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Challenge Medical Indemnity

Inside this issue:

Mr David Walsh, MD

Dear Consultant,

Welcome to our Challenge Medical Indemnity newsletter – January 2018 edition.

The introduction of our indemnity offering in 2012 was undoubtedly the first significant and welcome change to the private consultant indemnity market in decades. At Challenge, we have shown that competition in the market is the best route forward to improving indemnity conditions for private consultants in Ireland:

- we now supply indemnity to half of all full time private consultants in Ireland
- we have saved consultants over €15,000,000 in subscriptions in the process.
- we have kept rates stable as promised
- we back up our comprehensive product up with a professional local service.
- we provide 21 years Run-Off cover

What consultants have valued the most over the past 6 years has been the opportunity Challenge has afforded them to maintain comprehensive indemnity coverage, whilst significantly reducing their indemnity costs and accessing local expertise in the private healthcare sector. We continue to address the imbalance of unfair pricing particularly for full time private consultants. We have kept consultants working, many of whom were considering retirement, ceasing specialist practices or initially reluctant to commence a private practice.

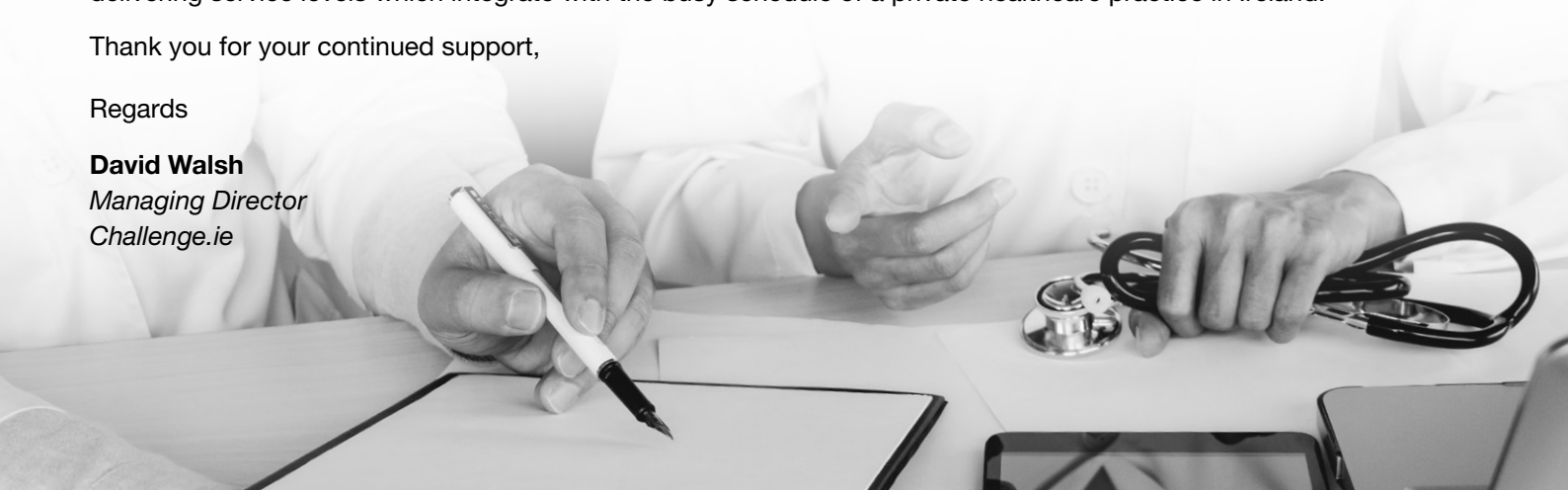
In this edition we are pleased to be providing you with a comprehensive piece on 'Consent' from Barrister at Law, Asim A. Sheikh BL. This is a very significant area when it comes to defending allegations of negligence and I would urge you to review your current consent process based on Asim's expert opinion.

Challenge are committed to delivering comprehensive indemnity at competitive rates. We are also committed to delivering service levels which integrate with the busy schedule of a private healthcare practice in Ireland.

Thank you for your continued support,

Regards

David Walsh
Managing Director
Challenge.ie



Medico-legal issues in consent and medical practice

– by Asim A. Sheikh B.L.

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He lectures and has published widely on aspects of medical law.

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Introduction

This article will examine the issue of consent with a view to discussing the translation and implementation of legal theory to medical practice. Whilst this article does not have scope to discuss every aspect of consent, it will attempt to examine some issues which arise in practice and what underlies consent and what the doctrine of consent actually hopes to achieve.

The Basic Aspects of Consent

In medicine, an essential pre-requisite to the commencement of any healthcare treatment is the requirement that a patient gives his/her consent to medical treatment. Without such consent, the treatment of a patient would constitute a trespass and battery. An adult (an individual who has attained the age of 18) of sound mind has the right to give or refuse consent to medical treatment, even if that refusal may result in the death of the patient. This right is entrenched in law by virtue of the Common law, the Irish Constitution and its judicial interpretation, and the values developed through medical ethics, human rights law and as expressed in professional guidelines. In law, an individual's right to self-determination is expressed through their consent, and this is protected by law and neither a person's age nor incapacity invalidates this self-determination. As McMenamin J noted:

> *"A person suffering from such incapacity continues to enjoy individual rights such as the exercise of freewill, self-determination, freedom of choice, dignity and autonomy."*[1]

The latest edition of the Medical Council guidelines tells practitioners that they:

> *"… must make sure that patients have given their consent before you provide any medical investigation, examination or treatment. Consent is required by law and is an essential part of respect for patients' autonomy. Patients have the right to decide what happens to their own body."*[2]

Describing the basic concept of consent to medical treatment, the Irish Supreme Court has stated that:

> *"Medical treatment may not be given to an adult person of full capacity without his or her consent. There are a few rare exceptions to this e.g., in regard to contagious diseases or in a medical emergency where the patient is unable to communicate. This right arises out of civil, criminal and constitutional law. If medical treatment is given without consent it may be trespass against the person in civil law, a battery in criminal law, and a breach of the individual's constitutional rights. The consent which is given by an adult of full capacity is a matter of choice. It is not necessarily a decision based on medical considerations. Thus, medical treatment may be refused for other than medical reasons … the person of full age and capacity may make the decision for their own reasons."*[3]

Exceptions to the General Rule

There are exceptions to the general rule that consent is required prior to medical treatment. Some examples are: in an emergency where there is no evidence of a patient's wishes and no way to ascertain them, in which case a doctor is obliged to treat the patient, in his/her best interests, and no consent is required; if an outbreak of a notifiable disease occurs in which case legislation requires that individuals can be detained for public health reasons and; a Court of law may order medical treatment in certain situations.[4]

Types of Consent

In medicine therefore, prior to commencing any medical treatment, the doctor must seek the patient's consent. The consent can be *expressed* (given verbally or in writing) or it can be *implied* (where the patient's specific behaviour implies that they have consented to a particular procedure). In relation to written consent, apart from in situations where this is

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1 *HSE v (M)X [APUM]*[2011] IEHC 326 (HC, 29/7/11) at para 2. The latest edition of the Medical Council Guidelines (see below FN 2), at para 10.2 also states this: *"Adults who are considered not to have the capacity to make a decision are entitled to the same respect for their dignity and personal integrity as anyone with full capacity."*

2 *Guide to Professional Conduct and Ethics for Registered Medical Practitioners* (Medical Council, 8th Edition, 2016) at para. 9.2.

3 *In Re a Ward of Court* (withholding medical treatment) (No. 2) [1996] 2 IR 79, Denham J at p. 156.

4 Just some examples arise when an adult or child is made a Ward of court, in which case the President of the High Court will ultimately make a decision in relation to the care of the patient where no consensus exists: see further in relation to children e.g. *SR (A Ward of Court)* [2012] 1 IR 305 in relation to a 6 year old ward suffered extensive irreversible brain damage with no prospect of recovery and *An Irish Hospital v. RF (minor)* [2015] 2 IR 377; and in relation to adults see *HSE v. J.M. a Ward of Court & Ors* [2017] IEHC 399 where the applicant hospital sought the consent of the court to withhold an increase in the existing ventilator support in the event of a clinical or respiratory deterioration of the respondent/patient who was in a minimally conscious state and unable to give his consent, and *In Re a Ward of Court* (withholding medical treatment) (No. 2) [1996] 2 IR 79. It should be noted that the Wardship system will be changed after the full implementation of the Assisted Decision-Making (Capacity) Act 2015.

Medico-legal issues in consent and medical practice (Continued)

required by statute[5], firstly, there is no general legal mandate requiring consent to be in writing (although many practitioners sometimes incorrectly assume otherwise) and secondly, there is no longer a place in the practice of modern medicine for the stubborn insistence and rationale of a consent form being the 'be all and end all' in relation to consent.

Valid Consent

Whatever the type of consent (as has been stated *"The validity of consent does not depend on the form in which it is given"*[6]), it is vital that any consent given is a valid consent. If a patient gives consent to a medical procedure but has not been given any information whatsoever in relation to the procedure, or is clearly not able to understand anything that has been explained, the informed consent to that procedure will not be valid: *"Consent is not valid if the patient has not been given enough information to make a decision."*[7] In order for a consent to be valid, a number of minimal criteria are necessary. The consent must be:

(i) given by a person with capacity;

(ii) voluntarily given, without any element of duress and;

(iii) with the requisite information of risks, side-effects and alternatives such that the patient is able to make an informed decision as to whether or not to proceed with treatment.

Capacity

The HSE National Consent Policy states that:

> *"Those who provide health and social care services must work on the presumption that every adult service user has the capacity to make decisions about their care, and to decide whether to agree to, or refuse, an examination, investigation or treatment."*[8]

What therefore does 'capacity' mean and who is a person with capacity? The British Medical Association (BMA) states that:

> *"To demonstrate capacity individuals should be able to:*
>
> - *understand (with the use of communication aids, if appropriate) in simple language what the medical treatment is, its purpose and nature and why it is being proposed*
> - *understand its principal benefits, risks and alternatives*
> - *understand in broad terms what will be the consequences of not receiving the proposed treatment*
> - *retain the information for long enough to use it and weigh it in the balance in order to arrive at a decision*
> - *communicate the decision (by any means).*[9]
>
> *In order for the consent to be valid the patient must be able to make a free choice (i.e. free from pressure)."*

Fitzpatrick v K: Assessment of Capacity

The issue of capacity was discussed in length in this jurisdiction in the case of *Fitzpatrick v K.*[10] The case concerned an adult patient from the Democratic Republic of Congo, who after giving birth to a baby boy suffered a massive postpartum haemorrhage resulting in cardiovascular collapse. As a result, she was being prepared for an immediate blood transfusion, however, she refused consent on the basis that she was a Jehovah's Witness.

The hospital sought a declaration from the High Court to transfuse the patient and this was granted. The matter subsequently proceeded to the High Court for a full hearing where the plaintiff (Hospital) argued that the patient, although fully conscious, may not have been in a position to make a fully informed refusal. It was claimed that the State was obliged to protect the constitutional rights of the patient's baby which included the right that the child be reared by K. K, in her defence claimed that the transfusion was unlawful and unnecessary and that her right to refuse medical treatment could not be overridden by her baby's constitutional rights. In addition, she stated that the hospital had committed an assault and trespass of her person in administering the blood transfusion and that her constitutional and convention rights had been breached.

The court found in favour of the hospital stating that the patient, at the relevant time, did not have the ability to make a valid refusal in relation to the treatment as her capacity was impaired. The blood transfusion therefore was not an unlawful act and did not breach the patient's constitutional or convention rights. Since the refusal was not a valid one, the question of balancing the rights of the new-born child under the Constitution in this matter did not arise to be considered.

The court for the first time in a medico-legal context, expressed the law in relation to the test for assessing capacity and came to a number of important conclusions, paraphrased below;

(1) There is a presumption that an adult patient has the capacity, but that presumption can be rebutted;

(2) The test in relation to capacity is the functional test – i.e. in determining whether a patient is deprived of capacity to make a decision to refuse medical treatment (whether due to permanent cognitive impairment or temporary factors) the test is whether the patient's cognitive ability has been impaired to the extent that he or she does not sufficiently understand the nature, purpose and effect of the proffered treatment and the consequences of accepting or rejecting it in the context of the choices available (including any alternative treatment) at the time the decision is made;

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[5] e.g. (1) in relation to the provision of certain types of treatment under sections 58 – 60 of the Mental Health Act 2001 were written consent is required for psycho surgery, electro-convulsive therapy and the continuation of medication and (2) in relation to subject participation in clinical trials under the provisions of S.I. No. 190/2004 - European Communities (Clinical Trials on Medicinal Products for Human Use) Regulations, 2004 Schedule 1(3).

[6] *HSE National Consent Policy* (HSE, May 2013) para. 7.4.

[7] *Guide to Professional Conduct and Ethics for Registered Medical Practitioners* (Medical Council, 8th Edition, 2016) at para 11.1.

[8] See above, footnote 6, at para. 5.3.

[9] *Consent Tool Kit* (BMA, 2016) at: https://www.bma.org.uk/advice/employment/ethics/consent/consent-tool-kit/5-assessment-of-competence.

[10] [2009] 2 IR 7, [2008] IECH 104, 25/4/08, Laffoy J.

Medico-legal issues in consent and medical practice (Continued)

(3) ***The three-stage approach*** *to the patient's decision-making process is a helpful tool in applying that test. This test states that the patient's cognitive ability will have been impaired to the extent that he or she is incapable of making the decision to refuse the proffered treatment if the patient:*

(I) has not comprehended and retained the treatment information and, in particular, has not assimilated the information as to the consequences likely to ensue from not accepting the treatment,

(II) has not believed the treatment information and, in particular, if it is the case that not accepting the treatment is likely to result in the patient's death, has not believed that outcome is likely, and

(III) has not weighed the treatment information, in particular, the alternative choices and the likely outcomes, in the balance in arriving at the decision.

(4) The treatment information by reference to which the patient's capacity is to be assessed is the information which the clinician is under a duty to impart – information as to what is the appropriate treatment, that is to say, what treatment is medically indicated, at the time of the decision and the risks and consequences likely to flow from the choices available to the patient in making the decision.

(5) In assessing capacity, it is necessary to distinguish between misunderstanding or misperception of the treatment information in the decision-making process (which may sometimes be referred to colloquially as ***irrationality****), on the one hand, and an* ***irrational decision*** *or a decision made for irrational reasons, on the other hand. The former may be evidence of lack of capacity. The latter is irrelevant to the assessment;*

(6) In assessing capacity, whether at the bedside in a high dependency unit or in court, the assessment must have regard to the gravity of the decision, in terms of the consequences which are likely to ensue from the acceptance or rejection of the proffered treatment. In the private law context this means that, in applying the civil law standard of proof, the weight to be attached to the evidence should have regard to the gravity of the decision, whether that is characterised as the necessity for "clear and convincing proof" or an enjoinder that the court "should not draw its conclusions lightly".[11]

The court also commented in relation to what it thought was the duty of a clinician caring for a patient in K's circumstances.

Laffoy J stated:

> *"The duty of the clinician caring for a patient in the circumstances which prevailed in relation to Ms. K … is to advise the patient of, and afford him or her the opportunity to receive, appropriate medical treatment. If, as a competent adult, the patient refuses to accept the treatment and no issue arises as to the capacity of the patient to make that decision, the clinician's duty to provide such treatment is discharged. However, if an issue arises as to the capacity of the patient to refuse treatment, the duty of the clinician to advise on and provide the appropriate treatment remains. As a matter of law and common sense, the duty of care which the clinician owes the patient in those circumstances is no different from what it would be if there was no refusal or if the patient was unconscious. What is required of the clinician is to take the steps to have the capacity issue be resolved, with the assistance of the court if necessary…. the assessment of the patient's capacity to refuse treatment falls to be determined by reference to the clinician's responsibility to give to the patient the relevant information in relation to the appropriate treatment and the risks attendant on the patient refusing the treatment."*[12]

A number of important points arise from the above:

Firstly, there is a presumption of capacity in relation to the adult patient. This presumption is important for practical reasons in relation to a patient's care. For example, if a patient with a late onset disease (Dementia/Alzheimer's) presents to a doctor over a period of time, the presumption compels the practitioner to presume that he/she has capacity and therefore to deal with such a patient in a way a practitioner would deal with any other patient. Not to so presume, would potentially allow a practitioner to rely primarily on the wishes of others in relation to the care of such a patient as they might presume that this patient does not have capacity, which may not in fact be the case at all. The presumption therefore protects an individual's right to self-determination.

Secondly, the test is one of functional capacity. This looks at the status of the patient at the time at which the decision is to be made. Therefore, in certain patients, capacity may fluctuate. However, the functional approach takes into account the person's ability to make certain decisions at certain times and excludes the possibility, in theory, of making a general assessment of a lack of capacity thereby depriving the patient the ability to make decisions in relation to other aspects of their healthcare. In this respect, the Medical Council guidelines compels practitioners not simply to assess capacity, but to go further by facilitating the decision-making process:

> *"As their doctor, you have a duty to help your patients to make decisions for themselves by giving them information in a clear and easy-to-understand way and by making sure that they have suitable help and support. Patients have the right to have an advocate of their choice during discussions about their condition and treatment."*[13]

Thirdly, the assessment of capacity by the test as elucidated, clearly requires a 'doctor to patient' engagement for the purposes of being able to understand a patient's rationale within the three steps laid out. This issue of engagement is of the essence and will be further discussed in conjunction with the issue of informed consent.

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11 [2009] 2 IR 7 at p 41-42.

12 See footnote 11 at p. 78.

13 *Guide to Professional Conduct and Ethics for Registered Medical Practitioners* (Medical Council, 8th Edition, 2016) at para 10.1.

Fourthly, the High Court made a distinction between *"an irrationality"*, in which case an individual's capacity may be open to scrutiny (therefore e.g. in *Fitzpatrick* the patient suggested that, as opposed to a blood transfusion, she could be helped by being given Coca-Cola and tomatoes and that this *"would improve her blood"*[14]) and *"an irrational decision"*, which is irrelevant to the assessment of capacity: an adult patient of sound mind, with capacity and competent to make a decision, can refuse medical treatment - even if this leads to death. Whilst to a medical practitioner this may seem antithetical to their medical training and to modern Hippocratic tradition, i.e. - it may seem irrational, as the choice to refuse treatment would lead to the deterioration of health or to death of the patient – respect for an individual's autonomy allows such an individual to self-determine the regulation of their healthcare as it affects them, and it therefore keeps the patient at the centre of the healthcare provider – healthcare receiver relationship[15]. O'Flaherty J in the Ward case, endorsed the US case of In *Re Conroy*[16], which stated that, *"no right is held more sacred, or is more carefully guarded by the common law, than the right of every individual to the possession and control of his own person…"*, stating that in Irish law, this right was founded at common law in the constitutional right to bodily integrity and privacy. The ultimate consequence of this thinking was that, *"consent to medical treatment is required in the case of a competent person… and, as a corollary, there is an absolute right in a competent person to refuse medical treatment even if it leads to death."*[17]

Fifthly, the court described the duty of the clinician in such circumstances which was to resolve the issue of capacity, if necessary, with the assistance of the court and that in doing so, there was a duty to give the patient relevant information in relation to the appropriate treatment and its risks.

The Assisted Decision-Making (Capacity Act) 2015

In relation to capacity, the provisions of the ***Assisted Decision-Making (Capacity) Act 2015*** are notable. A full discussion of the Act is reserved for another day. However, when the Act is fully implemented[18], it will provide a statutory framework allowing individuals to make agreements to be assisted by appointed individuals in relation to decisions about their welfare, property and affairs. For healthcare practitioners, such agreements will have to be borne in mind as they will be part of the decision-making process in relation to an individual's healthcare regime[19] and will require a personal investment of time and effort by organisations, by practitioners with their patients and decision-makers. Further, the Act lays down a number of guiding principles to protect the personal rights of individuals (including the presumption of capacity[20] and the principle of functional capacity[21]). Importantly, the concept of "best interests" is not mentioned in the Act, but rather, it is the *"will and preferences"*[22], of an individual that must be taken into account and given effect to by any intervener in relation to decisions affecting an individual's welfare. In addition, advance health care directives will be placed on a statutory footing[23].

Informed Consent

As we have seen therefore, consent is the means in law and medicine by which a patient translates that he/she wishes to have something done to his/her person/body and what he/she wishes to have done to his/her person/body. The Supreme Court has stated that, *"The requirement of consent to medical treatment is an aspect of a person's right to bodily integrity under Article 40, s. 3 of the Constitution"*[24] and the UK Court of Appeal has stated that, *"Every human being's right to life carries with it, as an intrinsic part of it, rights of bodily integrity and autonomy--the right to have one's own body whole and intact and … to take decisions about one's own body."*[25] It is this rationale that underpins the concept of self-determination and in medical law it existed prior to what are regarded as the modern tenets of medical ethics as stated by the Nuremburg Code (1947) and the Declaration of Helsinki (1964-2004) and thus, in the oft-quoted case of *Schloendorff v. Society of New York Hospital*, Cardozo J. stated that, *"Every person being of adult years and sound mind has a right to determine what shall be done with his own body."*[26]

In order for such self-determination to be exercised in a proper manner, the issue of 'informed consent' has been discussed in some depth. Lord Scarman elucidated the doctrine well stating that:

> *"The existence of the patient's right to make his own decision, which may be seen as a basic human right protected by the common law, is the reason why a doctrine embodying a right of the patient to be informed*

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[14] *Fitzpatrick*, footnote 10 above, at p. 66, para. 163.

[15] Donnelly, M. *Healthcare Decision-Making and the Law: autonomy, capacity and the limits of liberalism* (Cambridge University Press, 2010), see further pp 10-48 for discussion on the debate regarding the value of the concept of autonomy.

[16] (1985) 98 N.J. 321.

[17] *In re a Ward of Court (withholding medical treatment)* (No. 2) [1996] 2 I.R. 79 at p 129.

[18] As a result of Commencement orders signed in October 2016, some parts of the Capacity Act have been brought into effect. These orders mean that the Decision Support Service (DSS) can be established and the working group to establish the code of practice for Advance Healthcare Directives can also be convened: (S.I. No. 515 and 517 of 2016). Also see further: http://www.thirdageireland.ie/assets/site/files/pr/New_Times_2nd_Ed._June_2016_website_version.pdf

[19] s 8(7)(d).

[20] s 8 (1) – (10).

[21] See further sections 3(1) –(7). s3 (1) states that, *"… a person's capacity shall be assessed on the basis of his or her ability to understand, at the time that a decision is to be made, the nature and consequences of the decision to be made by him or her in the context of the available choices at that time."*

[22] s 8(7)(b).

[23] Part 8, ss 82-90. It should be noted that at common law, the validity of an advance directive in general has been accepted. Thus Baker J in *X v PMcD* [2015] IEHC 259 stated at para. 126 that: *"I consider that as a matter of law … that a person may make a freely stated wish in regard to their future care and that this ought to be, and can in an appropriate case be, respected by those with care of that person."*

[24] *Ward* case (footnote 17) at p. 156.

[25] *In re A (Children) (Conjoined Twins: Surgical Separation)* [2001] FLR 147 (CA), at p. 258, (Robert Walker LJ).

[26] (1914) 105 NE 92.

of the risks of surgical treatment has been developed in some jurisdictions in the U.S.A. and has found favour with the Supreme Court of Canada. Known as the "doctrine of informed consent," it amounts to this: where there is a "real" or a "material" risk inherent in the proposed operation (however competently and skilfully performed) the question whether and to what extent a patient should be warned before he gives his consent is to be answered not by reference to medical practice but by accepting as a matter of law that, subject to all proper exceptions (of which the court, not the profession, is the judge), a patient has a right to be informed of the risks inherent in the treatment which is proposed."[27]

The Disclosure of Risks: What information / risks must be disclosed to a patient?

The Irish Courts have grappled with the issue of informed consent in relation to the relevant test to be used in an action for negligence for non-disclosure and it has been stated that, *"The extent to which a medical practitioner is obliged to inform his or her patient of the nature of the proposed treatment – of its risks and the chances of success – is a question that has given rise to much analysis…"*[28]

Walsh v. Family Planning Services Ltd: A distinction between elective and non- elective treatment

Whilst the distinction between these two categories of treatment can be sometimes blurred, the courts have made a distinction between elective and non-elective treatment. The former, where a patient undergoes the treatment more out of choice than necessity and the latter being treatment which the patient undergoes by virtue of necessity. The courts have placed a higher burden on the medical profession to disclose risks in elective treatment.

This issue was discussed at some length by the Supreme Court in the case of Walsh v. Family Planning Services Ltd.[29] where the plaintiff, subsequent to a vasectomy procedure, suffered from orchialgia, a condition resulting in constant testicular pain. His claim, which failed on appeal to the Supreme Court, was based on the premise that he was not informed of the risk of this condition.

Finlay CJ., making the elective / non-elective distinction stated that:

"I am satisfied that there is, of course, where it is possible to do so, a clear obligation on a medical practitioner carrying out or arranging for the carrying out of an operation, to inform the patient of any possible harmful consequence arising from the operation, so as to permit the patient to give an informed consent to subjecting himself to the operation concerned. I am also satisfied that the extent of this obligation must, as a matter of common sense, vary with what might be described as the elective nature of the surgery concerned. Quite obviously, and apart even from cases of emergency surgery which has to be carried out to persons who are unconscious or incapable of giving or refusing consent, or to young children, there may be instances where as a matter of medical knowledge, notwithstanding substantial risks of harmful consequence, the carrying out of a particular surgical procedure is so necessary to maintain the life or health of the patient and the consequences of failing to carry it out are so clearly disadvantageous that limited discussion or warning concerning possible harmful side-effects may be appropriate and proper. On the other hand, the obligation to give warning of the possible harmful consequences of a surgical procedure which could be said to be at the other end of the scale to the extent to which it is elective, such as would undoubtedly be the operation of vasectomy, may be more stringent and more onerous. I am satisfied, however, that the standard of care to be exercised by a medical practitioner in the giving of the warning of the consequences of proposed surgical procedures is not in principle any different from the standard of care to be exercised by medical practitioners in the giving of treatment or advice, and that there are not good grounds for suggesting that the issue of negligence arising under this heading is outside the general principles which have been enunciated by this Court in previous cases concerning the standards of care and the methods of ascertaining them arising in medical negligence cases which were summarised in Dunne (Infant) v. National Maternity Hospital [1989] I.R. 91…"[30]

Thus, the principles enunciated from Walsh were (i) there is a general duty to inform patients of any possible harmful consequences arising from an operation (ii) that a warning must be given in every case of a risk, however remote, of grave consequences involving severe pain continuing into the future and involving further operative intervention[31] (iii) in elective treatment the duty to disclose risks is higher than in non-elective treatment (iv) There may be situations (even leaving aside emergencies) where limited discussion of risks may be permissible in order to maintain the life/health of a patient – even where there may be harmful consequences (v) That the standard to be applied to cases where the issue of disclosure is at issue is the same as was enunciated by the Supreme Court in the *Dunne* case.

Whilst the Supreme Court re-visited[32] the issue, the law was not expanded on in any meaningful way in terms of principle and was left in a somewhat unsatisfactory state.

Geoghegan v. Harris: the Reasonable-Patient Test

The issue of informed consent was then analysed in great depth by the High Court in the case of *Geoghegan v. Harris*[33],

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[27] *Sidaway v. Governors. of Bethlem Royal Hospital* [1985] AC 871(HL) at p. 882.

[28] McMahon & Binchy. *Law of Torts* (4th Edn, Bloomsbury, Dublin, 2013) 540. For an in-depth analysis see: pp 540-560.

[29] [1992] 1 IR 496.

[30] footnote 29 at p. 510.

[31] Confirmed in *Fitzpatrick v. White* [2008] 3 I.R. 551 (SC) by Kearns J. at p563-564.

[32] *Bolton v. Blackrock Clinic* (SC, 23 January 1997).

[33] [2003] 3 IR 536.

Medico-legal issues in consent and medical practice (Continued)

a case concerning dental negligence. The plaintiff's case concerned the alleged failure of the defendant dentist to warn the plaintiff of a risk of chronic neuropathic pain which might result after a bone graft in the course of an implant procedure. The procedure was elective, but involved both a "cosmetic and functional component"[34]. Following a detailed commentary on the law of informed consent, the High Court concluded by favouring the 'reasonable patient' test which requires full disclosure of all material risks.

Kearns J., stated that:

> *"The application of the reasonable patient test seems more logical in respect of disclosure. This would establish the proposition that, as a general principle, the patient has the right to know and the practitioner a duty to advise of all material risks associated with a proposed form of treatment. The Court must ultimately decide what is material. 'Materiality' includes consideration of both (a) severity of the consequence and (b) statistical frequency of the risk.…The reasonable man, entitled as he must be to full information of material risks, does not have impossible expectations nor does he seek to impose impossible standards."*[35]

In relation to the risk of chronic neuropathic pain, Kearns J., stated that,

> *"It seems to me that nerve damage must be seen as a "known complication" of this procedure be it implants per se, or bone grafts, in the chin area. The particular symptom of neuropathic pain is in a subdivision, not in a different species of risk or unrelated risk. Once that is established, the fact that the particular manifestation of the nerve damage is very remote and unusual seems to me immaterial from a legal point of view. It is within the range of what is known or can or should be known by the medical practitioner."*[36]

This, at first glance seems to suggest that any risk, once known, would need to be disclosed. However, the court went on to state that:

> *"…at times a risk may become so remote, in relation at any rate to the less than most serious consequences, that a reasonable man may not regard it as material or significant. While such cases may be few in number, they do suggest that an absolute requirement of disclosure in every case is unduly onerous, and perhaps in the end counter productive if it needlessly deters patients from undergoing operations which are in their best interest to have…Each case it seems to me should be considered in the light of its own particular facts, evidence and circumstances to see if the reasonable patient in the Plaintiff's position would have required a warning of the particular risk."*[37]

Summarising the court's view of what the law was, Kearns J., stated that:

> *"It is the view of this Court that current Irish law imposes the following obligations on a medical practitioner in relation to disclosure of risks as follows-*
>
> *(a) The requirement on a medical practitioner is to give a warning of any material risk which is a known or foreseeable complication of an operative procedure properly carried out.*
>
> *(b) The test of materiality in elective surgery is to inquire only if there is any risk, however exceptional or remote, of grave consequences involving severe pain stretching for an appreciable time into the future."*[38]

And continued to observe that:

> *"This Court is of the view that the 'reasonable patient' test, which requires full disclosure of all material risks incident to proposed treatment, is the preferable test to adopt, so that the patient, thus informed, rather than the doctor, makes the real choice as to whether treatment is to be carried out. It is the view of this Court that assessment of the duty of disclosure on this basis is more logical than the professional standard test, whereby the Court adopts the standard of the medical profession, yet reserves the right to override the views of the medical experts as and when it sees fit…"*[39]

Thus, by virtue of this decision, the High Court adopted the view that under Irish law the *prudent/reasonable patient test* is preferable.

According to this approach, the doctor has a duty to advise a patient of all material risks (known or foreseeable complications) in a proposed form of treatment. In elective surgery, a material risk is any risk which entails a grave consequence(s) involving severe pain stretching for an appreciable time into the future. There may however, be certain risks that are so remote that they need not be disclosed (unless the consequences of the risk are 'most serious').

The decision does not express definitive principles that can be applied to every situation. However, it can be said that such an approach attempts to respect patient autonomy to a higher degree by compelling a clinician to look at the care to be given from the patient's perspective. The patient thus, in such a position and possessed with relevant information, is in the most appropriate mind-set within which to be able

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[34] footnote 33 at p. 559.

[35] see footnote 33 at p. 549.

[36] see footnote 33 at p. 544.

[37] see footnote 33 at p.549-550. The decision of Cross J in *Hill v Health Service Executive* [2016] IEHC 746 (HC, Cross J, 14/12/16) is also interesting. In that case, the defendant performed a procedure to extract a stone with a dormia basket. The plaintiff suffered from a perforationof his distal left ureter. One of the plaintiff's complaints was that there was no proper or adequate consent to the procedure. The form was signed by the patient and by a medical practitioner, but the name of the medical practitioner was not inserted in the area of the consent form which referred to the nature and purpose of the procedure or whether it was explained to the patient. The plaintiff argued that the anaesthetist sat down beside him and asked him a couple of questions about his general health and that he then signed the consent form. It is interesting to note that the judgment does not refer to any other case law in relation to informed consent. However and nevertheless, Cross J concluded that: *"Notwithstanding suggestions in some decisions to that effect I do not believe that there is a duty on a hospital, or doctor, to explain to a patient every possible complication rather than doing so in general. There is a need of course to reassure a patient as well as to procure informed consent. Informed consent does not necessarily require being advised of possible though highly unlikely complications."*

[38] *Geoghegan v Harris* (HC, 21 June 2000, Summary Section) 1-2.

[39] see footnote 38, pp. 3-4.

to make a decision with regard to medical treatment that concerns him/her.

Fitzpatrick v Eye and Ear Hospital

The issue of informed consent found itself before the Supreme Court again where in a three-judge Supreme Court in the case of *Fitzpatrick v Eye and Ear Hospital*[40] lead by Kearns J., the Court stated that:

> *"This case provides the Court with the first opportunity in many years to revisit in any detail the issue of informed consent since the matter was last addressed in Walsh v. Family Planning Services Ltd. & Ors. [1992] 1 IR 496. In that case all five judges of this Court were at one in holding that in elective surgery any risk which carries the possibility of grave consequences involving ongoing severe pain for the patient must be disclosed. Although different members of the court approached the issues by reference to different principles, they arrived at the same conclusion in relation to two critical questions, that is to say:-*
>
> *(a) The requirement on a medical practitioner to give a warning of any material risk which is a "known complication" of an operative procedure properly carried out*
>
> *(b) The test of materiality in elective surgery is to enquire only if there is any risk, however exceptional or remote, of grave consequences involving severe pain stretching for an appreciable time into the future."*[41]

Very importantly, Kearns J, examined in detail the usual arguments and opposition voiced in relation to the taking of an informed consent and countered these by making it clear that:

> *"(a) the rule recognises individual autonomy which should be viewed in the wider context of an emerging appreciation of basic human rights and human dignity which requires informed agreement to invasive treatment, save for that which might be required in an emergency or otherwise out of necessity;*
>
> *(b) reality demands a recognition of the fact that, sometimes, defects of communication will justify the imposition of minimum legal obligations so that even medical practitioners who are in a hurry, or who may have comparatively less skill or inclination for communication, are obliged to pause and provide warnings …*
>
> *(c) such obligations redress, to some small degree, the risks of conflicts between interest and duty which a medical practitioner may sometimes face in favouring one healthcare procedure over another;*
>
> *(d) the legal obligation to provide warnings may sometimes help to redress the inherent inequality and power between a medical practitioner and a vulnerable patient;*
>
> *(f) that provision of detailed warnings will enable the ultimate choice to undertake or refuse an invasive procedure to not only rest, but also be seen to rest, on the patient rather than the healthcare provider thereby reducing the likelihood for recriminations and litigation following the disappointment that sometimes ensues in the aftermath of treatment."*[43]

It is worth emphasising the point made at paragraph (b): a recognition by the Supreme Court of the reality that there are defects in communication in healthcare settings and that as a result of these, a legal obligation is imposed upon practitioners *"to pause and provide warnings."* Complementing this obligation, it is important to note that Medical Council guidelines emphasise the importance of the use of resources, stating that:

> *"All doctors should use resources responsibly. You must consider the needs of all patients alongside your primary duty to your own patients. You should actively balance these duties to try to get the best possible outcomes where resources are limited."*[44]

Further, in line with the concept of "partnership", the Medical Council emphasise that good communication:

> *"…is central to the doctor-patient relationship and essential to the effective functioning of healthcare teams. Good communication involves listening to patients and colleagues, as well as giving information, explanations or advice. When communicating with patients, you should be honest and give all relevant information. You should welcome questions from patients and respond to them in an open, honest and comprehensive way."*[45]

In this respect, it can be argued that one of the resources which always needs to be taken into account by practitioners, is the resource of time. If practitioners are too busy to take such a pause, as is legally required, due to patient lists which are too busy by virtue of organisational or personal work arrangements, then this is an issue which must be addressed, as otherwise, duties to ensure good communication will not be possible as required legally and professionally.

The Supreme Court concluded, stating that this analysis supported, *"…the argument that the giving of an adequate warning, far from being a source of nuisance for doctors, should be seen as an opportunity to ensure they are protected from subsequent litigation at the suit of disappointed patients."*[46]

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[40] [2008] 3 I.R. 551, [2007] IESC 51 (Unrep. SC, Kearns J., Macken J., Finnegan J., 15/11/2007)

[41] see footnote 40 at p. 559-560.

[42] see footnote 40 at p. 562.

[43] Kearns J at p. 563 extrapolating from the Australian decision in *Rogers v. Whitaker* (1992) 175 C.L.R. 479.

[44] *Guide to Professional Conduct and Ethics for Registered Medical Practitioners* (Medical Council, 8th Edition, 2016) at para. 5.7.

[45] *Guide to Professional Conduct and Ethics for Registered Medical Practitioners* (Medical Council, 8th Edition, 2016) at para. 4.4.

[46] see footnote 40 at p. 563.

Montgomery v Lanarkshire, the UK Supreme Court

In *Montgomery v Lanarkshire Health Board*[47], the plaintiff was of small stature, suffered from insulin dependent diabetes and was expecting her first child. Hers was a high-risk pregnancy. One of the concerns in this respect was that of shoulder dystocia. The plaintiff was told that she was having a larger than usual baby but was not told of the risks of shoulder dystocia, which in her case was 9 – 10%. The obstetrician accepted this was a high risk but that it was not her practice to spend any time discussing the potential risks of shoulder dystocia as the risks of a problem for the baby were very small. She gave evidence that if you mentioned shoulder dystocia to every patient and that there was a small risk of the baby dying in labour, then these mothers would seek a Caesarean section and that this was not in their interest. Unfortunately, the plaintiff encountered a shoulder dystocia. This was not overcome by a number of manoeuvres and resulted in significant traction of the baby's head. During this time, the umbilical cord was completely or partially occluded and deprived the baby of oxygen causing him to suffer from cerebral palsy and a brachial plexus injury resulting in Erb's palsy.

In its conclusions in relation to the disclosure of risks, the Supreme Court endorsed the reasonable patient test, having reviewed the law, and also what the court described as a position, *"...away from a model based on a view of the patient as being entirely dependent on information provided by the doctor."*[48] In an important passage in the judgments of Lords Kerr and Reed, perhaps the essence of the consent process was outlined:

> *"…the doctor's advisory role involves dialogue, the aim of which is to ensure that the patient understands the seriousness of her condition, and the anticipated benefits and risks of the proposed treatment and any reasonable alternatives, so that she is then in a position to make an informed decision. This role will only be performed effectively if the information provided is comprehensible. The doctor's duty is not therefore fulfilled by bombarding the patient with technical information which she cannot reasonably be expected to grasp, let alone by routinely demanding her signature on a consent form."*[49]

In a similar fashion to Kearns J, the UK Supreme Court looked at the arguments and the pros and cons of the disclosure of material risks and came to the same conclusions as the Supreme Court in Fitzpatrick stating that:

> *"It is nevertheless necessary to impose legal obligations, so that even those doctors who have less skill or inclination for communication, or who are more hurried, are obliged to pause and engage in the discussion which the law requires."*[50]

Thus, at the centre of the requirement is clearly the provision of information. Further, both the Irish and UK Supreme Court have made the clear point in relation to the necessity for medical practitioners to pause and engage in discussion in dialogue with patients – a duty now required by law. In this respect, the concept of consent in medical practice must now be seen as something more than just a once-off event that commences and ends with the signing of a consent form. Consent, requiring the provision of information, so that a patient better understands options, clearly requires better communication between doctor and patient, including through dialogue and discussion, and therefore has correctly been described as being a process. Internationally, this is now accepted as a more appropriate manner in which patients ought to be treated. The World Medical Association (WMA) has also recently stated that:

> "A necessary condition for informed consent is good communication between physician and patient. When medical paternalism was normal, communication was relatively simple; it consisted of the physician's orders to the patient to comply with such and such a treatment. Nowadays communication requires much more of physicians. They must provide patients with all the information the patients need to make their decisions. This involves explaining complex medical diagnoses, prognoses and treatment regimes in simple language, ensuring that patients understand the treatment options, including the advantages and disadvantages of each, answering any questions they may have, and understanding whatever decision the patient has reached and, if possible, the reasons for it. Good communication skills do not come naturally to most people; they must be developed and maintained with conscious effort and periodic review."[51]

Other Issues in Consent

The Timing of Consent

In the *Fitzpatrick* case, on appeal, the plaintiff accepted that a comprehensive warning had been given (of double vision or diplopia as a result of muscle slippage, which was a rare side effect of the surgery which he underwent to correct a squint

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[47] [2015] 2 W.L.R. 768.

[48] Footnote 47 at p 791, Lords Kerr and Reed. It is interesting to note, that on this point, the Irish Court of Appeal in *Healey v. Buckley* [2015] IECA 251 stated as follows: *"In the neighbouring jurisdiction the latest decisions in the UK Supreme Court, including Montgomery v Lanarkshire Health Board …reflect enhanced status of the patient as the chooser of treatment. … The law on consent in this jurisdiction may require to be re-considered in the light of developments, especially in regard to the patient's capacity to choose between treatment and no treatment. However any expansion of patient power will require careful delineation."* At para. 59, Ryan P. It should be noted that the Court of Appeal made two further important findings that (1) *"A doctor cannot be held negligent for not knowing or discovering that plaintiff has a mistaken belief about her condition, when there is nothing to indicate that to him."* (at para 67) and (2) that whilst, *"The option of doing nothing is always available to a patient"* (at para. 64), where a patient *"…has a serious medical condition and has presented herself to the doctor through the agency of her general practitioner in quest of treatment to alleviate her condition, it is difficult to see how he ought to be considered negligent for not debating the merits of doing nothing as compared with treatment that is effective, minimally invasive and safe i.e. not known to pose a grave danger to her life or health"* (para. 66). This was because whilst, *"It is true that there is an option to do nothing, but when a person visits a specialist doctor on referral from her General Practitioner, it may reasonably be assumed that she wishes to receive medical treatment for her condition. There is a sense in which she has chosen to do something about her condition and to have excluded the "do nothing" option"* (para. 65). To see a further discussion on the issue of the the balance of power in the doctor-patient relationship in Ireland: Chapter 6 - "Patient Autonomy and Responsibilities within the Patient-Doctor Partnership: Two Sides of the Same Unequal Coin?" in: Donnelly, M. and Murray, C (eds). *Ethical and Legal Debates in Irish Healthcare: Confronting Complexities* (Manchester University Press, 2016).

[49] footnote 47 at p. 793.

[50] footnote 47 at p. 794.

[51] *Medical Ethics Manual* (World Medical Association, 3rd Ed, France 2015) p 43.

in his eye). The issue to be decided was whether or not the timing of the consent, delivered shortly before the operation, was sufficient to discharge the duty of care of the medical practitioner. In this case, it was decided that even with the late warning of risks, the plaintiff had properly understood what was stated on the day of surgery and therefore the warning was not invalid in the circumstances. However, the Supreme Court sounded a clear warning in relation to the practice of seeking consent close to a medical procedure stating that:

> *"There are obvious reasons why, in the context of elective surgery, a warning given only shortly before an operation is undesirable. A patient may be stressed, medicated or in pain in this period and may be less likely for one or more of these reasons to make a calm and reasoned decision in such circumstances. In the instant case, the plaintiff had his eyesight fully tested and evaluated four months before his operation and the options for surgical intervention were plain from the orthoptist's report from that time. The plaintiff was seen on three occasions prior to his operation. The risks associated with squint surgery could have easily been explained to the plaintiff at any of these meetings, or certainly well in advance of the time when they were explained - a mere 30 minutes before his operation. While I have noted the views of a number of the experts to the effect that this practice of warning day patients on the day of their operation had its advantages, it seems to me that the disadvantages were far greater, including the possibility of an embittered patient later asserting that he was too stressed or in too much pain to understand what was said or to make a free decision and that he was thus, effectively, deprived of any choice."*[52]

In this respect, the Medical Council guidelines also state that:

> *"Whenever possible, you should discuss treatment options and their risks at a time when the patient is best able to understand and retain the information. You should also give the patient enough time before the treatment to consider their options and reach a decision. You should not usually seek consent from a patient when they are stressed, sedated or in pain, and, therefore, less able to make a calm and reasoned decision."*[53]

Written Consent and the Consent Form

As we have discussed above, except for in limited circumstances, there is no legal requirement in clinical practice for a written consent. It is sometimes thought the consent form absolutely protects practitioners from litigation by proving consent. However, in fact, the consent form is only evidence of an aspect of the process. In this respect, the US Agency for Healthcare Research and Quality in its 2013 Report stated that

> *"The document patient signs to verify that he has engaged in a dialogue with a healthcare practitioner about a proposed medical treatment is commonly referred to as an "informed consent". However, it is the dialogue itself that constitutes the actual informed consent process."*[54]

Therefore, if a signed consent form exists, but e.g. no discussion of the risks has actually taken place, the consent form may not necessarily provide probative value of an informed consent and a warning of the risks. Likewise, if a consent form is completed only shortly prior to a procedure, the undesirability of this practice, as indicated by the *Fitzpatrick* case, ought to be borne in mind. This has been highlighted by the courts. In the UK decision of *In Re T*, Lord Donaldson (albeit in relation to refusal of treatment forms) stated that:

> *"It is clear that such forms are designed primarily to protect the hospital from legal action. They will be wholly ineffective for this purpose if the patient is incapable of understanding them, they are not explained to him and there is no good evidence (apart from the patient's signature) that he had that understanding and fully appreciated the significance of signing it. With this in mind it is for consideration whether such forms should not be redesigned to separate the disclaimer of liability on the part of the hospital from what really matters, namely the declaration by the patient of his decision with a full appreciation of the possible consequences, the latter being expressed in the simplest possible terms…"*[55]

Kennedy and Grubb also make clear that:

> *"A patient's consent need not be given in writing. The common law does not impose such a requirement, although in analogous circumstances statutory provisions may do so. However, ''consent forms" are routinely used in hospitals when a patient undergoes a surgical intervention. They do not, as is sometimes assumed within the medical profession, in themselves constitute a patient's consent. Their function, in law, is purely evidentiary. In stating that the patient has agreed to a particular procedure which has been explained to him and which he has understood, the ''consent" will not be worth the paper it is written on if these recitations are not, in fact, true. It is the patient's actual state of mind which is crucial. Consent expressed 'in form only' is no consent at all."*[56]

The HSE National Consent Policy states that:

> *"The provision of information and the seeking and giving of consent should involve a continuing process of keeping service users up to date with any changes in their condition and the interventions proposed. It should not be a once-off, sometimes 'eleventh hour' event, exemplified by getting a hurried signature on a consent form."*[57]

In a similar vein, the Medical Council make it clear that:

> *"When patients give consent, they are making a voluntary choice. You should help patients make decisions that are informed and right for them. You should not give patients*

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[52] footnote 40, at p 565. In *Heffernan v Mercy Hospital* [2014] IEHC 43: (HC) 5/2/14 it was also accepted by the experts that a consent form filled on a trolley on the way to the procedure – would not be acceptable practice: at para. 6

[53] *Guide to Professional Conduct and Ethics for Registered Medical Practitioners* (Medical Council, 8th Edition, 2016) at para 12.2.

[54] *Making Healthcare Safer II: An Updated Critical Analysis of the Evidence for Patient Safety Practices* (Agency for Healthcare Research and Quality, US, March 2013): Chapter 39.

[55] *In Re T (Adult: Refusal of Treatment)* (C.A.) [1993] Fam. 95 at p. 114.

[56] "The Nature of Consent" in *Principles of Medical Law* Eds. Kennedy & Grubb (OUP, UK, 1998) at p. 124.

[57] *HSE National Consent Policy* (HSE, May 2013) para 7.3.

the impression that their consent is simply a formality or a signature on a page."[58]

The Doctor's "usual / invariable practice" Defence and Documentation of Risks discussed

In medical practice, it will often be the case, especially in elective procedures, that a practitioner in the outpatient department may see a patient in relation to a procedure which is to be carried out in the future and that the risks of the procedure are discussed at this stage. There is then a passage/gap of time between this discussion and the actual procedure. When the patient returns for the procedure, it is at that point that they will sign a consent form. Even in other situations where a patient is admitted, it will often be the case whilst a discussion of risks takes place, the consent form filled in might state something general in relation to the fact that "risks have been discussed and the patient has had the opportunity to ask questions". However, the actual risks discussed are not documented on the consent form[59], and may not be documented elsewhere in the records. This will also arise if the completion of the consent form is inappropriately delegated to a practitioner who does not have enough experience to discuss the risks and therefore, there may be no such discussion of risks and therefore no confirmation of it on the consent form.[60]

Subsequently, a patient may argue in litigation that no such discussion of risks took place. The issue therefore, in relation to the recording and documentation of the discussion of risks arises. Clearly, from an evidentiary perspective, it is advisable that the discussion of the risks with the patient is recorded in the medical records or on the consent form if space allows. It should be remembered that in litigation, only the relevant records in relation to the plaintiff/patient will be before the court, including a practitioner's records and consent forms. If the plaintiff/patient alleges that no discussion of risks took place and if there is no actual evidence in the records or on the consent form of any such discussion, the court will rely on the oral evidence and any other relevant evidence before it when deciding the credibility of the evidence given. If the defendant/doctor can corroborate the discussion of the risks, this will obviously assist in defending against such allegation. However, this is likely to be rare especially where the only two parties present for the discussion in relation to the risks, if it took place, maybe only the doctor and the patient. Such a situation allows appropriate weight to be given to plaintiff's evidence that no such discussion took place. Therefore, a recording of the risks discussed will clearly assist in defending against such an allegation as it provides probative value that the discussion of material risks took place, was recorded and thereafter, the process was continued by the completion of the consent form. Without the recording of such a discussion, a practitioner is left to convince a court that a discussion of the risks would be his/her "usual or invariable practice". Of course, it should be noted that actual evidence of a practitioner's usual or invariable practice is, in effect, evidence in relation to every other patient other than the plaintiff and in this respect, the records and consent forms and any other evidence in relation to those other patients will obviously not be before the court. Therefore, without any actual documentation/records or evidence of the discussion of the risks with the actual plaintiff/patient, the court is left in a situation where it must adjudicate the credibility of the viva voce evidence given by the parties. Therefore clearly, it is far more desirable for a practitioner to record the discussion of the risks which took place, which will put the practitioner in a better position to defend against an allegation that no such risks were ever discussed.

Conclusions

Whilst the detailed examination and discussion above might seem complicated, a common issue repeatedly arises: *communication and dialogue*. To really understand and embrace consent from a practice perspective, matters, perhaps are far simpler than might seem: the respect for a patient's autonomy i.e. that which allows a patient to control their own destiny vis-à-vis their own healthcare, arises and is achieved from understanding any particular patient's circumstances and context. Such an understanding and acting upon it is what brings the patient to the centre of their care.

A stark example arose in the case of *Rogers v Whitaker*[61] where the risk was of blindness in one eye, but where the plaintiff was already blind in the other eye. This obviously gave the risk a greater significance than it would otherwise have had. Where the patient is a concert pianist who suffers an injury to a dominant hand, clearly any material risks involved in medical treatment of that hand, even relatively minor ones, are likely to be of significance to such a patient. However, such circumstance and context will only be taken into account and understood if the practitioner engages in communication and dialogue with such a patient. This is what underlies the reasonable patient test: as this places a reasonable person, including the treating doctor, in the patient's position. In such a position, one can then understand the circumstance and context of the particular patient. Regardless which jurisdiction or professional guideline is examined, at the crux of the consent process and of understanding patient autonomy is the professional and legal necessity to pause and engage in discussion and dialogue and the provision of warnings. This cannot be done with undue hurry or at the very last minute.

Further, a consent form which is inconsistent to what should be the appropriate underlying process, will not necessarily provide consolation or protection to a practitioner in litigation. Such engagement with a patient will also assist in relation to the issue of ascertaining capacity. With the imminent full rollout of the Assisted Decision Making (Capacity) Act 2015, in relation to patients with fluctuating or limited capacity, or no capacity at all, this professional and legal necessity will become even more essential to the doctor-patient relationship, as perhaps it always has been. The courts, it seems, have emphasised a "back to basics" commandment, without which the doctor-patient relationship cannot exist in any effective way. That commandment is clear: *engage in dialogue with your patients.*

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[58] *Guide to Professional Conduct and Ethics for Registered Medical Practitioners* (Medical Council, 8th Edition, 2016) at para 9.1.

[59] As was noted in *Heffernan v Mercy Hospital* [2014] IEHC 43: (HC) 5/2/14 at para. 6.

[60] In this respect, the practice of sending junior doctors "to do the consent", where such a doctor is clearly not in a position to engage in a discussion about the risks with the patient due to their inexperience, is clearly inappropriate. The Medical Council guidelines make it clear that whilst delegation can take place, *"The person to whom you delegate must know enough about the proposed investigation or treatment, understand the risks involved and be able to explain and discuss these issues with the patient. If you delegate all or part of the consent process, you remain responsible for making sure that the patient has given their consent."* At para 13.1.

[61] (1992) 175 CLR 479.

Medico-legal issues in consent and medical practice (Continued)

Some Do's and Don'ts in consent

DO

- ✓ Regard consent as a process
- ✓ Think of consent as an on-going process
- ✓ Engage in discussion and dialogue with your patient
- ✓ Ensure you protect the resource of time to allow for discussion and dialogue with your patient
- ✓ Know that there is a presumption of capacity in relation to an adult patient
- ✓ Understand that the the test in relation to capacity is the functional test
- ✓ Take the steps to have the capacity issue resolved, with the assistance of the court if necessary, where a capacity issue arises
- ✓ Disclose material risks associated with the treatment to the patient in a way the patient will understand
- ✓ Understand that a patient is entitled to make 'an irrational decision'. However, an 'irrationality' by a patient might lead to scrutiny in relation to capacity
- ✓ Document the discussion of the risks with the patient
- ✓ Ensure that the consent form, procedure specified and agreed to and the discussion of risks are consistent e.g. that the correct procedure has been discussed and documented on the consent form
- ✓ Know and understand the basic aspects of the Assisted Decision Making (Capacity) Act 2015 and its guiding principles
- ✓ Develop and maintain communication skills with conscious effort and periodic review

DON'T

- ✗ Think of consent as a once-off event or just a signature on a consent form
- ✗ Regard consent as an administrative formality
- ✗ Inappropriately delegate the taking of consent to someone who does not know enough about the proposed investigation or treatment and does not understand the risks involved and is not able to explain and discuss these issues
- ✗ Rush the discussion of risks with patients
- ✗ Treat an adult patient on an assumption that they do not have capacity
- ✗ Ignore or exclude family members views in relation to a patient with no capacity, as this information can be taken into account to establish the preferences of the patient
- ✗ Ignore the views of children
- ✗ Explain material risks in a way that the patient will not understand them
- ✗ Take consent at a very short stage before a procedure or at an 'eleventh hour'
- ✗ Seek consent from a patient when they are stressed, sedated or in pain
- ✗ Ignore an Advance Directive

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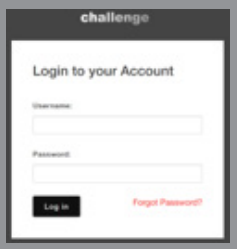

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