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To What Extent Should the Bolam Test Be Applicable to the Cases of Clinical Trials? What Should Be the Right Direction of the Law?

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2013
INTRODUCTION

During the first six months of 2012, over 200 people died in India because of their participation in clinical trials.¹ Worse still, a parliamentary committee report revealed that ‘2,374 people had died during such trials between 1 January 2007 and 30 June 2012, and only 37 [victims’ families] had been paid a small compensation’.² The news sparked international concerns. In addition to advocating a fairer financial compensation to the trial participants and/or their families, there are also voices urging better protection of the patients’ rights – their right to information and right to give an informed consent.

As time passes, advancement of technology becomes inevitable and this accounts for the increasing number of clinical trials. However, the law in this field is unsettled. Therefore, the major aim of this study is to explore the problems of the legal regime in this area.

Moreover, as our society is becoming more rights-conscious, there is a need to review the present framework and pay more attention to the patients’ rights. In this paper, the major drawbacks of the current law on medical negligence will also be examined.

This paper is presented in six parts. In Part I, the law of medical negligence and its development will be addressed, followed by Part II, which highlights the practical obstacles in applying the test laid down in Bolam v Friern Hospital Management Committee³ (“the Bolam test”) to the cases of clinical trials.

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³ [1957] 1 WLR 582.
Part III focuses on the patients’ rights, including their right to give an informed consent and right of self-determination. These rights are directly affected by the scope and standard of disclosure. The good and bad sides of the two antagonistic approaches, namely the doctor-centred test (i.e. the Bolam test) and the patient-orientated test, will also be discussed.

In Part IV, the historical developments will be addressed. In the past, the Bolam test was unquestionably applied in the area of information disclosure. As time goes by, doctors are now expected to disclose more than before. While the UK and Hong Kong courts are still adopting the doctor-centred approach, the US and Australian courts prefer the patient-orientated test. In Australia, the Bolam approach was rejected by the High Court of Australia, and the earlier decision of the US Supreme Court was followed. This may be explained by the fact that the Bolam test had always been, and still is, heavily criticized. The major criticisms will be covered in Part V.

In Part VI, I will suggest ways to offer more concrete protection to the patients’ rights. An integrated disclosure approach will be proposed. It incorporates both the objective and subjective patient-orientated tests, which should be a practical and feasible way to mitigate the respective drawbacks of the two tests. The current situation in Hong Kong will also be highlighted. Arguably, patients in Hong Kong are not as well-protected as in other jurisdictions. There is no statute law which entitles patients to seek legal redress in case their rights are infringed. In this respect, the New Zealand framework is a good blueprint to which Hong Kong can refer. The paper will then be summarized and concluded.

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5 (1972) 464 F 2d 772.
PART I. NEGLIGENCE AND MEDICAL NEGLIGENCE

The English law on negligence was authoritatively set out in *Donoghue v Stevenson*, where Lord Atkin’s “neighbour principle” was laid down. “Neighbour” in this sense means a person who is so ‘closely and
directly affected by [the] act’ that one ought reasonably to be in mind when considering the act. There is no
doubt that the relationship between a doctor and his patient fits into this definition and that a duty of care is
owed by a doctor to his patient.

In concordance with the general principles of negligence, a doctor’s failure to exercise reasonable care and
skill in any given circumstances constitutes a breach of the duty, which may give rise to liability on his part.

The *Bolam* test and subsequent legal development

While *Donoghue v Stevenson* plays a decisive role in general negligence cases, *Bolam v Friern Hospital
Management Committee* is equally authoritative in professional negligence claims.

Relying on *Hunter v Hanley* as the basis, McNair J in the landmark case *Bolam v Friern Hospital
Management Committee* laid down the now famous *Bolam* test, which first gained recognition in the
House of Lords in *Whitehouse v Jordan*. Since then, this universal test of professional negligence has
taken root in the English law, it has also been approved in other jurisdictions.

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7 [1932] AC 562.
8 [1932] AC 562 at 580.
9 [1932] AC 562.
10 [1957] 1 WLR 582.
12 [1957] 1 WLR 582.
14 Catherine S K Tay, ‘Interpretation of the *Bolam* Test in the Standard of Medical Care: Impact of the *Gunapathy* case and
Under the **Bolam** test, professionals are not expected to possess the highest expert skill and work to an unrealistically perfect standard. As put by McNair J,

> it is sufficient if he exercises the ordinary skill of an ordinary competent man exercising that particular art, [accordingly, 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.\(^\text{16}\)

Based on the principle enunciated in **Bolam**,\(^\text{17}\) a doctor acting in conformity with the accepted practice endorsed by his counterparts will be absolved from negligence.\(^\text{18}\) It was noted that, under the **Bolam** test, the standard of care is essentially ‘set by the medical profession and evidenced by expert testimony, with minimal court scrutiny’.\(^\text{19}\) This may sound plausible because a judge who is inexperienced to the issue of clinical judgment may find it hard to decide on matters relating to the intricacies of medical science.\(^\text{20}\) As such, it seems that the question of “negligence or no negligence” is left in the hands of the medical profession. Strictly speaking, a judge does not have a say. This is particularly the case where there is a conflict of medical opinion. According to **Maynard v West Midlands Regional Health Authority**,\(^\text{21}\) ‘a judge’s preference for one body of distinguished professional opinion to another also professionally distinguished is not sufficient to establish negligence’.\(^\text{22}\) This implies that, a doctor does not need to second-guess the possible options which may be preferred by his colleagues and compel himself to make the perfect decision.\(^\text{23}\) It is sufficient for him to act in accordance with a practice which is accepted by a responsible body of medical opinion. Furthermore, the greatest beauty of the **Bolam** test is that, the threshold can still be

\(^{15}\) e.g. Malaysia: *Chiu Keow v Government of Malaysia* [1967] 2 MLJ 45; Singapore: *Dr. Khoo James and Another v Gunapathy d/o Muniandy* [2002] 2 SLR 414.

\(^{16}\) [1957] 1 WLR 582 at 586.

\(^{17}\) [1957] 1 WLR 582.


\(^{21}\) [1984] 1 WLR 634.

\(^{22}\) [1984] 1 WLR 634 at 639.

satisfied with a minority respectable view. In *De Freitas v O’Brien*, the defendant relied on the expert evidence from a small body of only eleven spinal surgeons, whose opinion was different from the larger body of over a thousand orthopaedic surgeons and neuro-surgeons. Nevertheless, Otton LJ held that the body of spinal surgeons did not have to be substantial, ‘it was sufficient if [the court] was satisfied that [it] was a responsible body’. 

Four decades after *Bolam*, *Bolitho (Deceased) v City and Hackney Health Authority* was believed to be capable of heralding ‘the dawn of a new era’. Lord Browne-Wilkinson held that, ‘the court has to be satisfied that the exponents of the body of opinion relied upon can demonstrate that such opinion has a logical basis’. He added that, expert testimony can be overridden if the court views that the opinion is ‘incapable of withstanding logical analysis’, or is otherwise ‘unreasonable and illogical’. It is essentially encouraging ‘a dilution of the *Bolam* test’ which allows the courts to look beyond the *Bolam* test and take a more enquiring approach to assess expert evidence.

Under *Bolitho*, ‘conformity with accepted practice is not, by itself, conclusive’. Lord Browne-Wilkinson instanced *Hucks v Cole* to manifest that expert medical evidence was no longer decisive of the legal acceptability of a medical procedure. In that case, the doctor was aware of the septic spots on his patient’s skin and knew that they could lead to puerperal fever, but he had not treated her with penicillin. Although a

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26 [1957] 1 WLR 582.
number of expert witnesses testified and confirmed the acceptability of non-treatment in such circumstances, the court held that the doctor had been negligent.

‘Bolitho’ is a significant and welcome decision to the extent that it reins in the Bolam test’. It is also regarded as ‘[a] pivotal case in the gradual evolution of medical negligence’ – with its emergence, liability for medical negligence should become more coherent with the ordinary law of negligence. It also encourages the courts to adopt a more interventionist stance in scrutinizing expert testimony.

Nevertheless, Bolitho turns out to have disappointed many legal academics and practitioners. ‘[It] was initially thought to be the missing link in the standard of care in clinical negligence cases’, which could potentially justify the courts’ rejection of expert opinion. Eventually, it fails to promote a judicial move to shift away from Bolam.

Heywood viewed that, ‘Bolitho remains shrouded in controversy’, which may be attributed to its ambiguity. Bolitho itself does not provide much useful guidance as to what amounts to “unreasonable and illogical”. Mulheron further observed that ‘more than a decade after Bolitho was handed down, there has been no judicial (or academic) undertaking of the type of close analytical exercise – of identifying

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42 [1957] 1 WLR 582.
“Bolitho factors”.

The unarticulated factors may explain why Bolitho failed to gain a strong foothold in the English medical jurisprudence.

Moreover, the use of “logic” to measure “reasonableness” is assailable. ‘Judgments of what is reasonable must rest on normative appraisal rather than on conclusions entailed by deductive reasoning’.

In view of the complexity nature of medical science, Glover and Heywood opined that just because a decision is illogical does not necessarily mean that it is wrong.

In addition, it remains a riddle as to whose logic Lord Browne-Wilkinson was referring to. If he meant the reasonable person’s logic, it is sensible that expert evidence will be taken into account and may even be attached to a heavy weight. On the other hand, if what he intended to consider was the doctor’s logic, then it is no different from the Bolam test.

Last but not least, as emphasized by Lord Browne-Wilkinson himself, ‘it will very seldom be right for a judge to reach the conclusion that views genuinely held by a competent medical expert are unreasonable,’ especially when the assessment of the relative risks and benefits have been carried out. Lord Woolf also conceded that ‘in reality, it is unlikely that a court will find an opinion on a highly technical topic to be illogical’. Accordingly, it is expected that only in very rare situations can the Bolitho trump card be triggered to circumvent Bolam.

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55 [1957] 1 WLR 582.
The Bolam test is still alive and remains the cornerstone to determine the standard of care in medical negligence cases.\(^{56}\) Although it is now supplemented by Bolitho,\(^{57}\) there is hardly any major change in the law. Unless in rare and exceptional cases where the body of medical opinion ‘cannot be logically supported at all’,\(^{58}\) the opinion of a body of responsible practitioners is usually accepted.

**PART II. CLINICAL TRIALS AND THE APPLICABILITY OF THE BOLAM TEST**

In addition to the orthodox and approved treatments, patients may sometimes be treated with untested methods, which are known as “clinical trials” or “therapeutic experiments”. The main feature of these treatments lies in their novelty.

Advancement of medicine is inevitable as time passes. One of the effective ways to propel the progress is to introduce new treatments, and human experimentation is ‘a necessary prelude to the introduction into general use of many valuable drugs and medical procedures’.\(^{59}\)

Experimental therapy has potential benefits for patients — they can receive new treatments which have not been widely available yet. Their participation can also help test the effectiveness of the treatments.

However, in addition to the benefits, the potential risks cannot be neglected. Usually, the procedures have not been proven to be perfectly safe and/or effective,\(^ {60}\) thus, the participating patients may experience adverse side-effects or even complications. For instance, in 2006, six men became seriously ill during a drug

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trial. Two of them were critically ill and developed multiple organ failure, whereas the other four suffered an unwanted reaction to the new drug.\textsuperscript{61}

It is also noteworthy that, there is a \textit{dark side} to clinical trials. In some circumstances, informed consent is not obtained. Even worse, some doctors ‘may fraudulently describe the experimental procedure as either a diagnostic procedure or a treatment for the patient’s condition’.\textsuperscript{62} This practice must be disallowed. In any event, ‘the interests of the patient should be the highest priority of the medical practitioner treating the patient’.\textsuperscript{63} This principle is also enshrined in the Declaration of Helsinki,\textsuperscript{64} which is an international instrument passed by the World Medical Association. It provides the ‘ethical guidelines for medical research involving human subjects’,\textsuperscript{65} and is a useful indicator to the expected standards with regard to therapeutic experiments. It also stipulates that ‘concern for the interest of the subject must always prevail over the interest of science and society’.\textsuperscript{66} The Declaration is expressly referred to in the Code of Professional Conduct formulated by the Medical Council of Hong Kong.\textsuperscript{67}

\textsuperscript{66} Declaration of Helsinki principle I para 5.
\textsuperscript{67} Code of Professional Conduct s 23 para 2: ‘Clinical trials should be conducted in accordance with the ethical principles that have their origin in the Declaration of Helsinki.’.
Applicability of the *Bolam* test

As the whole premise of clinical trials is to test the efficacy of new medical treatments, it is within reasonable contemplation that even doctors may not be very knowledgeable about *all* the risks and complications. Therefore, patients who undergo clinical trials are likely to be exposed to a greater level of risks due to the uncertain outcomes. Thus, patients in such circumstances should deserve more protection. This coheres with Giesen’s view that the rights of the participating patients ‘must be guarded more vigilantly than … in the non-controversial area of ordinary therapy’.\(^68\) Consequently, a higher standard of care is deemed more appropriate.

Furthermore, in reality, there are practical obstacles in applying the *Bolam* test to the cases of clinical trials. Wingfield noticed the hardship of identifying expert witnesses.\(^69\) As the treatments are new, it is likely that only few practitioners have knowledge of the experimental procedures and there can hardly be any responsible body of medical opinion to comment on them. It is also noteworthy that the standard required by law is reasonableness but not perfection, therefore, a doctor who fails to take steps to prevent an unforeseeable risk will unlikely be condemned as “negligent”. Consequently, ‘the legal emphasis shifts in many cases involving new [medical] procedures from one establishing a breach in duty in the performance of the procedure to one of consent’,\(^70\) where the claimants argue that there is no informed consent on their part.

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\(^{69}\) Katrina Wingfield, ‘Risks in the Advancement of Medicine’ (2002) 152 NLJ 325, 326.

\(^{70}\) Katrina Wingfield, ‘Risks in the Advancement of Medicine’ (2002) 152 NLJ 325, 326.
PART III. PATIENTS’ RIGHTS

The concepts of “informed consent”, “right of self-determination” and “disclosure” are inter-related. The right to give an informed consent is actually derived from one’s right to information and right of self-determination. Most importantly, with no adequate disclosure, the patients are no more than exercising an empty right.

Consent and Informed consent

According to Jones,71 a study reveals that ‘69% of patients admitted that they had not read the consent form before signing it’,72 and even for those who had done so, they were not well-informed of the details of the medical procedures either.73 Doctors are always assiduous in obtaining their patients’ signatures on the consent form, probably because they believe that the form can shield them from any claims if anything goes wrong. This is, of course, a fallacy. ‘Signing a consent form has no legal effect per se when it comes to providing disclosure’.74 An informed consent is more than just a legal formality. Thus, a doctor will not be insulated from liability simply because the consent form is signed, and no legally valid consent is given if the patient is not properly informed of the risks and prognosis of the treatment. In Halushka v University of Saskatchewan,75 the claimant volunteered to participate in the study of a new anaesthetic. He was reassured of the safety of the test. He had also signed the consent form, on which there was a line “I understand fully

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75 (1965) 52 WWR 608.
what is proposed to be done”. Unfortunately, while he was under the anaesthetic, he suffered from a cardiac arrest. The doctors were held to be liable for trespass and negligence because the claimant had never been given a full explanation of the study.

At common law, battery is defined as ‘an act of the defendant which directly and intentionally brings about contact with the body of the claimant’. It is actionable per se. Therefore, with no consent given by the patient, a medical practitioner will be liable for trespass or battery, regardless of the fact that what he has done is for the somatic good of the patient. Lord Goff of Chieveley in *F v West Berkshire Health Authority* expressly confirmed this principle by stating that ‘the performance of a medical operation upon a person without his or her consent is unlawful, as constituting both the crime of battery and the tort of trespass to the person’.

In *Chatterton v Gerson*, Bristow J pointed out that the charge of trespass or battery cannot be brought so long as the patients are informed ‘in broad terms of the nature of the procedure’. However, it must be noted that, the appropriate cause of action for a failure to disclose risks is negligence, not trespass. The Supreme Court of Canada in *Reibl v Hughes* also agreed that ‘unless there has been misrepresentation or fraud to secure consent to the treatment, a failure to disclose the attendant risks, however serious, should go to negligence rather than to battery’.

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80 [1990] 2 AC 1 at 71.
84 [1980] 2 SCR 880.
Therefore, it can be concluded that there are two facets of “consent”. To preclude liability for trespass, consent to the general procedures suffices. However, ‘the consent of the patient which makes lawful the touching that would otherwise constitute trespass to the person does not have to be “informed” in the sense that the patient must have knowledge of risks’. This suggests that, a consent which can effectively preclude a finding of trespass does not mean that there is no liability for negligence. Failure to explain the risks of a medical procedure does not invalidate the “consent” and render the medical practitioner liable for trespass. On the other hand, information about the risks and/or prognosis is highly relevant to the issue of “informed consent”. ‘The disclosure of material risks by doctors is seen in every common law jurisdiction as part of the general duty of care owed to patients, so that a failure to disclose is sanctioned through the tort of negligence’.

According to Pearce v United Bristol Healthcare NHS Trust, an omission to disclose a significant risk of a treatment option denies the patient the opportunity to make an informed decision and give an informed consent, thereby providing the basis for a negligence claim.

The term “informed consent” originated in an American case, Salgo v Leland Stanford, Jr. University of Board of Trustees. It was later defined by Justice Kirby as “[a] consent which is obtained after the patient has been adequately instructed about the ratio of risk and benefit involved in the procedure as compared to alternative procedures or no treatment at all’. Some scholars viewed that, ‘informed consent to medical treatment is a vexed topic [and] is underpinned by the notion of [patients’] autonomy and the right of self-

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91 (1957) 154 Cal App 2d 560.
determination’, which empowers patients to make unfettered decisions concerning their health. In Hong Kong, the notion of “informed consent” is enshrined in section 23.11 of the Code of Professional Conduct, which outlines the importance of the concepts of voluntariness and informed consent in the context of therapeutic experiments.

The principle of “informed consent” is also enunciated in Chappel v Hart. Hart had not been warned of a very rare risk involved in an operation which she unfortunately experienced. Dr. Chappel was held to be negligent. Honoré noted that, ‘Dr. Chappel violated Mrs. Hart’s right to choose for herself, even if he did not increase the risk to her’. Subsequently, the House of Lords in Chester v Afshar held that ‘a surgeon owes a legal duty to a patient to warn him or her in general terms of possible serious risks involved in the procedure’. Although the risk would not have been decreased had Chester been warned, it is Dr. Afshar’s duty to inform her of the inherent risk of the operation. Therefore, the failure to warn had resulted in negligence. In Hong Kong, the Court of Final Appeal in Kong Wai Tsang v Hospital Authority also confirmed ‘the availability of negligent failure to warn as a basis of claim’.

As the participating patients are “lab rats”, it is expected that more information should be disclosed to them so that they can make intelligent judgments as to whether to take part in the trials. This proposition is supported by Giesen, who expressed that ‘the changed nature of the treatment and the greater risks

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95 Code of Professional Conduct s 23 para 11: ‘Freely given informed consent should be obtained from every subject prior to clinical trial participation.’
97 Tony Honoré, ‘Medical non-disclosure, causation and risk: Chappel v Hart’ (1999) 7 Torts LJ 1, 8.
99 [2005] 1 AC 134 at 143.
100 [2006] HKEC 528.
accompanying therapeutic experiments necessitate higher levels of disclosure.

Hall JA in *Halushka v University of Saskatchewan* set an even higher disclosure standard. In his opinion, ‘the subject of medical experimentation is entitled to a full and frank disclosure of all the facts, probabilities and opinions which a reasonable man might be expected to consider before giving his consent’.

**Right of self-determination**

The concept of “informed consent” is premised on the patients’ right of self-determination, which is a basic human right. It is also where the central tenet of medical ethics lies. “Self-determination” in this context connotes that the patient voluntarily submits himself to the experimental treatment with an informed consent.

Despite the notion of “doctor knows best”, patients should never be disempowered to ‘make for themselves decisions intimately affecting their own lives and bodies’. Patients are best-positioned to know “what is in their own interests”. True that doctors can always make the best medical decisions, nevertheless, those decisions are not necessarily the best decisions in the patients’ eyes. Lord Scarman pointed out that, ‘a patient may well have in mind circumstances, objectives and values which he may reasonably not make known to the doctor but which may lead him to a different decision from that suggested by a purely medical opinion’ because non-medical factors can play a significant part in the patients’ decision-making process. Also, ‘the choice over what is done to one’s body is one in which ultimately each person has a selfish

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103 (1965) 52 WWR 608.
104 (1965) 52 WWR 608 at 616-7.
107 [2005] 1 AC 134 at 140.
interest, to the exclusion of almost all others’. As such, it is perfectly fine for a patient to make a decision which is viewed as completely irrational and nonsensical by others. Lord Donaldson MR also agreed that ‘the patient’s interest consists of his right of self-determination – his right to live his own life how he wishes, even if it will damage his health or lead to his premature death’. Adults with sound mind should be entitled to the right to decide whether to accept or refuse medical treatments. ‘The obvious rationale is patient autonomy and respect for the reality that it is the patient who must bear any consequences if a risk transforms itself into a reality’.

Disclosure

Disclosure is a cardinal concept. While the patients’ right of self-determination shapes the boundaries of the doctors’ duty to disclose, the scope of disclosure ‘is a recognition of [patients’] autonomy that is to be viewed in the wider context of an emerging appreciation of basic human rights and human dignity’. However, it is very difficult for the law to come up with a consensus on the adequacy of disclosure. This includes two issues, namely:

(a) the scope of disclosure; and

(b) the standard of disclosure.

‘Almost all of the relevant cases heard by the courts have concerned patients complaining that they should have received information relating to a specific risk or alternative. The courts have therefore been directed towards considering whether certain information should be classed as material’. Lord Browne-Wilkinson

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110 Re T (Adult: Refusal of Medical Treatment) [1992] 3 WLR 782 at 799.
112 (1972) 464 F 2d 772 at para 41.
in *Sidaway v Board of Governors of the Bethlem Royal Hospital*\(^\text{115}\) ruled that *materiality* of any particular risk depends on ‘the relationship between the object to be achieved by the operation and the nature of the risk involved’.\(^\text{116}\)

Unfortunately, the absence of concrete guidelines puzzled the medical practitioners. Thus, they have developed a practice which pays attention to the percentages and statistics, and adopted ‘the figure of between 1 and 2% occurrence rates as the apparent threshold for risk disclosure’.\(^\text{117}\)

While this rule of thumb may be a useful indication, the scope of disclosure cannot be *solely* defined by reference to statistical information. In some circumstances, a less than 1% risk can have a very substantial effect on patients.\(^\text{118}\) Lord Browne-Wilkinson instanced that, ‘if there is a half per cent risk of total paralysis, that might well be a material risk in the context of an operation designed to get rid of a minor discomfort, but not in the context of an operation required to avoid death’.\(^\text{119}\) Kearns J in *Geoghegan v Harris*\(^\text{120}\) ruled that, any material risk that is a *foreseeable consequence* of a medical procedure must be disclosed, even if the risk is only ‘one in multiple thousands’.\(^\text{121}\) In fact, ‘even a very low risk, perhaps 1:10,000 or 1:20,000, may not be enough to exclude disclosure if the risk is “typical” of the [medical treatment]’.\(^\text{122}\)

Byrne summarized concisely that ‘while the seriousness of the risk attached to a medical procedure may be due either to the gravity of its consequences or its statistical frequency, its materiality includes a

\(^{115}\) [1984] QB 493.


\(^{120}\) [2000] 3 IR 536.

\(^{121}\) [2000] 3 IR 536 at para 76.

consideration of both of these factors’. 123 This echoes with Lord Woolf’s view 124 that ‘when one refers to a “significant risk”, it is not possible to talk in precise percentages’. 125 Two elements, namely, the likelihood of the risk and the nature of the harm, must be considered. 126

It is also noteworthy that, in the arena of “disclosure”, the issue of “therapeutic privilege” has aroused wide debate. This privilege entitles a doctor to legitimately withhold information if, in his opinion, the disclosure may jeopardize his patient’s health 127 or his patient is psychologically unfit to be informed of the risks. While Kennedy and Grubb opined that there is no room for therapeutic privilege to justify doctors’ non-disclosure of information, 128 the concept has been confirmed by the UK 129 and Australian 130 courts.

Fortunately, the availability of therapeutic privilege in clinical trials is relatively uncontroversial. According to Ferguson, there is no such kind of privilege in the clinical trial settings, 131 thus, all relevant information must be disclosed to the participating patients, and doctors cannot get themselves off the hook by claiming that the non-disclosure is in the patients’ best interests. This approach is adopted by the Canadian Medical Protective Association – “The concept of therapeutic privilege is inappropriate and no information about a project or clinical trial may be hidden from a patient on the ground that disclosure would result in undue worry or anxiety”. 132

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**Doctor-centred test VS Patient-centred test**

Another debate surrounds the appropriate standard of disclosure – should the benchmark be based on the doctors’ perspectives or the patients’ viewpoints? ‘This dichotomy was at the heart of the argument in *Sidaway*’. While Lord Scarman was in favour of the patient-centred approach, the majority of the House of Lords opted for the “reasonable doctor” test.

The “reasonable doctor” test is essentially the *Bolam* test. In England, *Sidaway* confirms the applicability of the *Bolam* test in the context of information disclosure. This insinuates that ‘patients are entitled to know only what their doctor thinks they should’.

Although Lord Bridge ruled that the court has residual power to disapprove expert medical opinion if ‘the disclosure of a particular risk was so obviously necessary to an informed choice on the part of the patient that no reasonably prudent medical man would fail to make it’, which he cited a 10% risk of stroke from the operation in *Reibl v Hughes*, he concluded that “[whether to disclose a particular risk] must primarily be a matter of clinical judgment [and] that the issue whether non-disclosure in a particular case should be condemned as a breach of the doctor’s duty of care is an issue to be decided primarily on the basis of expert medical evidence, applying the *Bolam* test”.

Subsequently, in *Gold v Haringey Health Authority*, the court stated that ‘the judge was not free, as he thought, to form his own view of what warning and information ought to have been given, irrespective of

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133 [1985] AC 871.
137 [1985] AC 871 at 900.
139 [1985] AC 871 at 900.
any body of responsible medical opinion to the contrary’.\footnote{\[1988\] 1 QB 481 at 490.} This decision implies that, even though it is the courts which decide whether the disclosure falls on the right side of the line, the line is actually drawn by the doctors themselves.\footnote{Michael A Jones, ‘Informed Consent and Other Fairy Stories’ [1999] Med L Rev 103, 112.} This echoes with Lord Scarman’s opinion that ‘the law imposes the duty of care; but the standard of care is a matter of medical judgment’.\footnote{[1985] AC 871 at 881.}

In Hong Kong, the plaintiff in Ho Yee Sup v Dr. May Chan Yuk May & Ors\footnote{[1991] 1 HKC 499.} was not informed of the continuing risk of pregnancy before the doctor operated on her. The sterilization procedure was ineffective and she gave birth to a child afterwards. The court applied the Bolam test and held that the doctor was not liable because there was a substantial body of medical opinion supporting the non-disclosure of the risk. Later, in Lee Hau Chi Mariam Teresa v Chung Chee Keung Peter & Ors,\footnote{DCPI 1594 /2006.} the court reaffirmed the applicability of the Bolam test to the issue of disclosure.

Despite the prevalence of the Bolam approach in the UK and Hong Kong courts, many scholars support the adoption of the patient-centred test. Glass contended that the law on informed consent ought to be restructured to give more consideration to the patients’ perspectives.\footnote{Eleanor L Glass, ‘Restructuring Informed Consent: Legal Therapy for the Doctor-Patient Relationship’ (1969-70) 79 Yale LJ 1533, 1534.} Laskin CJ in Reibl v Hughes\footnote{[1980] 2 SCR 880.} pointed out that, ‘[the law cannot] hand over to the medical profession the entire question of the scope of the duty of disclosure’.\footnote{[1980] 2 SCR 880 at 894.} The informational needs of the patients should have the major role to play when drawing up the scope.\footnote{Dieter Giesen, ‘From Paternalism to Self-determination to Shared Decision Making’ [1988] Acta Juridica 107, 112.}
In the context of the doctors’ duty to inform, there are cogent reasons to adopt the patient-orientated approach:

First and foremost, due respect must be given to patients’ autonomy and dignity. The current law on informed consent plainly undermines their rights. The right of self-determination is seriously sabotaged by the application of the conclusive professional disclosure standard. ‘In effect, the patient will be told only what the doctors think is fit for her to know, not what she might consider necessary to make an informed decision for herself’.\(^{150}\) To realize patients’ autonomy, the law should focus on their informational needs, otherwise, it is no more than paying lip service to honour the patients’ right of self-determination.

Furthermore, ‘to allow doctors to be judges is … open to criticism that the courts delegate the power to doctors to decide what patients should be told’.\(^ {151}\) In Germany, the courts have ‘maintained a distinction between malpractice, which is primarily a matter of medical judgment, and disclosure, where the focus is more directly on medical ethics’.\(^ {152}\) Therefore, the doctors’ duty to disclose is not just a legal requirement, it is also an ethical imperative. Doctors are legally and ethically obligated to make sure that their patients’ consent is given with understanding so as to protect their constitutionally entrenched rights.

Last but not least, it seems that medical practitioners have a rooted perception that it is unnecessary to make a detailed disclosure to patients.\(^ {153}\) This viewpoint makes them particularly unsuitable to define the scope of disclosure. In addition, in \textit{Canterbury v Spence},\(^ {154}\) the judge noted the danger of adopting the doctor-orientated test ‘that what in fact is no custom at all may be taken as an affirmative custom to maintain silence, and that physician-witnesses to the so-called custom may state merely their personal opinions as to

\(^{154}\) (1972) 464 F 2d 772.
what they or others would do under given conditions’. This concludes that the use of the so-called “accepted practice” to gauge the exact amount of information for disclosure is inappropriate and undesirable.

“Reasonable patient” test and “Individual patient” test

Beyond doubt, the patient-centred approach is preferable because it focuses on the patients’ perspectives. However, the debate does not stop there. The “reasonable patient” test does not receive universal approval because it only endorses a limited view of patients’ autonomy.

Using a hypothetical reasonable patient as a basis to set the disclosure standard is inadequate to protect patients’ autonomy and dignity. Robertson noted that, a failure to recognize a distinction between inquisitive and reticent patients is ‘tantamount to a complete rejection of the patients’ right of self-determination’. Also, in McPherson v Ellis, the court indicated another undesirability of applying the “reasonable patient” test – ‘[the patient’s] supposedly inviolable right to decide for himself what is to be done with his body is made subject to a standard set by others’. The application of the objective test suggests that the patient is expected to behave reasonably, in accordance with the reasonable patient’s value-judgment. Nevertheless, a patient has a right to have values and interests which may sound absurd to the others.

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155 (1972) 464 F 2d 772 at para 34.
The “reasonable patient” is an abstract concept which is an inappropriate yardstick to measure disclosure. It is unrepresentative of the wide gamut of values and interests, which vary from one patient to another. ‘Preferences for information disclosure, risk taking, quality of life outcomes and tolerance of side effects differ greatly amongst the patient population’. Accordingly, it is impossible to formulate a general standard of disclosure that can cater for all patients. Furthermore, the use of an objective standard implies a danger of ‘bypass[ing] an investigation into the actual importance’ of the undisclosed information to each patient. By simply looking at the chances of a risk transpiring, a reasonable patient may regard the risk as trivial and immaterial. However, a reasonable patient is not in a good position to make the decision. If the risk eventually materializes, its potential effects vary among patients. Certain slight risks may have significant impact on particular patients. For instance, in *Chappel v Hart*, the patient’s vocal cord was paralysed, leaving her with a weak and husky voice. There was evidence showing that she had been very concerned about the possible damage to her vocal cords because she was a Principle Education Officer. Therefore, although a reasonable patient might have regarded the risk as trivial, it was material to her.

According to Maclean, ‘the question of a risk is a subjective issue coloured by the individual’s character, experiences and goals’ and thus a subjective test is more appropriate. ‘The communication of risks and other information is a highly personalized and sensitive activity and the extent to which patients wish to be kept informed invariably depends on their individual character’. Under the subjective test, disclosure can

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be tailored to correspond to different patients’ informational needs. Factors such as the patient’s individual circumstances, characters, medical history, values and priorities, are all relevant.

Unfortunately, the law does not operate in utopia, the “individual patient” test is not impeccable. ‘A standard which employs any measure of subjectivity is dangerous because it embraces the potential idiosyncrasies of patients, making it unpredictable and impractical’. Furthermore, the test may allow patients to take advantage of hindsight – after the adverse outcome is known, they can then use the “lack of disclosure” to claim against their doctors. This problem is also recognized in Cobbs v Grant, where it was noted that,

since at the time of trial the uncommunicated hazard has materialized, it would be surprising if the patient-plaintiff did not claim that had he been informed of the dangers he would have declined the treatment. Subjectively he may believe so, with the 20/20 vision of hindsight, but we doubt that justice will be served by placing the physician in jeopardy of the patient’s bitterness and disillusionment.

The “individual patient” test inevitably places the doctors in a difficult position because they should not be expected to be able to read their patients’ minds. This explains why medical practitioners are strongly against the adoption of the “individual patient” approach to determine the standard of disclosure.

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167 [1985] AC 871 at 888.
169 (1972) 8 Cal 3d 229.
170 (1972) 8 Cal 3d 229 at 245.
PART IV. LEGAL DEVELOPMENT

Before going into the discussion, the legal development in this area is worth looking at. As negligence emphasizes the doctors’ duties rather than the patients’ rights, the patients’ right of self-determination has only been afforded a “severely limited” protection by the law.172 Shaw observed that ‘English judges remain overwhelmingly traditional in their attitudes to the liability of doctors for failure to disclose pertinent information to patients about medical procedures’.173 This may be justified by the perception that ‘the medical duty of care is a comprehensive one that includes all aspects of the medical practitioner’s relationship with the patient, covering diagnosis, treatment, care, information and advice’174 Lord Diplock in Sidaway175 shared the same view. He emphasized that a doctor’s duty should not be ‘subject to dissection into components parts to which different criteria of what satisfy the duty of care apply’176 and held that the Bolam test was ‘comprehensive and applicable to every aspect of the duty of care owed by a doctor to his patients in the exercise of his healing functions’.177 This is consistent with Mulheron’s observation that some courts are always willing to invoke Bolam178 even where ‘the judgment under challenge [does] not appear to be particularly clinical at all’.179

The House of Lords in Sidaway180 confirmed the applicability of the Bolam test to non-disclosure of risks. A heated debate ensued. Many academics voice against this pro-doctor approach. They are convinced that ‘the

175 [1985] AC 871.
176 [1985] AC 871 at 893.
177 [1985] AC 871 at 893.
178 [1957] 1 WLR 582.
180 [1985] AC 871.
*Bolam* test is a particularly inappropriate test to determine negligence with respect to the duty to inform*.\(^{181}\)

Also, there are worries that medical paternalism may override patients’ autonomy.\(^{182}\)

In the past, doctors were regarded as having a “special parental function”\(^{183}\) because of their expertise and technical knowledge, and patients had full faith in their doctors. The litany of excuses offered to justify non-disclosure was usually accepted: the procedures are too complex and technical for the patients to comprehend;\(^{184}\) detailed disclosure is cumbersome and time-consuming\(^ {185}\) and may even burden the patients. Therefore, the ubiquitous application of the *Bolam* test and the uncritical acceptance of expert evidence were not problematic at all.

However, changes have taken place in the medical world. ‘Gone are the days of all patients accepting what information and care they are meted by doctors’.*\(^{186}\) The patients are now expecting much more than before. As observed by Grubb, ‘paternalism was more appropriate to a bygone age when the population were presumed to be uneducated and therefore incapable of playing an equal role in the doctor-patient relationship. Such a view has no foundations in our present society and consequently does not have any right to be reflected in our legal system’.*\(^{187}\)

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\(^{186}\) Katrina Wingfield, ‘Risks in the Advancement of Medicine’ (2002) 152 NLJ 325, 325.

The climate of the society has changed from duty-based to rights-based. The changes demonstrate ‘a commitment towards keeping the patients better informed than was once the case’. Thus, the trite proposition that the disclosure of risks may have an adverse impact on the patients’ physical and mental well-being is no longer plausible.

Moreover, evidence suggests that doctors may have underestimated patients’ desire for information and their ability to understand. A research report revealed that a majority of patients actually preferred knowing about ‘all aspects of their medical treatment’. In addition, there is no evidence indicating that ‘more information always leads to refusal’.

Some academics argue that patients are generally unfit to make medical decisions because of their lack of the relevant knowledge and training. I believe that there are few, if not none, medical geniuses in the world. Back when the doctors were still studying in the medical school, their lecturers must have spent a great deal of time and effort explaining the difficult concepts to them. By the same token, given patience and proper communication skills, it is assailable to argue that the esoteric technical jargons cannot be transformed into intelligible and understandable information for patients’ comprehension.

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With the increasing recognition of patients’ rights, ‘the “sovereignty” of patients has been reinstated’. 196 They enjoy the right to make the final decision as to whether to accept or refuse treatments. The “sovereignty” also vests them with the right to information. 197 Giesen believed that, the pro-doctor decisions, like Sidaway, 198 are untenable for much longer ‘where public policy considerations demand a more patient-centred philosophy of healthcare and needs-oriented solutions’. 199

Since the 1990s, some noticeable changes have taken place. Smith v Tunbridge Wells Health Authority 200 seems to be a retreat from Bolam. 201 In Smith, 202 the patient made a successful claim against his doctor for failing to disclose the inherent risk of impotence before the rectal surgery. Even though there was medical evidence in support of the non-disclosure, Morland J held that it was ‘neither reasonable nor responsible’. 203 Later, in Pearce v United Bristol Healthcare NHS Trust, 204 the term “reasonable patient” was firstly introduced into the English medical law. Subsequently, in Chester v Afshar, 205 the importance of patients’ autonomy and right of self-determination was emphasized. The House of Lords held that, due to the surgeon’s failure to warn the patient, no “informed consent” had been given. 206 The standard suggested by Lord Woolf MR in Pearce 207 was implicitly accepted. In essence, this is ‘resurrecting the spirit of Lord Scarman’s famous dissent in Sidaway, 208 which rejected the application of Bolam 209 to the duty to warn’. 210

198 [1985] AC 871.
201 [1957] 1 WLR 582.
205 [2005] 1 AC 134.
206 [2005] 1 AC 134 at 143.
208 [1985] AC 871.
209 [1957] 1 WLR 582.
Accordingly, ‘it appears [that] doctors are now under a duty to disclose all the significant risks that a reasonable patient would want to know in the circumstances’. In addition, Chester also implies the significance of “understanding” – obtaining an “informed consent” has more to do with merely imparting information to patients, doctors should also ensure that the consent is given with understanding.

This can be reflected in the 2011 amendment of the Code of Professional Conduct by the Medical Council of Hong Kong, which is probably a response to Chester. A number of provisions regarding “consent” were added. In particular, section 2.7 expressly provides that a consent is valid only if three requirements are satisfied, namely,

(i) voluntariness;

(ii) proper explanation by the doctor; and

(iii) the patient’s understanding of the information.

While Chester is seen as a breakthrough in the English medical jurisprudence, the patient-centred approach was not something new. Almost two decades before Chester, Lord Scarman, in his famous dissenting judgment, noted that patients should be informed of the “material” risks involved in the proposed treatment and materiality of the risks ought to be determined by applying the “reasonable patient” test. This approach can further be traced back to a 1972 American case, Canterbury v Spence, where it was held that ‘a risk is material when a reasonable person, in what the physician knows or should know to

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212 [2005] 1 AC 134.
215 Code of Professional Conduct s 2 para 7.
218 [1985] AC 871.
220 (1972) 464 F 2d 772.
be the patient’s position, would be likely to attach significance to the risk or cluster of risks in deciding whether or not to forego the proposed therapy’. This obligates doctors to disclose all material risks that a reasonable patient would wish to know in those particular circumstances.

The American approach was then followed by the Supreme Court of Canada in *Reibl v Hughes* and the High Court of Australia in *Rogers v Whitaker*. According to Gaudron J, medical practices are irrelevant to the issue of information disclosure. The scope of the doctor’s duty of disclosure is to warn a patient of a material risk inherent in the proposed treatment; a risk is material if, in the circumstances of a particular case, a reasonable person in the patient’s position, if warned of the risk, would be likely to attach significance to it or if the medical practitioner is or should reasonably be aware that the particular patient if warned would be likely to attach significance to it.

In *Rogers*, the patient had incessantly asked questions to clarify her concerns about her good eye before the operation. With such a vehement expression of concerns, a seemingly remote risk, a 1:14,000 chance of developing sympathetic ophthalmia causing loss of sight to the good eye, had become “material”, which should have been disclosed.

Today, doctors are expected to give proper respect to their patients’ autonomy and dignity. As such, the introduction of the patient-orientated approach is welcomed. It is a good beginning because it accents the patients’ rights. The *Chester* decision is even hailed ‘as a victory for autonomy’. It is undoubtedly a step in the right direction. It follows that, if the law continues to move and develop in this path, the *Bolam* test will soon be held inapplicable in the context of information disclosure.

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221 (1972) 464 F 2d 772 at para 44.
224 ‘There is simply no occasion to consider the practice or practices of medical practitioners in determining what information should be supplied.’ ([1992] HCA 58 at para 26).
PART V. CRITICISMS OF THE BOLAM TEST

True that the Bolam test may be appropriate in the realm of diagnosis and treatment, this does not necessarily mean that it should be equally applicable to the issue of disclosure. Indeed, the approval of the Bolam test in the context of non-disclosure will ‘endorse poor communication between doctors and patients and deprive patients of their ability to make meaningful choices about their treatment’. Gaudron J in Rogers pointed out that, the communication skills involved in the provision of information are not exclusive to medical practitioners, and can thus be judged by layman. Therefore, with regard to disclosure, professional opinion should only be regarded as ‘a matter of evidential rather than substantive law’.

Other than the abovementioned drawbacks which are peculiar to the scope of disclosure, the Bolam test has been subject to other criticisms as well. This may serve as additional arguments to support why the test should not be used in this respect.

The test has been incessantly derogated for its failure to distinguish “what is normally done” from “what ought to be done”. It essentially equates “accepted practice” with “reasonable practice”. However, an accepted practice can be below the standard of “what ought to be done”, which can potentially render the doctors liable for negligence. As noticed by King CJ in F v R, medical practitioners ‘may adopt unreasonable practices … not because they serve the interests of the [patients], but because they protect the

234 (1983) 33 SASR 189.
interests or convenience of members of the profession’.\footnote{235} For instance, in \textit{Anderson v Chasney},\footnote{236} the surgeon, after operating on a child’s tonsils, had carelessly left a sponge inside his throat, which led to his suffocation. It was the hospital’s accepted practice not to count the number of sponges used during an operation, nor to attach strings to them. The surgeon was, of course, negligent.

Therefore, the equation has the potential of degrading medical negligence to being determined by a low standard of care and depriving the courts of the power to decide what the reasonable standard should be. In view of this, Montrose advised that, in deciding the question of negligence, instead of asking the question of “what is normally done”, the court should apply an \textit{objective} and \textit{normative} approach and ask what a reasonable doctor ought to have done in the circumstances.\footnote{237}

The \textit{Bolam} test has also been dispraised as being overly reliant on expert testimony and unduly deferential to medical opinion.\footnote{238} It seems to have empowered the medical profession to set the legal standard of care for self-adjudication,\footnote{239} which in turn creates an easy path for them to get themselves off the hook. This coheres with Coyne JA’s observation that “[a group of professionals] can legislate themselves out of liability of negligence to the public by adopting or continuing what was obviously [a] negligent practice”.\footnote{240}

The non-interventionist approach ‘clearly reduces the scope of judicial evaluation’\footnote{241} of medical practices. The situation exacerbated after \textit{Maynard v West Midlands Regional Health Authority},\footnote{242} which predicated that compliance with the accepted medical practice can absolve a doctor from the liability of negligence.

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\begin{enumerate}
\item (1983) 33 SASR 189 at 194.
\item [1949] 4 DLR 71.
\item J L Montrose, ‘Is Negligence an Ethical or a Sociological Concept’ (1958) 21 MLR 259, 259.
\item Ash Samantha and Jo Samantha, ‘Legal Standard of Care: A Shift from the Traditional \textit{Bolam} Test’ (2003) 3 CM 443, 443-4.
\item Anderson v Chasney [1949] 4 DLR 71 at 85.
\item [1985] 1 WLR 685.
\end{enumerate}
even if the court is in disagreement with the expert opinion. This appears to be asking the court to abdicate its judicial responsibility and implying the possibility that the medical profession can be “above the law”.

In reality, expert evidence is seemingly having a determinative status in the English medical jurisprudence. Gleeson CJ in *Rosenberg v Percival* observed that, ‘in many cases, professional practice and opinion will be the primary, and in some cases it may be the only, basis upon which a court may reasonably act’. In other words, the application of the Bolam test may carry the risk of “dictating” the court to rule in favour of the medical profession.

The determination of the legal standard of care is a matter for the courts, which must never be delegated to the medical profession. This does not mean that no weight should be attached to expert evidence. Instead, the courts should, after considering all the relevant evidence, ‘employ their own sense of reasonableness as the operative criterion’ to decide professional negligence cases.

Another principal criticism is that the application of the Bolam test seems to be unduly favourable to the medical profession. According to Lewis, ‘although the Bolam principle has been represented as nothing more than the general principle that applies to all skilled callings, … it is unlikely that a court would treat evidence of professional practice as conclusive in any other than the medical context’. Teff also noticed that medical negligence cases are treated differently from other professional negligence cases, where the courts usually conduct a circumspect analysis of the professional evidence and use their own judgment to decide the appropriate standards and are more readily to find a non-medical professional practice.

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244 [2001] HCA 18.
negligent. For instance, in *Edward Wong Finance Co Ltd v Johnson Stokes & Master*,\(^{249}\) the defendant solicitors were held liable for the loss facilitated by their conveyancing practice, which was actually widely accepted in Hong Kong. On the contrary, doctors who act in accordance with the general and accepted practices within their sphere are likely to be absolved from liability. Sedley LJ in *Dr. S.R. Burne v A*\(^ {250}\) ruled that, ‘medicine is a highly specialized field, what is and is not negligent has to be determined by reference to accepted or tolerated practice’.\(^ {251}\) What lies within “the accepted practices” depends upon expert testimony. In reality, as noticed by Castle, ‘in nine cases out of ten’,\(^ {252}\) the practice is endorsed by expert medical evidence as defendable.

**PART VI. THE WAY FORWARD**

While the *Bolam* test and the “reasonable patient” test fail to consider each patient’s informational needs, the “individual patient” test allows patients to give self-serving testimony with the benefit of hindsight.\(^ {253}\)

In my opinion, an approach that incorporates *both* the objective and subjective patient-orientated standard of disclosure is probably the best way to mitigate the respective drawbacks. The objective standard can be used as a starting point to stipulate the minimum informational requirement which forms the baseline expectation of a reasonable disclosure. After the objective assessment, the subjective consideration of the individual patient will be looked into.\(^ {254}\) In this stage, the court can undergo a subjective examination to see whether there is anything peculiar to the patient which justifies a more detailed disclosure. Under this test, the scope

\(^{249}\) [1984] 1 AC 296.

\(^{250}\) [2006] EWCA Civ 24.

\(^{251}\) [2006] EWCA Civ 24 at para 11.


of disclosure can, for example, include the risks which may lead to the removal or loss of function of an organ and/or those which may affect the patient’s future earning capacity.

Indeed, it appears that the objective/subjective test has already been adopted by the Australian courts. In *F v R*, King CJ explained that the court would look at a “complex of factors” to determine the appropriate scope of disclosure, namely, “the nature of the matter to be disclosed; the desire of the patient for information; the temperament and health of the patient; and the general surrounding circumstances”. Subsequently, in *Rogers v Whitaker*, a 1:14,000 chance of developing sympathetic ophthalmia would not have been a significant risk on an initial objective inquiry. However, as the patient had lost sight in her right eye and had expressed concerns regarding the vision of her good eye, the court, after taking the actual circumstances into consideration, held that ‘any risk of blindness was operating her mind and would therefore have been significant to her’.

King CJ held that, in every case concerning medical disclosure, there is a conflict of values. Therefore, it is necessary for the law to intervene so that a balance can be struck between protection of the patients’ rights and the extent of the resulting burden borne by their doctors. I am convinced that a fine balance can be established with the use of the objective/subjective test, which is predominantly objective in nature, with consideration of the subjective factors of the patients. While the objective inquiry can sift out evidence tainted with hindsight, the subjective element can ensure that every patient’s particular informational needs

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259 ‘Determination of the scope of the doctor’s duty to disclose involves consideration of two values which are sometimes in conflict, namely the duty of the doctor to act in what he conceives to be the best interests of his patient and the right of the patient to control his own life and to have the information necessary to do so.’ ((1983) 33 SASR 189 at 191).
will be considered. Furthermore, this hybrid approach ‘provides the necessary safeguards for the courts to remain the final arbitrators of fact’.  

The subjective examination cannot be removed, as it ‘provides a more certain framework for disclosure’ and is where the actual legal protection of patients’ rights lies. Moreover, the subjectivity can help promote communication and encourage the development of a collaborative partnership between doctors and patients to replace the currently prevalent paternalistic model.

Communication is essential to establishing ‘a “therapeutic alliance” between doctors and patients’ as well as ‘promoting the ideal of shared decision-making’. Roter and Hall commented that, it is ‘the fundamental instrument by which the doctor-patient relationship is crafted and by which therapeutic goals are achieved’. Also, according to Justice Kirby, ‘the fact that the patient gave an informed consent usually will not prevent him from suing; a warm relationship with a competent and caring physician will’. It follows that, with good communication, a relationship of mutual trust and confidence can be built up, which can effectively mitigate against possible litigation.

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266 Debra L Roter and Judith A Hall, Doctors Talking with Patients/Patients Talking with Doctors: Improving Communication in Medical Visits (Greenwood Publishing Group, Connecticut 2006) 3.
Situation in Hong Kong and the preferable way of development

The Medical Council of Hong Kong published the Professional Code and Conduct in 1994, which was recently amended (and renamed as the “Code of Professional Conduct”). Although the Code is not a legal document, its contravention ‘may render a registered medical practitioner liable to disciplinary proceedings’.\(^\text{268}\) The Code also makes a special reference to the “Patients’ Rights and Responsibilities”\(^\text{269}\) published by the Hong Kong Medical Association, which the doctors are expected to observe.

Albeit a seemingly sound protection under the Code, it should be noted that it is only a guide and is not law. In addition, no compensation scheme to the injured patients is available under the Code. This can be instanced by a 2013 judgment of the Medical Council of Hong Kong,\(^\text{270}\) where Dr. Chow Kwan Lung wrongly informed his patient that she was not pregnant, when in fact she was pregnant within the 1 to 10 weeks range. The Medical Council of Hong Kong found that his conduct ‘fell below the standard expected amongst registered medical practitioners’,\(^\text{271}\) thereby constituting “professional misconduct”. Dr. Chow was then ordered to have his name removed from the General Register for a period of two months (with suspension for a period of one year). Nevertheless, the Medical Registration Ordinance, which empowers the Medical Council to exercise disciplinary powers for the medical practitioners,\(^\text{272}\) provides no remedies to the affected patients.

Arguably, patients in Hong Kong are not as well-protected as in other jurisdictions. For example, in New Zealand, the Code of Health and Disability Services Consumers’ Rights was passed in 1996, pursuant to the

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\(^{269}\) The Hong Kong Medical Association, Patients’ Rights and Responsibilities <http://www.hkma.org/english/pubmededu/right.htm> accessed 3 January 2013.

\(^{270}\) MC 10/151.

\(^{271}\) MC 10/151 at para 13.

\(^{272}\) Medical Registration Ordinance s 21 para 1.
powers conferred by sections 20 and 74 of the Health and Disability Commissioner Act 1994.\textsuperscript{273} The Code lays great emphasis on information disclosure and it commits itself to the patient-centred standard of disclosure.\textsuperscript{274} It enshrines the patients’ right to information\textsuperscript{275} as well as their right to make an informed choice and give an informed consent.\textsuperscript{276} There may not be any striking differences between the Hong Kong Code and the New Zealand Code in terms of the patients’ substantive rights. However, unlike the New Zealand Code, the Hong Kong Code lacks the force of law and is not supported by any statutory structure.\textsuperscript{277}

Under section 51 of the Act, the aggrieved person, whose rights are infringed, can lodge a claim to the Human Rights Review Tribunal and seek legal remedies,\textsuperscript{278} such as damages.\textsuperscript{279} Moreover, while the New Zealand Code clearly stipulates the standard of disclosure as what a reasonable patient in that particular patient’s position requires,\textsuperscript{280} section 2.10.2 of the Hong Kong Code merely provides a vague guidance.\textsuperscript{281}

In Hong Kong, the only useful resort is Article 3 of the Hong Kong Bill of Rights, which provides that ‘no one shall be subjected without his free consent to medical or scientific experimentation’.\textsuperscript{282} Unfortunately, section 7 of the Hong Kong Bill of Rights Ordinance makes it clear that the Ordinance only binds the Government, the public authorities and persons acting on behalf of them.\textsuperscript{283} Accordingly, the legislation does not provide any redress to patients whose rights are violated by their treating doctors.

\textsuperscript{273} Healthy and Disability Commissioner Act 1994 ss 20, 74.
\textsuperscript{275} Code of Health and Disability Services Consumers’ Rights right 6 para 1.
\textsuperscript{276} Code of Health and Disability Services Consumers’ Rights right 7.
\textsuperscript{278} Health and Disability Commissioner Act 1994 s 52.
\textsuperscript{279} Health and Disability Commissioner Act 1994 ss 54, 57.
\textsuperscript{280} Code of Health and Disability Services Consumers’ Rights right 6 para 2.
\textsuperscript{281} Code of Professional Conduct s 2 para 10(2): ‘The explanation should be balanced and sufficient to enable the patient to make an informed decision. The extent of explanation required will vary, depending on individual circumstances and complexity of the case.’.
\textsuperscript{282} Hong Kong Bills of Rights s 8 art 3.
\textsuperscript{283} Hong Kong Bills of Rights Ordinance s 7 para 1.
Regrettably, the law of tort is inadequate to protect the patients’ rights. In particular, the Bolam test is unsuitable for the issue of infringement. More importantly, as I have explained in Part II, the Bolam test is inapplicable to the cases of clinical trials. Therefore, to render more concrete protection to the patients’ rights, passing a new legislation is the most sensible way.

It is a valid concern that legislation may define an inflexible standard for clinical practice and may even fetter clinical discretion. However, it should be clarified that, the main focus of the legislation is to stipulate the patients’ entitlement to seek legal redress and the possible reliefs available to them when their rights are infringed.

To allay the fears, I suggest that the current Codes of Practice,284 formulated by the Department of Health in 2010, can be used as a blueprint to lay out the patients’ rights. The medical profession can also suggest ways or practices to realize the patients’ rights by means of guidelines, which can serve as an added dimension for the courts to evaluate the appropriate legal standard of care. It follows that, a failure to comply with the guidelines will not automatically render the medical practitioners liable for violating the patients’ rights. They can still adduce evidence to support and justify their acts. Ultimately, the courts will be the final decision-maker.

284 Code of Practice For Clinics Registered Under The Medical Clinics Ordinance (Cap. 343); Code of Practice For Private Hospitals, Nursing Homes and Maternity Homes.
Conclusion

Despite the inherent drawbacks, the primacy of the Bolam test remains even after Bolitho.\textsuperscript{285} However, while the use of the Bolam test is less controversial with regard to diagnosis and treatment, its applicability to the determination of the standard and scope of disclosure has spawned much dispute, especially in the cases of clinical trials. Due to the uncertain outcomes of the experimental treatments, a higher standard of care seems to be the right direction.

Whatever the motives of the participating patients in clinical trials, their acts are altruistic and are beneficial to the society.\textsuperscript{286} Consequently, the law should offer adequate protection to them and ensure that an “informed consent” is given in advance.

At the heart of “informed consent” is the respect for patients’ autonomy,\textsuperscript{287} and their right of self-determination entitles them to be informed about the risks of the proposed medical treatments. As each patient’s informational needs are different, their right to information is not protected by allowing the medical profession to rely on their accepted practices to set the standard of disclosure, nor is it protected by referring to the standard of a hypothetical reasonable patient\textsuperscript{288} because its unmitigated objectivity will thwart the appropriate scope of disclosure. As such, an objective/subjective patient-orientated test is more appropriate. The subjective element can cater for the specific informational needs of different patients, so that the scope of disclosure will not stand independently of the actual circumstances that the patients are in.

To offer concrete protection to the patients’ rights, the mere use of guidelines and codes is far from adequate, nor does the broad brush of common law principles suffice. Therefore, it is necessary to pass a

new legislation which stipulates their rights in detail. Guidelines can be formulated to assist the doctors to act in response to the patients’ statutory rights. Expert testimony is still important, but not determinative. After considering all available evidence, the judges will decide whether the patients’ rights are infringed by their treating doctors.

Our society is changing and it is important for the law to keep abreast with the times. With the increasing recognition of patients’ rights, the law should be molded accordingly. Patients, who are unschooled in the art of medicine, deserve more protection. In addition to legislation, less deference should be shown to expert evidence, so as to minimize the possibility of medical opinion overriding the judicial function to decide professional negligence cases.
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