused much damage to the families involved.

At appeal it transpired that the pathologist involved in the case had withheld evidence that one of the Clark boys had an infection which could have contributed to his death. Although a ubiquitous organism, it can prove fatal and perhaps contributed to Harry’s death. It is of course well known to the public as MRSA; Methicillin Resistant Staphylococcus Aureus and in modern times has contributed greatly to hospital acquired infection and subsequent mortality.

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54 R v Clark [2003] EWCA.


56 Alison Holt, ‘Patel case raises questions’ 11 June 2003. <http://newsvote.bbc.co.uk/mpapps/pagetools/print/news.bbc.co.uk/1/> accessed 17 April 2010. Trupti Patel was convicted of the murders of her three children who died at the ages of 3 months; two weeks and one day, and three weeks and one day old. The first two were classed as cot deaths but the third death aroused the suspicions of the authorities who subsequently charged Trupti with the murders of all three. It later transpired that her grandmother had lost five babies, cause unknown. With regard to these cases of multiple unexplained deaths, there may be a hitherto undiscovered genetic component linked to an immune deficiency.

57 8 week old Harry was infected with Staphylococcus aureus. Although a ubiquitous organism, it can prove fatal and perhaps contributed to Harry’s death. It is of course well known to the public as MRSA; Methicillin Resistant Staphylococcus Aureus and in modern times has contributed greatly to hospital acquired infection and subsequent mortality.
death. He had also just received the controversial combined vaccination routinely given at two months of age. The pathologist was also found to have acted beyond his competence. His behaviour, coupled with that of the ‘eminent’ paediatrician, resulted in a gross miscarriage of justice. The doctors’ arrogance beggars belief and, although the paediatrician was struck off by the General Medical Council, he was reinstated as the judge felt that he had acted in ‘good faith’. This latter point illustrates the problem that the judiciary face in judging the medical profession and their expertise. This will be expanded upon later.

There are inherent problems in the concept of the ‘expert witness’; not only can their expertise be questionable but time must also be factored into a situation. After the misadventure which is to be debated in court, the passage of time may well have determined the true risks associated with a new procedure; how then does ‘the expert’ reconcile events of the past with new knowledge unavailable at the time an incident occurred? Lord Denning’s famous 1947/1954 spectacles; a case must be determined in line with the practice of the time and not with knowledge subsequently acquired. In practice, this can be difficult to do.

III(e) – Consent

The Bolam test has generated many questions, not least that of informed consent. How much information should be imparted to a patient and can the patient fully comprehend that information? The issue of consent is difficult given that the majority of people will only retain a fraction of information imparted to them by clinicians and it is a problematic area of law. It could also be argued that the communication of too much information, by detailing every conceivable risk will do more harm than good. If the risks are negligible, it has been argued that ‘On the one hand you alarm unnecessarily, and on the other hand, you may put him in a position where he feels that he should take the decision, albeit the doctor is obviously much better qualified to weigh up the advantages and the desirability of the proposed operation as against the risks’. Ultimately, it is for the clinician to decide what is appropriate to share with the patient; it is not for medicine to further burden the ailing. Lord Diplock elaborated on this point ‘...To decide what risks the existence of which a patient should be voluntarily warned...is as much an exercise of professional skill and judgement as any other part of the doctor’s comprehensive duty of care’. 61

The venturing of Bolam into the area of consent in effect dismissed ‘informed consent’ from application in English law. This was much debated in Sidaway by Lord Bridge who considered the ‘different criterion as to the measure of the medical man’s duty of care to his patient when giving advice with respect to a proposed course of treatment’. 62 He also recognised that the competent adult, ‘of sound mind’, is entitled

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58 The combined vaccination consists of Diphtheria, Tetanus and Bordetella pertussis (whooping cough). It is the latter component that has caused much controversy and has been associated with brain damage and death. It has also been implicated in the causation of autism although the evidence to support the latter is the subject of much debate.

59 Roe v Minister of Health [1954] 2 All ER 131.

60 O’Malley v Board of Governors of the National Hospital for Nervous Diseases [1975] 1 BMJ 635.


to make a decision as to his fate, particularly when undergoing general anaesthesia; ‘this entitlement is the foundation of the doctrine of informed consent’. His basic premise was that although a clinician has an obligation to impart information regarding risks attributable to a procedure, it is for the clinician to temper that information in the interests of the patient. He warned against the dangers of being ‘alarmist’ by stating that ‘...once the doctor has decided what treatment is, on balance of advantages and disadvantages in the patient’s best interests, he should not alarm the patient by volunteering a warning of any risk involved, however grave and substantial, unless specifically asked by the patient’. He felt that it was the clinician’s duty to advise appropriately and answer those queries about specific risks when forwarded.

Truly informed consent can only be given if each and every risk potentially applicable to a treatment regime is detailed. Obviously this is nearly impossible to achieve and the requirement to do so has no basis in English law. There are risks inherent in all procedures; this is accepted and all is done to minimize them.

The current law pertaining to the issue of consent was established in *Chatterson v Gerson*, consent is real if a patient is informed in broad terms of the risks involved in a procedure and has given his consent. Most clinicians will not specify every risk attributed to a therapeutic regime but will elucidate those that most commonly occur. There will always be patients who desire more information, who might even request research materials. It is to be conceded that the likelihood of some events occurring is remote, as in *Bolam*. Consider the situation in *Bolam*, though; he was mentally ill and likely unable to comprehend the enormity of the procedure. Arguably, consent should have been obtained from a competent adult assuming responsibility for Bolam, as one would in the case of a child requiring treatment.

*Pearce v United Bristol Healthcare NHS Trust* elucidated the point pertaining to the informing of a patient of significant risks. In *Sidaway* Lord Bridge considered the question of risk and concluded that a risk of 10% could be regarded as significant. However, any risk is significant to the individual who sustains that risk and it is impossible to quantify that which is relevant to that individual.

*Pearce* elaborated on this point as it was considered that a risk of 0.1-0.2% relating to the chance of having a stillborn child when a mother is overdue is negligible, but surely not to the bereaved mother who had to deliver a dead child? The consultant in this case had withheld information when questioned by the expectant mother in

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63 ibid.
64 ibid.
65 [1981] 1 QB 432 at 443. Bristow J enunciated this principle. A patient sustained damage to her ilio-inguinal nerve during herniorraphy which resulted in severe, intractable pain. Subsequently a specialist attempted to ablate the pain by instilling a nerve block which cured the pain but resulted in paraesthesia to the limb. Held that although the patient had not been informed of this potential consequence of such a procedure, the clinician was not negligent in the application of his duty.
66 See earlier text, the risk of convulsions was estimated at 1:10,000.
68 ibid at 125.
deference to her emotional state. The judge applied Bolam but conceded that they were not bound to follow the test. He stipulated that the advice tendered should be rational with regard to the situation; did it address the concerns of the patient? Subsequently Sidaway was applied and the plaintiff did not succeed. So, it is incumbent upon a clinician to gauge that which his patient is capable of fully comprehending in any given clinical situation because there is no point in simply blinding someone with science.

**III(f) – Bolitho v City & Hackney Health Authority**

*Bolam* greatly influenced the outcome of medical negligence cases throughout the 1980’s and allowed the medical profession to in effect adjudge itself. It set standards determining the care that ought to be afforded to a patient and also determined when the duty of care was breached; a wholly unsatisfactory state of affairs. Bolam also entrenched the concept of the validity of dual therapies being acceptable if endorsed by a body of ‘reasonable, respectable and responsible’ medical men, who were defined by the profession itself, quite possibly to the detriment of patient care.

*Bolitho v City & Hackney Health Authority*[^69] heralded a change in the attitude of the courts towards the continued application of the Bolam test in that they were no longer willing to base their judgements on the medical profession’s assessment of their own. It was time to allow their own opinions and judgements to hold sway in the courts, and be less reliant upon often self-professed ‘expert witnesses’. Importantly, Bolitho allowed judges to distinguish between conflicting ‘expert’ opinions and decide which made more sense, notwithstanding the clinician’s perspective.

The case was tragic as it concerned the potentially avoidable death of a 2 year old boy, Patrick Bolitho. He had a history of croup[^70] which is characterised by paroxysms of coughing, laryngeal stridor[^71] and breathlessness which can lead to asphyxia and sudden death. Given the clinical features it is of importance to maintain the airway but intubation is associated with laryngeal spasm and may precipitate both respiratory and cardiac arrest and is therefore not without severe risk. Despite the risk attached to intubation it is accepted medical practice that maintenance of an airway at least ensures that respiratory failure does not lead to cardiac arrest.

The child was admitted in January 1984 with an upper respiratory tract infection but he was not treated with any great urgency, despite his clinical history. Given that he had already suffered episodes of respiratory difficulty he should have been treated urgently. On admission two doctors were assigned to his care, Drs Horn and Rodger, although neither appears to have treated his deteriorating condition with any degree of gravity. The next day his condition markedly deteriorated. He developed severe breathing difficulties leading to respiratory arrest, cardiac failure and resultant severe brain damage from which he never recovered. One of the doctors attended the first episode of respiratory crisis but neither attended the second which ultimately led to

[^70]: Croup, acute laryngo-tracheobronchitis, is an upper respiratory tract infection, usually viral in aetiology.
[^71]: On inspiration, *stridor* is characterised by a high pitched breath sound. It is usually caused by laryngeal obstruction.
the child’s demise. An experienced nurse alerted the more senior of the two doctors, Dr Horn, when the child began to deteriorate markedly but she declined to attend despite the alarming change in the child’s clinical condition of which she was informed, although in her defence she claimed that the batteries in her bleep were flat. But a doctor in a position of responsibility has a duty to ensure that at all times contact can be made by those dependent upon them.

**III(g) – The Bolitho judgement**

The main issue when the case came before the House of Lords was the question as to the alleged negligence on the part of Dr Horn who maintained that she would not have intubated even if she had attended the child during the final episode; did her care equate to that which would have been rendered by a doctor of similar skill and competency? The law of tort stipulates that those undertaking the acquisition of specialist skills are required to achieve the standard of the reasonable doctor of the same rank, had Doctor Horn in fact done so or was it yet another case of the medical profession applying their own standards?

The health authority conceded that Doctor Horn had breached her duty of care; negligence was therefore established but did her failure to attend the child result in the final catastrophic event? The question as to causation had to be addressed. Would intubation have saved the child, given that the gold standard of care pertaining to the condition expressly endorses the maintenance of the airway as paramount in the avoidance of the complications experienced by Bolitho? Dr Horn’s contention was that even if she had attended the child, she would not have intubated. Eight expert witnesses could not agree as to the proper course of treatment that should have been administered. Their views very much depended on the clinical condition of the child; some evidence indicated either that the child was quite well apart from the two acute episodes whereas opposing evidence indicated a progressive decline in respiratory function leading inexorably to the final event. The indications for intubation differed according to the physical condition of the child; five would have intubated, whereas three would not have done so.

Interestingly, the judge went with those who would not have intubated, thereby absolving Dr Horn, endorsing her care and finding that it did indeed measure up to those standards espoused by a doctor of similar skills and ability. One of the reasons that the judge was swayed by the arguments against intubation was the question of the discomfort that would be experienced by the child, who between episodes had appeared quite well. A counter argument, however, is that the child could have been sedated and therefore may have survived; as the old adage goes, ‘sometimes you have to be cruel to be kind’.

*Wilsher v Essex Area Health Authority* was considered and yet the doctor in this case was found to have fallen short of the standards expected of a doctor of the same level of training; a harsh judgement given the facts of the case which pertained to the

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72 *Wilsher v Essex Area Health Authority* (1986) 3 All ER 801.

oxygen therapy administered to a premature infant, resulting in blindness.\textsuperscript{74} The difference in judgements reached reveals an apparent dichotomy of opinion in the skills expected of junior doctors.

\textit{Bolitho} paved the way for development in the law related to medical negligence by no longer endorsing a medical viewpoint simply because a medical expert regarded a course of action, no matter how illogical, as an option, but still Lord Browne-Wilkinson held that ‘it will very seldom be right for a judge to reach the conclusion that views genuinely held by a competent medical expert are unreasonable. The assessment of medical risks and benefits is a matter of clinical judgement which a judge would not normally be able to make without expert evidence.’\textsuperscript{75} He felt that a judge’s position was to decide when a course of action could not be logically supported by the viewpoint of an expert and would, therefore, not provide a bulwark against a charge of alleged medical negligence.

\textbf{IV – Bolitho vs Bolam}

\textit{Bolam} traversed the world influencing the standard of care expected of all professionals but notably that expected of doctors. Increasingly, though, its use and validity were questioned, leading to \textit{Bolitho} which established that the judiciary could question the actions of clinicians that were patently illogical despite assertions by colleagues to the contrary. \textit{Bolitho} did much to challenge \textit{Bolam}. Importantly, it allowed the courts to challenge so-called expert witnesses and the apparent absurdity of some of the clinical decisions. For the first time the House of Lords criticised the medical profession which post-\textit{Bolam} could, in some cases, seem to have got away ‘with murder’. The House also rejected the notion that a doctor should escape liability for their actions simply because their colleagues would have acted in a like manner. In allowing a colleague to state that he would have acted in a similar manner given a comparable clinical scenario, a substantial benefit was awarded to those facing an allegation of clinical negligence and assured failure of the claim against them in most instances.

The whole premise of \textit{Bolam} depended upon the different treatment options available to clinicians and the concept that a ‘reasonable man’ would have acted in the same way, but \textit{Bolitho} challenged this by allowing the court to choose between two opinions proffered. Significantly Lord Browne-Wilkinson challenged the principle enunciated in \textit{Bolam} of the ‘responsible, reasonable and respectable’ medical man and stated that the use of this terminology should ‘show that the court has to be satisfied that the exponents of the body of opinion relied on can demonstrate that such opinion has a logical basis’\textsuperscript{76}. He felt that before accepting such opinions, he must be satisfied that the clinical position was one of strength founded on good medicine. It was simply not good enough for a court to accept the views of one body of experts as opposed to

\textsuperscript{74} This was an extremely harsh judgement as premature babies are prone to multiple ophthalmic problems including that of inadequate development of the eye. It is true that the administration of 100% oxygen does result in retrolental fibrodysplasia which is a cause of blindness in the premature, but in this case other factors could have contributed to the child’s blindness.

\textsuperscript{75} \cite{bolitho} at 780.

\textsuperscript{76} \cite{bolitho} at 779.
those of another without question; after all it is for the court to decide the standards of
care expected, not the profession itself.

The acceptance not to intubate in *Bolitho*, despite evidence to suggest that
maintenance of the airway would have obviated the clinical problems resulting in the
death of the child, is absurd and indeed was commented upon; ‘...the views of the
defendant’s experts simply were not logical or sensible’.77 He further commented on
the fact that despite the child having experienced respiratory difficulty on two
occasions prior to the terminal event, that ‘it was unreasonable and illogical not to
anticipate the recurrence of a life threatening event and take the step which it was
acknowledged would probably have saved Patrick from harm?’78

This was like a breath of fresh air through legal corridors. A judge had questioned the
illogicality of doctors electing not to act and accepting such inaction despite evidence
that a course of treatment possessed merit. Indeed Lord Browne-Wilkinson commented in *Bolitho* that ‘if, in a rare case, it can be demonstrated that the
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’79.

That rare case to which Lord Browne-Wilkinson referred was that of *Hucks v Cole*,80
which predated *Bolitho*. A doctor withheld penicillin from a patient with sepsis; a
body of expert witnesses concurred with this view but despite their evidence the Court
of Appeal held the defendant was negligent. Lord Sachs said: ‘When the evidence
shows that a lacuna in professional practice exists by which risks of grave danger are
knowingly taken then, however small the risks, the court must anxiously examine the
lacuna, particularly if the risks can be easily and inexpensively avoided...If the court
finds, on an analysis...of reasons given for not taking those precautions that, in the
light of current professional knowledge, there is no ...basis for the lacuna,...it is ...not
reasonable that those risks should have been taken, its function is to state the fact and
where necessary to state that it constitutes negligence’.

Following *Bolitho*, judges felt able to question medical evidence in situations where
they doubted its relevance. The opinions of all expert witnesses must be defensible,
given honestly and sincerely held. These views must be ‘capable of withstanding
logical analysis’81. The Court of Appeal, for example, disallowed medical evidence in
*Mariott v West Midlands AHA and Others*82. A General Practitioner (GP) failed to
recognise the seriousness of a head injury incurred by a man who had fallen down the
stairs rendering him unconscious. Subsequently he became increasingly lethargic,
suffered headaches and lost his appetite. His GP attended him but did not think that
his condition merited a referral to hospital. He lapsed into a coma and required


78 ibid at 779.

79 *Bolitho v Hackney Health Authority* 39 BMLR 1.


81 Emily Jackson ‘Medical Law Text, Cases, and Materials’ (Oxford University Press, 2nd ed, 2010)
118.

surgery to remove a haematoma which left him with a permanent disability. The expert witnesses disagreed as to what course of action the GP should have adopted; one agreed with the GP’s opinion but the other disagreed and maintained that he should have been referred to hospital. In the light of developments, the evidence offered by the witness could not be logically supported. Accordingly, the General Practitioner was indeed found to be negligent in his failure to attend to the patient, even though the injury he sustained when he fell downstairs was a rare consequence of such an event. The man was ill and was denied the necessary medical treatment; a simple statement of fact.

The importance of *Bolitho* is that a clinician’s actions were no longer considered above the law and perhaps more claimants have had cases settled in their favour, but it remains difficult to prove that a clinician did act negligently when confronted by the testimony of reasonable, responsible, respected experts, for the medical profession constitutes a powerful group of learned individuals. Notwithstanding this, it was to be expected that it would become more difficult for doctors to escape the consequences of their actions and make it harder for the profession to shield its own for none should be above the law, transgression is deserving of legal censure which should bode well for those ‘injured’ by the medical profession but is apparent that it is still very difficult to prove that a clinician’s conduct is negligent if so endorsed by another.\(^{83}\) The problem is that it remains very difficult for a judge to conclude that views genuinely held by a competent medical practitioner are unreasonable and therein lies the problem with regard to *Wisniewski*, as indeed Lord Browne-Wilkinson so commented.\(^{84}\) However, in rare cases the claimant’s action has succeeded.

**V – Testing Bolam**

In the common law jurisdictions, the three basic tenets pertaining to medical negligence remain applicable: the duty of care, breach of that duty and causation. It is the last that has proven the most difficult to establish as evidenced in *Bolitho* amongst others. Perhaps it is also worth considering the ‘but for’ premise; a defendant can only be found negligent if the claimant would not have sustained the injury ‘but for’ the defendant’s actions or inactions. Could this have been applied in *Bolitho*? ‘But for’ the inaction of the doctors would he have lived?

Different jurisdictions have dealt with the issue of consent differently. In England, *Bolam* has been applied and allowed the doctrine of informed consent to be partially negated; *Sidaway* established quite firmly the application of *Bolam* to consent. Lord Templeman was firmly of the opinion that it was not in the patient’s best interests to know everything; indeed ‘a little knowledge is a dangerous thing’ but conversely it is not for the clinician to decide for the patient unless the patient cannot do so for

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83 See *Wisniewski v Central Manchester Health Authority* [1998] Lloyd’s Rep Med 223 CA. This sad case concerned a young boy who suffered from cerebral palsy as a result of having the umbilical cord knotted around his neck during a delivery which went sadly wrong. The experts could not decide on the manner in which the labour should have been managed.

84 Ibid. Lord Browne-Wilkinson at p.1160A-E: ‘I emphasise that in my view it will very seldom be right for a judge to reach the conclusion that views genuinely held by a competent medical expert are unreasonable. The assessment of medical risks and benefits is a matter of clinical judgment which a judge would not normally be able to make without expert evidence’.
himself. The courts in Singapore have followed the English with regard to the application of Bolam to causation and a duty to warn patients of possible risks with several high profile cases.

The situation is very different in the United States of America and Canada. A patient’s consent is vitiated if full information related to a procedure is not given in some American states but it is difficult to understand just how such comprehensive information could be imparted. In both Canada and certain American jurisdictions, knowledge on which the patient has relied and based their decision to consent, may oust Bolam. It is therefore proposed that the test of informed consent should be an objective one based on the ruling in Canterbury v Spence; enough should be disclosed about a procedure to enable a patient to make an educated decision. Robinson J said that ‘respect for the patient’s right of self-determination on particular therapy demands a standard set by law for physicians rather than one which physicians may or may not impose upon themselves’. The principle with regard to consent is important because it establishes the right of the competent patient not only to consent to treatment but also the right to refuse treatment.

The Australian courts do not apply the Bolam test but rather consider each case on its merits; the nature of the treatment, the desire of the patient for information, the temperament and health of the patient and the general circumstances. The Australians consider it the duty of the physician to warn of the ‘material risks’, i.e. those to which a reasonable person could attach significance. But who defines ‘material’? The Australian position is exemplified in Rogers v Whittaker.

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85 The Singapore courts consider all the elements pertinent to the application of the Bolam Test; the duty of care, breach of duty, and causation. Consider Lily Pai v Henry Yeo. The claimant became blind in one eye when the defendant was found negligent in failing to refer her to a specialist with respect to a clinical suspicion that the eye was developing serious clinical problem.

86 See Denis Mathew Harte v Dr Tan Hun Hoe & Anor (Unreported) and Gunapathy Muniandy v Dr James Khoo and two others. The former case involved a patient who sustained severe bruising to both testes but his treating physician declined to examine him when requested to do so and the latter the failure of a clinician to diagnose a malignant brain tumour.

87 Schloendorf v Society of New York Hospital 211 NY 125 (1914) ‘Every human being of adult years and sound mind has a right to determine what shall be done with his own body and surgeon who performs an operation without his patient’s consent commits an assault for which he is liable in damages’.


89 Ibid page 47.

90 Ibid page 47. So spake Robinson J at p.748.


92 Ibid.

93 (1992) 175 CLR 479. This was an unfortunate case which resulted in blindness for the claimant who was not informed of the very small risk, 1:14000, which could result in the loss of sight after a surgical procedure. The claimant had been almost totally blind in her right eye following a childhood accident and the surgeon informed her that not only would surgery improve appearance it would also improve
The issue of consent is not a simple one and calls into question the very nature of the doctor/patient relationship. A doctor cannot be expected to educate a patient to medical degree level at consultation and it can be difficult to gauge that to which a patient will attach import. Simply applying Bolam to the question of consent may in fact be just that; too simple. Considering the judgement in Reibl v Hughes, ‘To allow expert medical evidence to determine what risks are material and ...should be disclosed and...what ...are not material is to hand over to the medical profession the entire question of the scope of the duty of disclosure...under consideration ...is the patient’s right to know what risks are involved...’ 94 Ultimately it is for the patient to make the final decision with regard to their own health.

VI – Auxiliary Influences

VI(a) – The Development of the Art of Medicine

The problem with the practice of medicine is that of an ever-increasing knowledge base, with new treatments and procedures being developed and administered almost daily. Such is the way of a rapidly developing, innovative, technological world that characterises modern society. The public are well aware of significant advances in medicine, courtesy of the media and the internet and expect such to be administered accordingly, should the need arise. There are few today who do not research their complaint either prior to seeing their general medical practitioner or, more usually, before seeing the specialist to whom they have been referred. It is also to be noted, unfortunately, that although there is a wealth of good, accurate information available on the various web sites that have proliferated in recent years, there is also some misleading and inaccurate information accessible, which can make the clinician’s discussion about a treatment regime something of a trial in itself.

VI(b) – The National Institute for Clinical Excellence

The main aim of the National Institute for Clinical Excellence (NICE), established in 1999 under s.11 of The National Health Service Act 197796 was to ensure and facilitate clinical excellence. It has a remit to evaluate which treatments and drugs should be available on the National Health Service (NHS) in England and Wales and has authority to rationalize the treatments available, thereby ensuring value for money. Critics argue that it is part of a health rationing exercise but it is also tasked with formulating clinical guidelines pertinent to the major issues in medicine today, one of which is clinical negligence, which is unfortunately very much on the increase within the United Kingdom and the source of both concern and controversy.

sight. Unfortunately she developed sympathetic ophthalmia, an inflammatory condition that can affect the healthy eye post trauma or surgery. It is rare with an occurrence of 1:14,000.


95 Kim Castle ‘Medical negligence: The Pathology of The Responsible Man’; Dissertation produced in April 2010 at The school of Law, Bangor University, North Wales Page 7.

96 This Act was subsequently modified in 1999 when a provision was made for the problem of clinical negligence.
With regard to clinical negligence allegedly perpetuated by any member of a healthcare team but principally by the clinician, the pertinent question relates to the standard of care expected of that individual as compared to responsible medical practice. The law in England has very much depended on the expert testimony provided by other members of the profession skilled within the same discipline and guidelines have been very much side-lined, as it were. But times are changing and it is to be anticipated that the latter will play an ever increasing role in tort law relevant to medical negligence. It is hoped that they will provide the basis of the standards of care expected within the NHS, and therefore assist the courts in their task when dealing with allegations of medical negligence.

VI(c) – Guidelines
The formulation of clinical guidelines is a lengthy process, involving more than one clinical agency. An issue has to be identified, addressed and researched before the information collated can metamorphose into workable guidelines. Once completed and put into practice, they require both annual review and regular updates; after all, medicine is not a static science.

The guidelines thus formulated are intended to provide a framework ensuring both good clinical practice and management strategy. By their very definition, that of being both research and clinically derived, it is obvious that there will inevitably be a bias towards the means of their evolution. If a research project involves only a particular part of a clinical population, as in those suffering with cancer, then the clinical guidelines will be inevitably biased in their favour. Also to be factored into the equation is that of individual susceptibility or indeed a racial one.

Recent times have seen a proliferation of guidelines with varying degrees of usage, which is disappointing given that they are designed to improve working practice. Perhaps the answer to poor uptake lies in the manner of their evolution and the failure to address all pertinent issues? Perhaps those drafting the guidelines should consider their potential in the legal arena?

VI(d) – Guidelines and English law
As a consequence of the importance attached to the gold standard of care as specified in Bolam and later modified by Bolitho, clinical guidelines have tended to get relegated to a secondary position with the judiciary attaching more weight to the spoken word. This was evidenced by Stuart Smith LJ when he spoke about the controversial pertussis\(^7\) vaccine which has been linked to autism, although the evidence both for and against is the subject of much controversy in the medical world. The judge preferred the spoken word as opposed to publications by learned bodies,\(^8\) which is entirely consistent with a person’s desire for their day in court to speak their piece.

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\(^7\) *Bordetella pertussis* is a bacterium which is the causative agent of whooping cough.

\(^8\) Ash Samanta, Jo Samanta and Michael Gunn ‘Legal considerations of clinical guidelines: will NICE make a difference?’ J R Soc Med. 2003 March; 96(3).
There is evidence to suggest that there is a move towards the acceptance of guidelines as was evidenced in *Bland*, perhaps one of the most high profile cases in recent times to invoke the use of guidelines, in this case those formulated by the Medical Ethics Committee of the British Medical Association (BMA). Lord Goff commented ‘if a doctor...acts in accordance with...medical practice now being evolved by the medical ethics committee of the BMA, he will be acting with the benefit of guidance from a responsible...competent body of...professional opinion, ...required by the Bolam test’. 100

In invoking *Bolam* he considered the duty of care owed to a patient unable to communicate with his carers who still owed him a duty to act in his best interests. He referred to cases in other jurisdictions, namely America and New Zealand, with reference to *re Quinlan* 101 and *Superintendent of Belchertown State School v Saikewicz* 102 in the former and *Auckland Area Health Board v Attorney General* 103 in the latter, which concerned a severe case of Guillain-Barre syndrome 104 resulting in a persistent vegetative state. 105 In all three jurisdictions, the dignity and privacy that ought to be accorded to all patients, whatever their clinical status, was emphasised and the concept of the ‘substituted judgement test’ was invoked; what would the patient have wanted if he could communicate?

Despite this very public use of guidelines the future is uncertain; will they in effect ‘hamstring’ the medical profession preventing innovation and compromise in the clinical setting? Would a departure from them lead to litigation even if such was done in the best interests of a patient? There is a practice in the UK of clinicians being able to prescribe ‘off licence’, i.e. disregarding the clinical indications for a drug and, as it were, go ‘off-piste’ in certain situations, having explained such to the patient and obtained written consent. Will this practice now be ‘outlawed’? Only time will tell as to how the law and guidelines will interact in the future. Perhaps this complex relationship is in an embryonic stage?

**VI(e) – Committees and Legislation**

Despite the best efforts of government to address the problem of medical negligence by the introduction of measures designed to curtail malpractice and encourage uniformity of care standards throughout the NHS, it remains a thorny problem. It has been estimated that negligence claims, which are rising annually, will cost the NHS

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100 Ibid at 872.
101 Ibid at 873. (1976) 355 A.2d 647
102 Ibid at 873. 370 N.E.2d 417
103 Ibid at 873. [1993] 1 N.Z.L. 235
104 Guillain-Barre syndrome is an ascending polyneuritis which can result in total paralysis necessitating respiratory support. It classically is a sequel to a viral infection and can be of varying severity. Recovery is time dependent and can be total but it can also result in death.
105 A persistent vegetative state is one in which an individual is totally unaware of their environment and cannot make any voluntary or purposeful movements. The important clinical feature is the complete lack of voluntary movement and they retain reflexes, but are doubly incontinent. It is usually regarded as a non-recoverable condition.
£15.7bn a year.\textsuperscript{106} One shudders to contemplate just how much NICE cost to set up and how much its legal wrangling in court have cost to date. It was envisaged that conformity would lead to improved standards of care and yet the NHS is still beset by problems. The Health Act 1999 s.19 led to the establishment of the Commission for Health Improvement (CHI), which has overall responsibility for the quality control within the NHS and a remit to oversee and inspect clinical governance at a local level.

Clinical governance\textsuperscript{107} was introduced to ensure consistent, high standards of care throughout the NHS and to promote continued medical education. The latter is of particular importance in the rapidly evolving world of medicine. Clinicians are expected to continue learning throughout their careers and it is incumbent upon their seniors to ensure this and audit their clinical work.

Yet more legislation was enacted with the introduction of the NHS Reform and Health Care Professions Act 2002, aimed at further regulation of the medical profession to ensure quality and accountability; it also has a further remit to audit.

The medical profession has attempted to curb the rising tide of clinical negligence complaints with the introduction of the licence to practise and revalidation. Both procedures are designed to ensure that a clinician is up to date with medical and therapeutic developments and fit to practise. The licence to practise was introduced in November 2009 and will require annual renewal. It is to be coupled with revalidation which is the process by which a doctor will demonstrate his capability to practise. Patients will be encouraged to provide feedback about the care they have received; but what if either should bear a grudge against a particular doctor?

\textbf{VII – Where to now? – Conclusion and Suggestions}

In spite of all the money and brain-storming that has gone into attempting to solve the problem of clinical negligence, it remains an ever-growing phenomenon. Perhaps it is time to consider the root causes instead of attempting to tackle the end result, that of the negligent doctor. It is my premise that medical education must be both improved and standardised, not only in the UK but also for those doctors who train overseas, particularly those from the third world. The issue of social engineering must also be considered in the context of medical education; we are not all equal and it is unlikely that those who do not shine at school are going to be able to cope with medicine. It is to be remembered that ‘All men are equal: but some are more so than others’.\textsuperscript{108}

Not only must education be scrutinised, but attempts must be made to improve communication by ensuring an agreed level of linguistic skills. The latter must not only apply to clinicians but to all staff employed in the NHS. Recent articles in the

\textsuperscript{106} M Wardrop, ‘NHS facing £15.7bn for rising number of clinical negligence claim.’ (7 February 2012) \textit{The Telegraph} \texttt{<http://www.telegraph.co.uk/news/politics/9065534/NHS-facing-15.7bn-for-rising-number-of-clinical-negligence-claims.html>} accessed 8 February 2012. However, perhaps the rising costs are not only being fuelled by clinical practice itself but also by the growth of legal services dedicated to seeking damages.


\textsuperscript{108} Alfred Walter Barrett (1869- 19??) ‘Cheerful Craft’ 1913. Most sources quote his date of death as 1920, but he was tried in court in 1921, after which his whereabouts cannot be verified.
daily press have emphasised this language problem, pointing out that although doctors entering from the EU have a requirement to pass a special English language test, ancillary workers do not. And yet the latter are just as capable of being found guilty of clinical negligence; consider the healthcare assistant who gives a meal to the ‘nil by mouth’ patient who perhaps is being prepared for theatre, or has lost the ability to swallow; either way, disaster looms.

Foreign doctors from outwith the EU who seek work in the UK are required to pass a language test but, until recently, no such provision was stipulated for those entering the UK from the EU despite stipulation by the latter that they “….‘shall’ have knowledge of languages necessary for practising the profession in the host member state”. The previous government compounded the medical manning crisis in this country with the directives it introduced with regard to the working hours of general practitioners, such that it has been necessary to ‘import’ doctors; a recipe for disaster as evidenced by the ‘German’ GP who accidentally killed a patient: the doctor’s English was so poor that, in spite of having been rejected by several locum agencies, when faced with an unfamiliar drug the doctor administered ten times the recommended dose of morphine resulting in the death of the patient. It was a potentially avoidable situation. If vetting both the language and clinical skills of all those who wish to work in the NHS either on a temporary or permanent basis had been mandated at the time, and enforced, this doctor would never have been allowed to practise in this country. There must be a level playing field with regard to medical education and language skills; it should matter not where a clinician originates but his skills must be above reproach.

The impact of the EU directives on working hours must also be considered in the context of the potential for medical negligence. Junior doctors learn their acute medicine on the wards after qualification, not during their lectures in a sterile environment. The impact of a shorter working week can only be a negative one. Knowledge of acute medicine is assimilated when manifested at its worst in the early hours of the night. That is when the acute asthmatics go into status, the myocardial infarctions occur, the diabetics ‘go off’ and the dying die; a steep learning curve is now lost in the name of reform. Not only are junior doctors not seeing acute medicine but, because of the working hours stipulated by the EU, they are not getting to follow up the patients with consequent loss of knowledge and, with it, the potential for future clinical disaster.

As to the future? There are those who envisage that the Human Rights Act 1998 has the potential to be applied in cases on medical negligence; there are others who

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110 ibid 1.


consider that legislation, committees and guidelines will combat the growing problem of clinical negligence, but at the cost of stifling innovation and the promotion of defensive medicine. And as to the judiciary, perhaps it is for them to expand on Bolitho. Time to polish the gloss?\footnote{Nicholas Wilkes “Bolam Out?” (15 September 2003) The Lawyer <http://www.thelawyer.com/bolam-out/?106892.article> accessed 19 January 2010}