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Medical imaging and informed consent – Can radiographers and patients agree upon a realistic best practice?

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ABSTRACT

Introduction: For radiographers, gaining informed consent with our patients represents a challenging undertaking. Reconciling the need to gain meaningful consent with time pressures represents one challenge, as does differing expectations of how risk communication should be undertaken. Different methods and thresholds of risk disclosure are considered, with the aim of finding a realistic best practice.
Methods: A cross-sectional study of radiographers and members of the public was undertaken. Participants were asked their preferences for how they would like to receive ionising radiation risk information. This included the health care professional(s) most suited to provide the information, the media through which the information was delivered, and the technique for delivering the information. In addition, participants were asked to consider hypothetical scenarios in which they were a patient receiving an ionising radiation examination, and to give the threshold of ionising radiation cancer risk which they would consider material. These scenarios considered variations in the cancer-onset time, and the accuracy of the test.
Results: One hundred and twenty-one (121) radiographer participants and one hundred and seventy two (172) members of the public met the inclusion criteria and completed the survey. There was strong agreement in the most appropriate media, and person, to disclose risk, as well as what represents a significant risk. There was considerable agreement in risk delivery technique. However, some of the agreed-upon strategies may be challenging to achieve in clinical practice.
Conclusion: Radiographers and patients fundamentally agree upon risk communication strategies, but implementing some strategies may prove clinically challenging.

Introduction

From the middle of last century, the so-called *Bolam Principle* set the standard of appropriate care for medical negligence cases, such that a practice is considered to be acceptable if it is in accordance with practices accepted by reasonable medical practitioners. The Bolam principle was originally applied not only to medical treatment but also to the duty of a medical practitioner to disclose medical risks.

However, the standard for "informed consent" has gradually changed, culminating in the 1992 Australian High Court judgement in *Rogers v Whitaker*.[1] Since then, doctors have been seen to have an obligation to disclose all material risks for a proposed course of action. A risk is considered material if, in the circumstances of the particular case, a reasonable person in the patient's position, if warned of the risk, would be likely to attach significance to it or if the medical practitioner is or should reasonably be aware that the particular patient, if warned of the risk, would be likely to attach significance to it.[1–5]

The Australian High Court recognised that a duty of disclosure includes both a *proactive* duty (the referrer must volunteer information which the hypothetical reasonable patient requires), and a *reactive* duty (the referrer must volunteer information in response to the *particular* patient's circumstances, concerns, or desire for information).[6,7] A 2002 report on a national review of professional negligence, the *Review of Negligence: Final Report* (which came to be known as the *Ipp Report*) endorsed the common law position established by the High Court.[7] The panellists recommended that risk disclosure should *only* be legislated for physicians, while recognising the duties of (non-physician) service providers (such as radiographers) to give particular categories of information in particular circumstances, "the historical source of these duties, and their nature and scope, differ from the duty of medical practitioners to inform their patients…The law is undeveloped in regard to

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determining precisely when a duty to inform will arise and on whom it will be imposed".[7] The Ipp panellists further acknowledged the possibility of overlapping duties of disclosure of more than one doctor (or health carer) involved in a patient's care.

Essentially, Australian law only formally recognises the physician's duty to disclose risk, but recognises that other health care providers may have an established tradition of doing so, in some circumstances, but that this practice is not legislated.

The *proactive duty* is of particular note, as this requires the medical practitioner to consider the information that a *reasonable person* in the patient's position would want to be given before making a decision about a course of action.[6,8] In Australian and international literature, there is no established standard of a *reasonable person*, nor is there a *threshold* of what represents a *material risk*.

Medical imaging examinations may represent an unusual case in risk disclosure. Most medical imaging techniques use ionising radiation (Magnetic Resonance Imaging and ultrasound are exceptions). Ionising radiation carries a small risk of harm,[9] with the induction of cancer being the primary stochastic risk. When recommending a medical imaging examination using ionising radiation, in the majority of cases, referring physicians do not disclose the radiation risk,[10] and are often unaware that a risk even exists.[10–17] Lack of awareness of the risks associated with higher-dose examinations such as CT scanning is particularly concerning, as CT has sustained rapid growth for over two decades,[18,19] often at a much higher rate than population growth,[20] with "no sign of reaching a plateau".[21]

In an ionising radiation medical imaging examination, given the medical involvement of both referring and providing doctors, and the technical involvement of radiographers, the question is raised about who should disclose the ionising radiation risk. It has been discussed elsewhere whether Australian radiographers might have a legal obligation to disclose the stochastic risks of ionizing radiation, concluding that it is unlikely that an Australian radiographer has a need to disclose ionising radiation risk that is driven by law; rather, any disclosure is driven by good practice as recommended by professional bodies such as the Medical Radiation Practice Board (MRPB).[22]

There has been no published research into what a health care provider, in the position of a patient, would consider a material risk. This research does not seek to establish a *standard of reasonableness*; the 'reasonable person' standard is a legal concept. Rather, this research seeks to investigate informed consent for ionising radiation medical imaging examinations in terms of a realistic best practice. The views of radiographers and members of the public on the informed consent process are investigated, including investigating who should disclose risk, and how risks should be disclosed. A hypothetical threshold of risk is also investigated, to see if radiographers and members of the public agree on what is a significant ionising radiation risk.

Methods

Study design

A cross-sectional survey administered through written and online questionnaires was conducted. The study received approval from the [redacted] Human Research Ethics Committee (Approval No. H-2013-0433).

Sample

The target populations were[1] members of the public, and[2] a population of radiographers. Eligible participants were eighteen years of age or older, able to read English, and not too anxious (self-assessed) to participate. The radiographer group all represented qualified (not student), currently-clinically-practicing graduate radiographers from all Australian States and Territories, from both private and public Australian health care settings. Power calculations were undertaken and met for both participant groups ($n \geq 64$ in each group).

Recruitment and data selection

Participants were recruited through flyers posted in the public domain of the [redacted]; a 200-invitation mailout through the [redacted] volunteer register, and through social networks, primarily Facebook.

Survey instruments

After an initial literature review, a pilot survey was draughted, and assessed by a panel of twenty reviewers, including medical physicists, radiography academics, members of the public, and ionising radiation health practitioners (including radiologists and radiographers). Their recommendations contributed to the final survey instrument.

The survey was administered using a paper format questionnaire or an online survey using Survey Monkey (surveymonkey.com). The survey included a number of scenarios where the participant considered ionising radiation risk in the context of a hypothetical medical imaging examination. Participants were instructed to consider nine (3×3) scenarios from the perspective of themselves as a patient, and asked to give a threshold at which they would want to be told of a risk. The scenarios each had two variables: the accuracy of the examination (80%, 50%, 20% accuracy) and the cancer onset time (latency) (1, 10, 20 years).

The survey asked participants about their demographic, their preferences for receiving risk information (including which health care professional(s) the participants believed could meaningfully provide risk and benefit information), and the most meaningful technique and media to provide such risk information.

Statistical analyses

Data analysis was conducted using SPSS (version 20, SPSS, Chicago, IL, USA). Age categories were regrouped to form "up to 30", "31–40", "41–50", "51–60" and "60 and above" for both the members of the public (MOP) and radiographer (MRS) groups. Chi squared analyses were used to check for, and to examine differences between age group and type of consent (face to face versus written). A three (onset of cancer in years: one, ten, twenty) by three (test accuracy: accurate (80%), reasonable (50%), poor (20%)) factorial analysis of variance (ANOVA) technique was used to analyse the variables for establishing risk threshold.

Level of risk was established using a seven point Likert scale and was treated as a continuous variable in this analysis. Greenhouse–Geisser or Huynh–Feldt corrections were applied to correct sphericity. Critical values for these analyses were set at $p < 0.05$.

Results

Sample

A total of 293 participants returned a completed survey, 172 members of the public (MOP hereafter) and 121 radiographers (MRS hereafter). The data was analysed by age and gender. The summary demographic details are presented in Table 1.

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