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Ionising radiation risk disclosure: When should radiographers assume a duty to inform?

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ABSTRACT

Introduction: Autonomy is a fundamental patient right for ethical practice, and informed consent is the mechanism by which health care professionals ensure this right has been respected. The ethical notion of informed consent has evolved alongside legal developments. Under Australian law, a provider who fails to disclose risk may be found to be in breach of a duty of disclosure, potentially facing legal consequences if the patient experiences harm that is attributable to an undisclosed risk. These consequences may include the common law tort of negligence.

Ionising radiation, in the form of a medical imaging examination, has the potential to cause harm. However, stochastic effects cannot be attributable to a specific ionising radiation event. What then is the role of the Australian medical imaging service provider in disclosing ionising radiation risk?

Methods: The ethical and legal principles of informed consent, and the duty of information provision to the patient are investigated. These general principles are then applied to the specific and unusual case of ionising radiation, and what responsibilities apply to the medical imaging provider. Finally, the legal, professional and ethical duties of the radiographer to disclose information to their patients are investigated.

Results: Australian law is unclear as to whether a radiographer has a common law responsibility to disclose radiation risk. There is ambiguity as to whether stochastic ionising radiation risk could be considered a legal disclosure responsibility.

Conclusion: While it is unlikely that not disclosing risk will have medicolegal consequences, doing so represents sound ethical practice.

Introduction

Radiographers are an integral part of modern health care, requiring a unique skillset and having a responsibility to provide the greatest diagnostic value to the patient, at the lowest achievable dose. It is the ionising radiation dose inherent in so many medical imaging procedures that drives this unique skillset. With any ionising radiation medical imaging examination, there is a risk of stochastic effects (such as carcinogenesis) and for some procedures, the potential for tissue effects (such as burns).

However, there is no guidance in the context of Australian healthcare as to whether radiographers have a duty to disclose any ionising radiation risk information to the patient for a medical imaging procedure. In this article the general ethical and legal principles of "informed consent" are applied to the specific case of ionising radiation. Consideration is given as to whether radiographers have any duty to inform their patients, and consider the scope of such information provision.

Autonomy and the ethical notion of "informed consent"

There are (potentially competing) prima facie obligations of the health carer. These obligations are approximately aligned with the four bioethical principles of Beauchamp and Childress, which requires respect for autonomy, beneficence, non-maleficence, and justice.[1]

For a patient referred for an ionising radiation examination, the competing obligations of beneficence and non-maleficence manifest in the desire to provide the individual patient with a benefit in diagnostic terms, while recognising that ionising radiation has the potential for causing harm. These ideas come together in the

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autonomy-based notion of "informed consent". A patient is entitled to understand what the benefits of an investigation might be, and judge for themselves whether they are prepared to take a risk of harm in order to achieve the benefits.

Of course, most patients cannot and will not expect to be as well informed as their doctor when deciding,[2,3] but clearly major risks must be declared for consent to be meaningful. What has always been contentious in health care is the disclosure of risks of very low probability. Some patients may refuse beneficial examinations by focussing on potential, low-risk side effects.[4] Medical imaging examinations that use ionising radiation have potential risks of lethality and life impairment but these risks are small in magnitude and they may not be realised for many years, a fact that further complicates considerations of how and indeed whether to inform the patient of stochastic risk for a particular investigation (for example, a chest x-ray).

The ethical notion of informed consent has developed alongside developments in the law, particularly with regard to the common law tort of negligence where a provider may be found to be in breach of a duty of disclosure. A review of the law in this area will be considered before returning to consider the specific application to ionising radiation.

Legal influences on the duty to inform

International and Australian precedents

The Salgo case (1957, North America) [154 Cal. App. 2d 564]

The Salgo case (*Salgo v Leland Stanford Jr University Board of Trustees*) coined the term 'informed consent', and the findings of the court stated that patients needed certain *material information* disclosed to them before they could make an informed decision about their care. The required information included the risks, benefits and consequences of an examination, and any alternatives.

This case led to the concept of an informed patient, and what is often phrased as the 'reasonable person standard of disclosure'.[5] However, there was no definition of a *reasonable person*.[6] What parameters of a risk should be disclosed were only broadly described in an appeal to the case, noting that there was a duty of a physician to disclose to the patient "all the facts which mutually affect his rights and interests and of the surgical risk, hazard and danger, if any …", and that a physician would violate their duty to the patient if they were to withhold facts "which are necessary to form the basis of an intelligent consent by the patient to the proposed treatment", while leaving discretionary consideration.[6]

The Bolam case (1957, England) [WLR582]

The Bolam case (*Bolam v Friern Hospital Management Committee*) was an English tort case, influential in English and Australian legal practice.[5] The findings of the case led to the oft-cited Bolam test of negligence, which states that "a medical professional is not guilty of negligence if he has acted in accordance with a practice accepted as proper by a responsible body of medical men skilled in that particular art … Putting it the other way round, a man is not negligent, if he is acting in accordance with such a practice, merely because there is a body of opinion who would take a contrary view".[7,8] The Bolam test was reviewed in a 2015 Supreme Court Case, of *Montgomery v Lanarkshire Health Board,*.[9,10] The Montgomery case moved the focus of risk disclosure from Bolam's paternalistic model, to that of a patient-centred care model, as espoused by the Australian Courts in the 1992 Rogers v Whitaker case.[11,12]

The Rogers v Whitaker case (1992, Australia) [175 CLR 479]

The case of *Rogers v Whitaker* was a landmark in the Australian medicolegal landscape, as it capped a gradual movement away from the Bolam Principle as far as patient information provision and risk disclosure was concerned. *Rogers v Whitaker* recognised a different standard of disclosure, the *subjective person* standard. As judged by the High Court of Australia, a health care professional has a duty to disclose information to their patient. This information is based upon what a reasonable person, in the position of the patient, would require, even when the patient does not make specific enquiries about the risks or benefits of their care[12] (this duty of disclosure is subject to therapeutic privilege). This represented the culmination of a paradigm shift in the duty of disclosure in Australian Health Care. The emphasis on patient information provision shifted from a doctor-led standard to a patient-led standard.

Justice Gaudron, while agreeing with the majority in Rogers v Whitaker, further commented that "A patient may have special needs or concerns which, if known to the doctor, will indicate that special or additional information is required. In a case of that kind, the information to be provided will depend on the individual patient concerned. In other cases, where, for example, no specific enquiry is made, the duty is to provide the information that would reasonably be required by a person in the position of the patient."

Since the *Rogers v Whitaker* decision, inadequacy of information provided by health carers has been raised a significant number of times in Australian courts.[5] The *Rogers v Whitaker* decision led to fears of an increase in litigation[5] amid concerns about the costs of professional negligence. While it is questionable whether there was any real litigation increase,[13] political and media pressures led to a Ministerial Meeting on Public Liability, comprising Ministers from Commonwealth, State and Territory government, at which it was agreed to appoint a panel of four eminent persons to review the law of professional negligence.[5]

An Australian review of the law of professional negligence: the Ipp Report (2002)

The *Review of Negligence Final Report*, which came to be known as the *Ipp Report* (after the Chairman, David Ipp), sought to establish the standard of care in cases where there was an allegation of a breach of said care (specifically to 'develop and evaluate options for a requirement that the standard of care in professional negligence matters (including medical negligence) accords with the generally accepted practice of the relevant professions at the time of the negligent act or omission'). It was further tasked to review the laws of professional negligence and to advise on law reform.

Duty to inform

The panel recommended that the standard for provision of information should remain unchanged from the standard established by the High Court in *Rogers v Whitaker*,[5,12] specifically stating that "The giving of information on which to base consent is not a matter that is appropriately treated as being one of medical expertise. Rather, it involves wider issues about the relationship between medical practitioners and patients and the right of individuals to decide their own fate".[14]

The panel recommended that a legislated duty of disclosure embody the principle of a separate *proactive and reactive duty*. The *proactive* duty requires the medical practitioner to take reasonable care to give (any) patient such information as the reasonable person in the patient's position would, in the circumstances, want to be given before making a decision whether or not to undergo treatment. The *reactive* duty requires the medical practitioner to give a patient (further) information when the patient asks for it "or

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