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Current standards of material risk

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The infrequent occurrence of negative results of treatment from all types of health care occasionally results in litigation. The primary points of informed consent and material risk have received greater focus in law since 1980. Supreme Court and lower court cases have stressed the priority of patient's rights to choose what is best for their body. The courts have given strong guidelines that the attending health practitioner has the responsibility to ensure that all possible consequences are told to the patient to ensure an informed consent to treatment. A material risk is found as a risk with grave consequences regardless of the frequency it is statistically shown to occur. If these have not been disclosed then the patient was not able to have provided an informed consent. Material risks are inherent to most treatments provided by health providers. Proper standards of care will necessarily include ensuring that the patient is aware of risks of care as well as providing the optimum care.
(JCCA 1990; 34(2): 87–89)

KEY WORDS: Material risk, informed consent, chiropractic, manipulation.

Les rares cas de résultats négatifs de traitement de tous les types de soins de la santé donnent parfois lieu à un litige. Les importants points du consentement éclairé et du risque corporel ont, depuis 1980, retenus l'attention de la loi. Des cas présentés devant la Cour suprême et des tribunaux inférieurs ont mis l'accent sur la priorité du droit du patient à choisir ce qui convient le mieux pour son corps. Les tribunaux ont donné des strictes directives stipulant qu'il est de la responsabilité du médecin traitant de s'assurer que le patient est averti de toutes les conséquences possibles, afin de donner un consentement éclairé pour le traitement, Un risque corporel est estimé être un risque avec de graves conséquences, quelle que soit la fréquence à laquelle il se produit selon les statistiques. Si les conséquences ne sont pas révélées, le patient ne peut pas donné un consentement éclairé. Les risques corporels sont inhérents à la plupart des traitements donnés par les spécialistes des soins de la santé. Les normes appropriées des soins doivent nécessairement inclure le fait que le patient connaît les risques et l'assurance que les meilleurs soins possibles sont offerts.
(JCCA 1990; 34(2): 87–89)

MOTS CLÉ: Risque corporel, consentement éclairé, chiropractie, manipulation.

Introduction

Health and the quality of its deliverance is primarily through the learned skills of the practitioner interacting with the patient. Quality should not be a consequence of payment, policy or statute. Despite the highest standards of care practised by a licensed practitioner, there still exists the statistical guarantee that some patient will become worse as a consequence of care. These are risks due to inherent human intangibles, preventive incompetence, and known hazards. It may be that any person in practice over a standard number of years may have knowingly or not, been the agent of his or her patient's greater pain or worse, their demise. Depending on how the patient or their family reacted to the events may determine whether litigation resulted.

Perhaps the only way for the patient and practitioner to avoid risk is for the practitioner to do nothing. This too may be challengeable when the patient has been accepted for care and the clinical decision of no action is chosen and the patient worsens. This varied reaction ironically becomes a catalyst by which standards or laws regarding health may develop. Material risk is perhaps such an example, which has been clarified by the Supreme Court of Canada.[1,2]

Material risk

Material risk is not a subject which is determinable by review of statute but has been developed through common law. It is defined as a grave or detrimental consequence of treatment, regardless of the infrequency of its occurrence. The element of informed consent in negligence involves the requirement that the patient has been informed of all material risks, including those aspects that may pertain to their particular situation. A

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review by Picard[3] indicates that a number of cases before 1980 permitted limitations on the disclosure of risks to the patient. While in another case, Halushka v. University of Saskatchewan, the court began to define the duty to disclose risks in broader terms.[4] The material risk in the Halushka case, included the point that the plaintiff was not receiving standard medical care but was involved in research, therefore there was a greater responsibility for disclosure of information to the patient.

In addition to informing the patient, the practitioner is also in a role of greater authority and knowledge in the practice of health care. This is noted as a fiduciary position as developed from Noctan v. Lord Ashburton.[5] The fiduciary duty, morally and legally, demands that the practitioner answer all questions of the patient and in the case of material risks, makes the patient aware of these without having to be questioned by the patient. Picard argues [comments to Chief Justice Laskin's opinion] that everyday risks need not be disclosed.[3] It will indeed be difficult to consistently establish what the public ought to know.

The public can be expected to take the position that available information is not complete, contemporary or in layman's language. When applying special and unusual circumstances to each case it may be that this premise is unworkable. It would be quite exceptional that the patient would be knowledgeable on all known aspects of a particular treatment. The assumption that a patient should have a standard knowledge of some categories of risks without having to be specifically informed by the attending practitioner should not be accepted. It would be more prudent to assume the public and the specific patient do not have 'standard knowledge'. The public has no base of education by which it can be expected to be fully informed as to the consequences of health delivery. There is *no familiar mechanism* in daily life to provide information, such as statistical frequency of incidence, the consequences of incidents, or recovery expectations from surgical care or nonsurgical care without disclosure from the attending practitioner.

Standards of material risk

The Supreme Court of Canada added to two standards in 1980. The first in Hopp v. Lepp[1], gives a broader standard of a material risk which clearly goes further in protecting the patient. This in turn further defines the positon of fiduciary trust. The second, in Reibl v. Hughes[2], the matter of causation is set out with an objective and subjective element which more fairly allows the application of what a reasonable person may choose given the consequences of having a particular treatment or not. This standard should also enable practitioners to have a clearer guideline of what is expected of them by both the patient and the courts. This hopefully will be implemented by the various regulatory bodies of each of the health disciplines.

While each case is always tried on its own facts, standards of material risk and the issue of causations, as seen in the 1980 cases, will serve as a *stare decisis* for future cases. This has already been seen in Mason v. Forgie[6].

Furthermore, in Hopp v. Lepp[1] Chief Justice Laskin cites from Kenny v. Lockwood that matters of risk which are either probable, special, or unusual must be disclosed to the patient. He further agrees that there were some risks, which if not asked about need not be disclosed. These risks would however, have to be disclosed if the patient's special circumstances would be affected. The court goes further to establish that risks with mere possibilities are material if the consequences are grave, regardless of frequency of occurrence. The duty of disclosure had not been met in this case as the material risk had not been disclosed. This case goes far to place the onus on the practitioner to fully understand and ensure that the patient fully understands the consequences of the treatment offered.

In yet another example, Chief Justice Laskin clarifies that failing to disclose material risk does not constitute an action of battery but rather negligence.[2] Of further significance is the position that expert medical evidence may not determine what are material risks. It was his view that the Ontario Court of Appeal had determined it was up to the judgement of the attending doctor what material risks were and whether to disclose them and also when a breach of the duty of disclosure had occurred. This responsibility rested with the trier of fact and not the practitioner nor their regulatory board. Medical evidence was necessary to present facts not judge them. Having established that the risks were unusual, special, probable, and grave in nature, the material risks would now be subject to assessment by the reasonable person.

The objective standard for assessing the impact of material risks to a reasonable person is a primary contribution arising since 1980. The standard here weighs the benefits and risks inherent in having an operation as opposed to not having it; but goes further to placing an evaluation on the patient's particular life style and circumstances. It is not adequate to advise the patient only on the risks associated with offered treatment but also for practitioner and patient to be aware of the consequences of negative results occurring and how that would impact on all aspects of the patient's life.

Picard gives several examples of gravity being considered in material risk.[3] In Bickford v. Stiles, Mr. Justice Stevenson found a loss or impairment of voice to be a material risk[7]. A further example of gravity is found in Reynard v. Carr when during drug treatment with prednisone, the patient developed side effects resulting in hip and shoulder replacements[8]. Such side effects had not been disclosed to the patient.

These cases indicate an increasing law making pattern that is intended to protect the patient and place the responsibility for their awareness and knowledge, squarely with the attending health provider. It is not adequate to deliver optimum care, but the practitioner must be fully aware of the negative effects of care on the patient's life and to ensure that the patient knowing these facts, has consented to treatment.

In Mason v. Forgie the court held for the plaintiff over non disclosure of a material risk. The risk in this case was the possibility of a stroke, eventhough the frequency was perhaps one in one million. The treatment involved a chiropractic treat-

ment, causing the judge to further state that where material risk was involved there was no distinction between surgical and non-surgical treatment.[6] This finding was an extension by Justice Jones taken from Hopp v. Lepp. The principle that it is the patient's right to decide what should be done to their body was cited from Parmley v. Parmley and Yule[9].

In the matter of the nature of the risk, both Reibl v. Hughes and Hopp v. Lepp were markedly cited to determine the Mason v. Forgie case. This case has a very low rate of incidence which was further stated to be subjectively determined. This goes further to underscore the point, that gravity makes a risk material regardless of its incidence and must be disclosed to a patient. In the matter of causation, the judge found that a reasonable person having given presenting symptoms would have declined the treatment sought if there had been full disclosure.

The defendants sought leave to appeal the case to the Supreme Court of Canada. The appeal was not granted. This case sets a precedent for the incidence of material risks, one that is perhaps lower than previously expected. Given that many treatments have material risks which the practitioner may ignore or literature may not widely report in favour of more frequently occurring risks, standards should be diligently observed to prevent overlooking disclosure due to a low incidence.

Conclusion

The courts have set the standard for characterization of risk, applying the test of the reasonable person, disclosure by the attending practitioner, and in the disclosure of information for an informed consent. The need for disclosure covers surgical and non-surgical treatments regardless of frequency of incidence. The standard of knowledge of common risks, which need not be disclosed when not asked, is likely very small when applied to the patient's particular circumstances. If there were no risks there would not be a need for disclosure. However, health is a considerable intangible with respect to health knowledge, human ailments and human skills. The need for informed consent is perhaps so great due to these elements.

The probability of proper disclosure occurring regularly is somewhat low as indicated by the decisions of the cases reported. There may be a bias in the analysis using the reasonable person standard in that these matters are always with benefit of hindsight. There is likely an inconsistency in the principle of the 'reasonable man' analysis of causation. In the doctor-patient relationship full disclosure, as the courts deem it, is seldom occurring. There is an inconsistency in what the courts decide a reasonable man's decision would be when compared to what is actually decided by patients in every day doctor-patient relationships. In daily practice, patient's choices are more of compliance rather than a reasonable man's decision based on the practitioner's fiduciary position and the patient's lack of health knowledge. Some of the conditions are of small consequence but will have treatments which have material risks. If the risk does not materialize then the matter is academic. This is no excuse for not giving a full disclosure. What then becomes of those instances which do unfortunately occur but do not appear to involve a dispute or litigation? In those incidences where the patient has worsened, the issue of material risk and informed consent is likely only to arise if the patient is sufficiently knowledgeable that treatment may have contributed to their worsening.

For those patients and practitioners who find themselves in the unfortunate position of dealing with whether the risk was material and whether or not it was disclosed, the Supreme Court of Canada has clarified the practitioner's responsibilty and upheld the patient's rights.

References

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2 Reibl v. Hughes [1980] 2 S.C.R. 880.
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4 Halushka v. University of Sask. (1965) 52 W.W.R. 608 (Sask. C.A.).
5 Noctan v. Lord Ashburton [1914] A.C. 932 (H.L.).
6 Mason v. Forgie (1984) 31 C.C.L.T. 66 (N.B.Q.B.).
7 Bickford v. Stiles (1981) 128 D.L.R. (3d) 516 (Q.B.).
8 Reynard v. Carr 28th December 1983, No. C772920 (B.C.S.C.) unreported.
9 Parmley v. Parmley [1945] S.C.R. 635.