

Describing ionising radiation risk in the clinical setting: A systematic review



C.W.E. Younger*, M.J. Wagner, C. Douglas, H. Warren-Forward

The University of Newcastle, University Drive, Callaghan, NSW 2308, Australia

ARTICLE INFO

Article history:

Received 28 June 2018

Received in revised form

7 November 2018

Accepted 9 November 2018

Available online 29 November 2018

Keywords:

Risk disclosure

Informed consent

Risk communication

Ionising radiation

Medical imaging

ABSTRACT

Introduction: Meaningfully explaining the risk of an ionising radiation examination is a challenging undertaking. Patients must contextualise the risk against the expected benefit of the imaging examination, often in a situation of heightened emotion. This systematic review seeks to explore the literature to identify what techniques are advocated for disclosing the risk to patients of ionising radiation from clinical medical imaging examinations.

Methods: A systematic review of peer-reviewed literature was undertaken. Electronic databases were searched to identify peer-reviewed, full-text articles published in English from 1990. Original articles discussing techniques for disclosing ionising radiation risks in the clinical setting were included. The reference lists of the included articles were searched for unpublished articles and reports of use.

Results: Sixteen papers out of 5959 unique titles met the inclusion criteria. The data was extracted independently by two researchers and assessed for quality using the Joanna Briggs Institute critical appraisal tools.

Conclusion: The two most commonly cited techniques for disclosing ionising radiation risk is to compare risk to the risk of common life events, and to describe risk as an additive risk to the baseline risk of cancer. The most commonly cited communication strategy was a graphical representation of the data, but simple language is also advocated. The use of a pictograph represents a technique which satisfied the advocated techniques of most articles.

Crown Copyright © 2018 Published by Elsevier Ltd on behalf of The College of Radiographers. All rights reserved.

Introduction

The process of gaining informed consent for a proposed medical procedure is challenging. Valid informed consent requires the disclosure of the benefits of an examination, the risks of the proposed examination, any alternatives, and the consequences of not having an examination.¹ Describing risk to patients is the focus of this review.

Meaningful risk disclosure is honest, contextualised to the benefit of the proposed procedure, and is expressed in a way that the patient can understand. Risks must be presented neutrally, in a way that uses a mathematical context honestly; any deliberate

framing of information to influence a patient's decision is potentially ethically questionable.²

People underestimate large risks, and overestimate small risks,³ and may focus on the risks almost to the exclusion of considering any benefit (an anchoring bias).⁴ The patient often receives this information at a time when they are affected by negative emotional states.²

Many diagnostic and interventional medical imaging procedures use ionising radiation. There are a number of obstacles to meaningfully describing ionising radiation risk. First, there is the language of ionising radiation, which is “not readily understood by non-specialists”.³ Second, patients may have preconceived notions of risk, and that “public perceptions of radiation risk differ from the assessments of the majority of experts”.⁵ Third, there is the challenge of describing the benefit of a medical imaging examination against a possible future risk of harm, often with a very long latency period.⁶ Finally, there are competing theories about what the actual risk of radiation is.

* Corresponding author.

E-mail addresses: cameron.younger@newcastle.edu.au (C.W.E. Younger), melanie.wagner@hnehealth.nsw.gov.au (M.J. Wagner), charles.douglas@newcastle.edu.au (C. Douglas), helen.warren-forward@newcastle.edu.au (H. Warren-Forward).

The radiation levels in most medical imaging techniques is very low. The risk of low level radiation is extrapolated from data from higher doses of radiation, such as from atomic bomb survivor cancer rates. This extrapolation of a dose-response relationship has caused debate in the scientific community about the accuracy of the risks cited for lower levels of radiation (below 0.2 Sv).^{7,8}

Recognising these challenges, how then should the risk of an ionising radiation medical imaging procedure be provided to a patient, such that they might make an informed decision about their care?

Aim

The aim of this review was to search for all available literature describing methods for explaining the ionising radiation risk of a clinical medical imaging examinations. The review sought to answer the following question:

Are there any established or recommended communication practices for explaining the risk of ionising radiation in a diagnostic imaging environment?

Methods

Dose-response model

This systematic review is predicated on the notion that low levels of ionising radiation have the potential to cause harm. Risk disclosure strategies are a moot point if there is no risk. However, if the risk not absolutely certain, a conservative estimation is the most defensible stance.

There is scientific debate about the response to low levels of radiation, both in terms of there being a threshold of a 'safe' dose, and the linearity of the response. Experimental models have indicated that non-irradiated cells can be affected by mutagenic change from proximity to irradiated cells (the *bystander effect*),⁹ suggesting that low levels of radiation might have a greater effect than is currently considered – a supra-linear effect. Other models have indicated that low levels of radiation might suppress spontaneous or environmental cancers (*radiation hormesis*),^{7,8} suggesting that low levels of radiation might have a sub-linear, even beneficial effect.

The linear, no-threshold (*LNT*) model states that there is a linear response to ionising radiation at all levels, and that there is no radiation dose without response. The LNT model is supported by the Committee to Assess Health Risks from Exposure to Low Levels of Ionising Radiation,¹⁰ and the International Commission on Radiation Protection (ICRP).¹¹ The ICRP concluded that the LNT model was the most appropriate, conservative theory for dose-response modelling.¹¹ Further, reviews have concluded that the evidence for radiation hormesis "is still not yet convincing enough and the implementation of the LNT model ... is still the safest way to go".¹² Given that "it is unlikely LNT theory will be abandoned as the philosophical and practical foundation of radiation protection practice",¹³ this systematic review has included much literature that recognises the LNT theory.

Literature search strategy

The protocol was initially created by reading through five key papers on informed consent for ionising radiation, taking note of the frequency of key terms from the title, keyword, abstracts and MeSH (Medical Subject Headings).

The literature search was then undertaken in three stages. First, a preliminary search was undertaken using CINAHL and Medline, which identified keywords and synonyms from the titles,

keywords, abstracts, MeSH and references from the identified articles. From this, a term query-list was created.

The second stage extended the literature search to CINAHL (Cumulative Index to Nursing and Allied Health Literature), Cochrane Economic Evaluations, Cochrane Reviews, Cochrane Trials (CENTRAL), EMBASE, Medline, Medline in Process and PsycINFO.

The third stage involved searching the reference lists of the literature found, to see if there were additional sources.

The search for this systematic review was undertaken on March 5th, 2018. The research question phrasing was divided into two broad categories: *radiation* and *consent*. The initial category searched for radiation terms, including common types of imaging examinations. Interventional studies were included at this stage. The search also included synonyms for ionising radiation examinations (x-rays, diagnostic imaging) and their various spelling variants.

The second category searched for informed consent. This search utilised a similar spelling and synonyms strategy for informed consent (disclosure, decision, choice), and risk. 'Risk' was included as a term as the practice of gaining *consent* (or *informed consent*) includes the practice of disclosing risk to the patient. The results of these searches were then combined, and limited to studies published in English, from 1990 onwards (Table 1).

Inclusions and rationale

Studies were included if they were full paper articles in the English language. Paediatric studies were included.

Articles were included if they represented risk disclosure strategies for a patient, where there is *potential for benefit* (such as diagnosing a pathology in a symptomatic patient), weighed against a *potential for harm*. For this reason, risk disclosure techniques for research subjects and screening studies of asymptomatic populations were excluded.

Diagnostic radiography and nuclear medicine examinations were included if they explicitly discussed the radiation component of risk as a separate consideration to other examination risks (contrast reactions, pneumothoraces, or infections, for example).

Exclusions and rationale

Research prior to 1990 was excluded as this represented a recent timeframe of research.

Radiation therapy was excluded, as a radiation therapy procedure has an *assumed* (often acute) therapeutic benefit to the examination for a patient who already has a cancer, whereas a diagnostic imaging examination has only the *potential* for improving the patient health. This difference, though fine, suggests a need for a different informed consent process.

Full-text reviews excluded articles which only discussed the *importance* of disclosure, or described risk disclosure without explicitly discussing ionising radiation.

Search returns

After duplicates were removed, 5947 unique citations remained. An additional twelve articles were identified by reference lists, creating a combined total of 5959 unique citations.

Protocol, screening and assessment

Following usual process, all 5959 unique citations were screened by title and then abstract by two independent researchers. After this initial screening process, 26 articles were

Table 1
Search strategy.

#	Searches
1	radiation, ionising/ or x-rays/
2	radiography/ or fluoroscopy/ or hysterosalpingography/ or lymphography/ or mammography/ or pneumoradiography/ or radiography, abdominal/ or radiography, dental/ or radiography, interventional/ or radiography, thoracic/ or tomography, x-ray/ or urography/
3	diagnostic imaging/ or neuroimaging/ or subtraction technique/ or tomography/ or whole body imaging/
4	1 or 2 or 3
5	Informed Consent/
6	(disclosure adj5 risk*).tw.
7	consent*.tw.
8	(informed adj5 (decision* or choice*)).tw.
9	5 or 6 or 7 or 8
10	4 and 9
11	limit 10 to (english language and humans and yr = "1990 -Current")

retrieved for full review (Fig. 1). The reviewers utilised a two-step review process for full text review.

Step 1: exclusions

Five articles were excluded because they only discussed the importance of disclosing ionising radiation risk. Four articles were excluded because the articles discussed general principles of discussing risk, but were not specific to ionising radiation.

Step 2: quality

The remaining 17 articles were assessed for quality by both reviewers. This second stage was assessed using the Joanna Briggs

Institute (JBI) Critical Appraisal Tools¹⁴ (Table 2). All seventeen articles were considered to be of adequate quality.

Results

Table 3 tabulates the authors, study data, and discussion of communication techniques that were discussed (both positively and negatively). After a review of these articles, a number of themes became apparent, and were categorised in two ways.

The first method was whether technique was advocated as positive (useful or helpful in patient understanding) or discouraged as being negative (misleading or unhelpful).

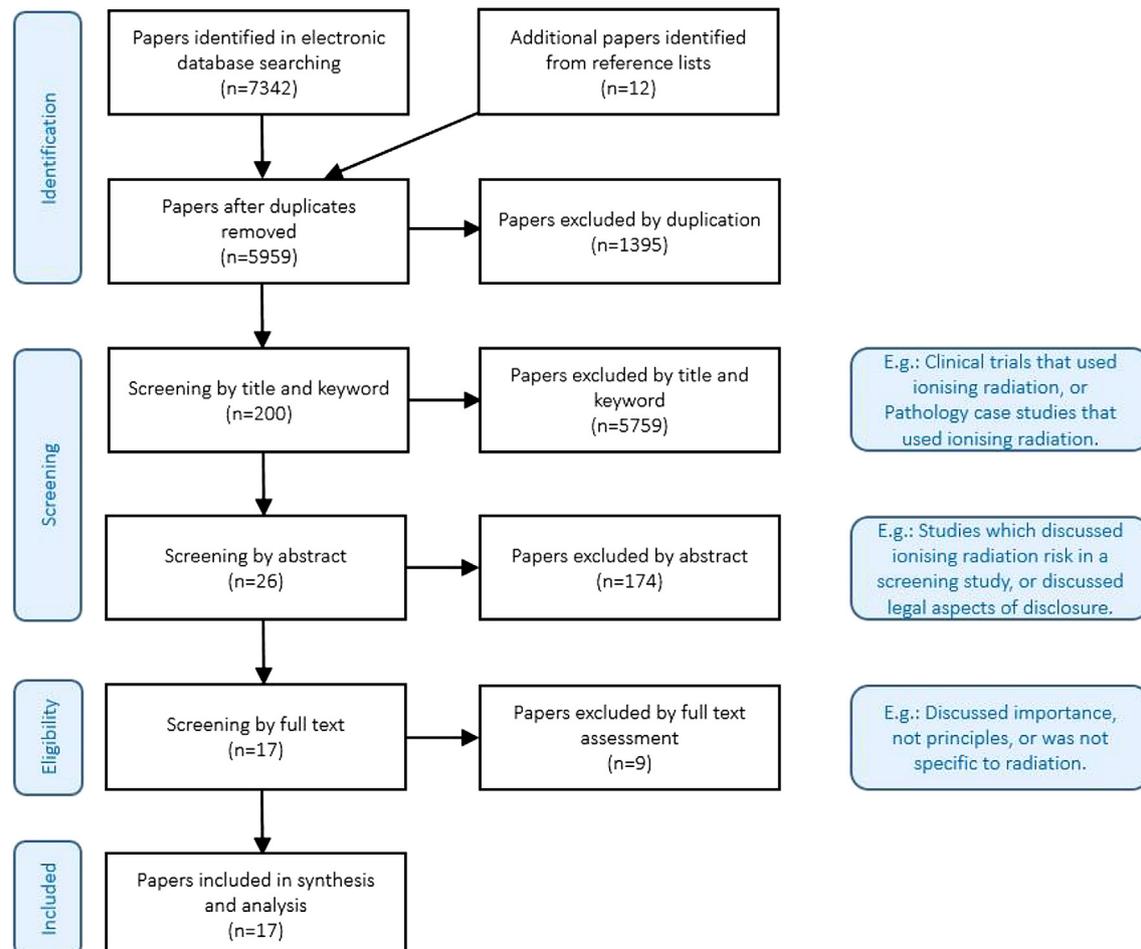


Figure 1. Search inclusion protocol.

Table 2
Joanna Briggs Critical Appraisal Quality Assessment Tool.¹⁴

Quality Checklist Question	Yes	No	Unclear	N/A
Is there congruity between the stated philosophical perspective and the research methodology?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Is there congruity between the research methodology and the research question or objectives?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Is there congruity between the research methodology and the methods used to collect data?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Is there congruity between the research methodology and the representation and analysis of data?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Is there congruity between the research methodology and the interpretation of results?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Is there a statement locating the researcher culturally or theoretically?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Is the influence of the researcher on the research, and vice-versa, addressed?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Are participants, and their voices, adequately represented?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Is the research ethical according to current criteria or, for recent studies, and is there evidence of ethical approval by an appropriate body?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Do the conclusions drawn in the research report flow from the analysis, or interpretation, of the data?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>

The second method was whether the technique was *what to say* (such as using a dose analogy/comparison), or *how to say it* (such as advocating that the use of diagrams). In Table 3, this second category is shown in italics.

Advocated ionising radiation risk communication techniques

Everyday risk

Comparing the risk of an ionising radiation examination to risks from life events were advocated in twelve articles,^{3,16–21,23–27} Common comparisons were driving,^{3,17,23} smoking,³ and increased-risk activities (e.g.: skydiving),^{19,25} although one study noted that comparison to increased-risk activity had a lower patient preference.²⁴

Extra cases of cancer per population

Nine articles advocated expressing the risk of an ionising radiation examination as an additive risk (an increased incidence), above the normal cancer incidence in nature.^{3,6,15–18,23–25}

Uncertainty of risk

Three articles recognised that ionising radiation risk estimation has a degree of uncertainty. All three articles indicated that disclosing such uncertainty represented ethical practice,^{8,20,24} a consideration supported by risk analysts, stating that consideration of uncertainty is required for informed consent.²⁸

Lost life expectancy

One article¹⁹ suggested that the risk of an ionising radiation examination could be represented in the concept of 'lost-life expectancy', a concept that dates to 1980,²⁹ suggesting that risks can be quantified in terms of the amount of days of life that are lost by an event, averaged over a population.

Graphical representations/contextualisations

The use of graphics (particularly when contextualised against risks of other life events) were advocated in ten articles.^{2,3,15–20,24,27} Different graphic types were suggested, such as displaying risk as a graph (such as a graph of dose vs. risk, showing common imaging procedures),^{3,15} or a pictograph (displaying an imaging risk as an addition to baseline risk, expressed with a constant unit).^{16–18}

Reading age and simplicity

Reading ages and/or language simplicity were discussed in eight articles.^{2,8,17–20,23,27} suggesting an ideal readability range of reading ages between 6th and 8th grade (equivalent to a 12–14 year old education).

Multimedia

Multimedia materials were advocated in one study,⁸ which noted that a variety of formats would provide timely information, and would encourage patient dialogue.

Contentious ionising radiation risk communication techniques

Comparison with other radiation events/dose analogy

There are a number of ways to express an ionising radiation examination radiation *dose* relative to common radiation events. Comparison with a chest radiograph or with a certain amount of flight time are two common approaches for communicating radiation risk.^{2,26} Four articles noted that describing the *dose* of an examination is not the same as describing the *risk* of an examination,^{2,3,16,17} describing such techniques as evading the challenge of describing the risk,¹⁶ or not educating effectively.² In total, three articles advocated comparison of an ionising radiation examination risk to that of other radiation events,^{18,25,26} and three articles discouraged their use.^{2,3,16,17}

Describing a risk event as a comparison to background dose

A radiation dose can be quantified in terms of Background-Equivalent Radiation Time (BERT), a unit first described by Professor John Cameron in 1991.³⁰ Six articles discussed quantifying an examination in BERT units.^{2,16,18,24–26} BERT comparisons were advocated in one case, citing patient preference,²⁶ and discouraged in two instances, citing that the practice is "highly variable",² and avoids actually quantifying the risk.¹⁶ BERT suffers from similar conceptual limitations to comparison to dose events, but also has an inconsistent geographic value.³¹ The three remaining articles were neutral in opinion.^{18,24,25}

Odds

Expressing ionising radiation risk as odds ('the risk is 1 in NNNN') was advocated in three articles,^{22,24,27} with one study showing a strong patient preference for risk presented as odds.²⁷ Odds were discouraged in three articles,^{2,16,17} with some odds being described as "difficult, if not impossible, to grasp", and that patients consider them to have poor effectiveness.¹⁷ Two articles stated that the framing of such odds could potentially raise ethical questions.^{2,16}

Descriptive language

Descriptive language ("your risk is low") was advocated in one study,²⁴ but discouraged in a second.²⁷ Interestingly, both studies were based on patient feedback. The 'advocating' study was based in Finland, from a large sample of people who had just had a medical imaging examination.²⁴ The 'discouraging' group was an Australian-based study, and the sample group were participants who were not having an ionising radiation examination at the time of the survey.²⁷

Table 3
Systematic review articles and findings.

Year	Authors	Country	Advocated Technique(s)	Discouraged Technique(s)	Notes
2004	Picano, E.	Italy	<ul style="list-style-type: none"> ■ Everyday Risk ■ Extra cancer cases per population ■ Graphic contextualisation 	<ul style="list-style-type: none"> ■ Chest radiograph comparison ■ Technical Jargon 	Viewpoint , as supported by the UK College of Radiologists. ³
2007	Bedetti, G. Lore, C.	Italy	<ul style="list-style-type: none"> ■ Extra cancer cases per population ■ Graphic contextualisation 	<ul style="list-style-type: none"> ■ Nil 	Viewpoint , derived from risk disclosure techniques used for research patients. ¹⁵
2009	Karsli, T. Kalra, M.K. Self, J.L. Rosenfeld, J.A. Butlet, S. Simoneaux, S.	United States	<ul style="list-style-type: none"> ■ Extra cancer cases per population 	<ul style="list-style-type: none"> ■ Nil 	Survey (n = 365) . Tertiary hospital physicians investigating the need for informed consent for low-dose ionising radiation examinations ⁶
2011	Dauer, L.T. Thornton, R.H. Hay, J. Balter, R. Williamson, M. St. Germain, J.	United States	<ul style="list-style-type: none"> ■ Graphic contextualisation ■ Reading Level awareness 	<ul style="list-style-type: none"> ■ Flight comparison ■ Occupational Doses ■ Background radiation dose ■ Odds 	Viewpoint , derived from research on generic risk disclosure. ^{2,16}
2011	Fahey, F.H. Treves, S.T. Adelstein, S.J.	United States	<ul style="list-style-type: none"> ■ Everyday Risk ■ Extra cancer cases per population ■ Graphic contextualisation ■ Reading Level awareness 	<ul style="list-style-type: none"> ■ Chest radiograph comparison ■ Flight comparison ■ Technical Jargon ■ Odds 	Viewpoint , supported by the American College of Radiology. ¹⁷ Paediatric, Nuclear Medicine focus.
2011	Carpeggiani, C. Picano, E.	Italy	<ul style="list-style-type: none"> ■ Everyday Risk ■ Extra cancer cases per population ■ Chest radiograph comparison ■ Background radiation dose 	<ul style="list-style-type: none"> ■ Nil 	Report , the European Society of Cardiology. ¹⁸
2012	Brink, J.A. Goske, M.J. Patti, J.A.	United States	<ul style="list-style-type: none"> ■ Reading Level awareness ■ Multimedia Materials. 	<ul style="list-style-type: none"> ■ Uncertainty of risk data 	Viewpoint , derived from reports on health literacy.
2012	Einstein, A. Berman, D.S. Min, J.K. Hendel, R.C. Gerber, T.C. et al.	United States	<ul style="list-style-type: none"> ■ Everyday Risk ■ Lost-Life Expectancy ■ Graphic contextualisation ■ Reading Level awareness 	<ul style="list-style-type: none"> ■ Statistical terms and constructs. 	Report , Cardiac Symposium ¹⁹
2012	Perez, M. (and Working Group).	Switzerland	<ul style="list-style-type: none"> ■ Everyday Risk ■ Uncertainty of risk data ■ Graphic contextualisation ■ Reading Level awareness 	<ul style="list-style-type: none"> ■ Complex Language ■ Technical Jargon 	Report , Workshop on communication in paediatric imaging. ²⁰ Supported by the World Health Organisation.
2014	Boutis, K. Fischer, J. Feedman, S. B. Thomas, K. E.	Canada	<ul style="list-style-type: none"> ■ Everyday Risk 	<ul style="list-style-type: none"> ■ Nil 	Survey (n = 126) of paediatric emergency physicians investigating risk disclosure practices. ²¹
2014	Westra, S.J.	United States	<ul style="list-style-type: none"> ■ Extra cancer cases per population ■ Everyday Risk ■ Graphic contextualisation 	<ul style="list-style-type: none"> ■ Background radiation dose ■ Chest radiograph comparison ■ Occupational Doses. ■ Odds 	Viewpoint , derived from research on generic risk disclosure ²
2015	Malone, J. Del Rosario-Perez, M VanBladel, L. Jung, S.E. Holmberg, O. Bettman, M. A.	United States	<ul style="list-style-type: none"> ■ Odds 	<ul style="list-style-type: none"> ■ Minority Opinions. 	Report . The International Atomic Energy Agency (IAEA) on appropriateness of medical imaging referral guidelines. ²² Supported by the World Health Organisation.
2015	Merck, L. Ward, L. A. Applegate, K. E. Choo, E. Lowery-North, D. L. Heilpern, K. L.	United States	<ul style="list-style-type: none"> ■ Extra cancer cases per population ■ Everyday Risk ■ Reading Level awareness 	<ul style="list-style-type: none"> ■ Nil 	Study (n = 7684) . Assessment of the influence of a written informed consent on CT scan utilisation. ²³ This was the only study whose advocated techniques were actually in clinical use.
2015	Ukkola, L. Oikarinen, H. Henner, A. Haapea, M. Tervonen, O.	Finland	<ul style="list-style-type: none"> ■ Extra cancer cases per population ■ Numerical values and scales ■ Descriptive language ■ Background radiation dose ■ Graphic contextualisation 	<ul style="list-style-type: none"> ■ Uncertainty of risk data ■ Everyday Risk ■ Complex Language 	Survey (n = 147) A survey of patients immediately after a radiological examination. ²⁴
2016	Carpeggiani, C. Paterni, M. Caramella, D. Vano, E. Semelka, R. C. Picano, E.	Italy	<ul style="list-style-type: none"> ■ Chest radiograph comparison ■ Background radiation dose ■ Extra cancer cases per population ■ Everyday Risk ■ Graphic contextualisation ■ Reading Level awareness ■ Simplicity of language 	<ul style="list-style-type: none"> ■ Nil 	Software : Discussion of software which could provide consumers (physicians and patients) with a theoretical risk estimation of a proposed ionising radiation examination. ²⁵
2017	Lumbreras, B. Vilar, J. González-Álvarez, I. Guilbert, M. Pastor-Valero, M. et al.	Italy	<ul style="list-style-type: none"> ■ Chest radiograph comparison ■ Background radiation dose ■ Everyday Risk 	<ul style="list-style-type: none"> ■ Nil 	Survey (n = 20) A group of patient respondents. ²⁶

(continued on next page)

Table 3 (continued)

Year	Authors	Country	Advocated Technique(s)	Discouraged Technique(s)	Notes
2018	Younger, C. W. Douglas, C. Warren-Forward, H.	Australia	<ul style="list-style-type: none"> ■ Odds ■ Everyday Risk ■ Graphic contextualisation ■ Reading Level awareness 	<ul style="list-style-type: none"> ■ Descriptive terms 	Survey (n = 293) Members of the public (n = 172) and radiographers (n = 121). ¹⁷

Discouraged ionising radiation risk communication strategies

Describing a dose event as a comparison to an occupationally exposed person

Two articles discouraged comparing the risk of a radiation event to the dose limits of an occupationally exposed person, citing the disconnect between a single radiation event and the long-term effects of the occupationally exposed.^{2,16}

Minority opinions

One study indicated that “In providing information to patients, evasion and minority positions should be avoided (e.g., views suggesting that radiation is good for you, or that it poses no risk). Radiation sceptics frequently do not advise patients about risk and often disregard it. Behaving as though there is no risk is inconsistent with the ... principles of radiation protection”.²² Conversely, one article indicated that classic informed consent would be imprudent until the associated risk is known reliably.⁸

Jargon

The use of technical terms,^{17,20} dose-specific units (such as millisieverts),^{3,24} and “statistical terms”¹⁹ were cited as being counterproductive to patient understanding of ionising radiation risk, with poor numeracy being a factor that “impairs understanding of health risks”.¹⁹

Discussion

This study performed a systematic literature review of eight databases. Following normal systematic review processes, seventeen journal articles that discuss a range of methods for describing ionising radiation risk to clinical patients were included in the final analysis. The articles selected were assessed to ensure good quality.

A number of common themes were evident from analysis of these articles. There was a good degree of agreement between articles on what constituted a good (or bad) technique. The most contentious points were the use of relative-dose analogies, the use of odds to express risk, and the use of descriptive language.

The use of a relative-risk or relative-dose analogy (comparing a potential medical imaging examination to another radiation event) is probably the most commonly utilised technique to inform a patient.^{2,26} However, the use of relative-dose analogy must be undertaken with care. A patient must be informed of the *risk* of an examination, not just the *dose*, and caution should be used to ensure that the right information is disclosed to the patient.

Telling a patient that their chest radiograph is equivalent to a plane flight of a specific duration or distance is certainly easily understood, but comparing a risk (by definition, a potentially negative outcome) to something which most patients could link with experiences that are positive or neutral (plane flights, or eating foods known to have low radioactivity levels) might allay fears, but it has the *potential* to be considered as framing a potential (albeit very low) risk as insignificant.

The need for accuracy of information represents a challenge in itself, as the radiation risk from a medical imaging examination is an estimate averaged over a *population*, not for the individual, for whom there are a great number of influential factors.

Radiosensitivity is not consistent across age, gender, reproductive cycles or gestational periods, and varies depending on the interval between radiation events.³² Thus, it is important for honesty of disclosure to recognise two caveats when disclosing ionising radiation risk for a diagnostic imaging examination: first, that the risk data is averaged over a population. Second, that there are potential margins for error.^{20,24,28}

This review assesses what is currently discussed in the literature on this subject. There may be a number of unidentified techniques in common use in the clinical environment. A survey of risk disclosure techniques in clinical use would serve as an interesting counterpoint to this study. What is *advocated*, and what is *used* might be quite different.

The ideal ionising radiation risk disclosure model

It is virtually impossible to have a universally agreed upon technique for describing ionising radiation risk, as patient cultures and perspectives are not universal. However, it may be worthwhile to devise what may be the *most advocated* technique, based upon the available literature. An amalgam of the suggested techniques is considered here, focussing on techniques which, when discussed, were advocated in all cases. Importantly, the caveats described above should be included when describing risk.

In this hypothetical technique, the risk must be contextualised against other risks. When comparing an ionising radiation risk with other risks, it is important to use the same scale,² and to have access to a number of comparison risks, as an individual patient may under- or over-estimate a risk based on their experiences.¹⁷ For this reason, it may be valuable for context to include both common life events and uncommon life events. The risk must show the naturally-occurring risk of cancer of the population, as well as the additive risk from a proposed procedure.^{3,6,15–18,23–25}

Graphs or pictographs would be used to express the ionising radiation risk information. This enables the patient to be provided with “information and not simply data”.² Single articles advocated a linear,¹⁵ or logarithmic² dose vs. risk graph, but four articles advocated the use of a pictograph^{16–18,25} of similar layout, albeit suggesting a range of scales.

The risk would be expressed using different media,⁸ using the simplest language possible,^{18,19} and focussing on key messages.² Individuals, even with high literacy levels, may still prefer simpler language.¹⁸

Combining these desirable values, the most agreeable method to express ionising radiation dose for a medical imaging examination appears to be a pictograph. The advantage of a well-designed pictograph is that it can be presented with little or no language, nor numbers. A pictograph can be provided to compare an examination's risk against other life-event risks, and can readily show an additive risk to a naturally-occurring risk. Pictographs could also be readily created that could be tailored to many patient demographics (gender, age or radiosensitivity). Finally, a pictograph could express margins for error, and can also express the source of baseline risks (such as background radiation).

For patients who have a preference for receiving information as odds, each pictograph unit represents a 1-in-X chance of dying. The use of odds is very powerful, and has the potential to be used

disingenuously. Even highly educated patients sometimes may not understand basic probability concepts.² Odds ('This test has a likelihood of cancer of 1-in-X') should not be confused with relative risk ('This test doubles your likelihood of cancer').^{33,34}

For this reason, the scale of a pictograph should allow for comparison with other risks, and be as simple and intuitive as possible. One study advocated expressing risk in units of a risk of one-in-2500,¹⁷ a scale cited by a second included article.¹⁶ Ronald A. Howard (a research pioneer in medical decision analysis), suggested that a one-in-one-million risk (a risk referred to as a *micromort*) has utility in decision making.³⁵

A risk unit of one-in-2500 seems unintuitive, and one-in-one-million is not a useful scale for disclosing ionising radiation risk. Given a base-ten counting system as a logical starting point, a more intuitive scale of 1-in-1000 is suggested for expressing medical imaging ionising radiation risk. One-in-one-thousand fatality risk (a *millimort*) is a scale that allows for ready comparison with many other everyday risks. For example, a one-in-1000 risk is comparable to the lifetime risk of drowning.³⁶ A one-in-1000 scale is useful for doses such as computed tomography, but may not be the scale of best-fit for doses received from a plain radiograph. However, explaining to a patient that their risk from (for example) a chest radiograph is so small that *it cannot be shown on such a scale* may help to alleviate fears of low dose examinations.

The use of such a 'millimort pictograph' or similar has not been tested in the clinical environment. Such a pictograph might represent a model of best-fit based on the literature reviewed, but this strategy cannot itself be advocated until it has been tested. It would be a worthwhile avenue for future research to undertake a pilot study to assess the efficacy, functionality and utility of such a technique in the clinical environment.

An example of such a pictograph is shown (Fig. 2). In the hypothetical scenario represented in Fig. 2, a 50-year old male patient has a baseline lifetime fatal cancer risk of around 25%³⁷ (indicated by the blue circles), and is considering a computed tomography scan of the abdomen, which has a projected dose of 10 mSv.³⁸ 10 mSv represents a 1-in-1000 lifetime fatal cancer risk.³⁸ This extra risk is shown by the single, extra, red circle.

To contextualise a lifetime risk, a second pictogram could show a comparable 'everyday' baseline risk and/or additive risk. For example, the lifetime risk of dying in a motor vehicle accident (just over 1-in-100) would show a pictograph with nine squares filled.³⁶

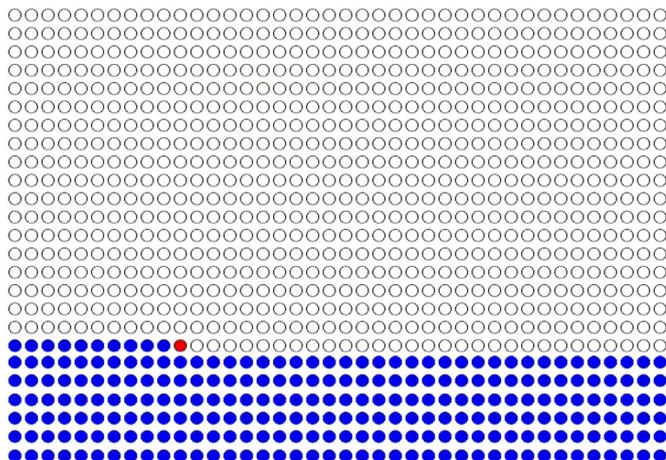


Figure 2. Example Pictograph, 50 year old male, proposed abdomen CT. Each circle represents a one-in-1000 risk of dying.

It is important to note that this systematic review examines techniques for disclosing ionising radiation *risk*, which is only one aspect of the informed consent process. Benefits, alternatives, and the consequences of *not* having an examination must also be disclosed.¹ The consequences of not having an examination is an obviously important consideration, but is obviously specific to the individual presentation. Not having an abdominal CT scan (based on the radiation dose) might not shorten the patient's life at all; however, the absence of an important diagnosis could lead to a rapid loss of life.

Limitations

This review covered a wide group of techniques (surveys, workshops, technical meetings). When surveys were undertaken, the respondent demographics differed (physicians, radiographers, and members of the public). It is difficult to assess the efficacy of the strategies proposed or advocated by the contributing articles. There is a degree of variability of responses, and it is difficult to place a value or degree of authority on the contributing articles.

Conclusion

Based on this systematic review and the literature available, the most supported technique for disclosing ionising radiation risk is to express an examination's ionising radiation risk as additive risk to the population natural cancer incidence, and to contextualise any further risk against other life events. The most advocated communication strategy would be a graphical representation, but when language is used, then simple language should be utilised. If presented neutrally, these techniques are encouraged by many researchers, and discouraged by none.

The most agreeable method, based on the findings of this systematic review, suggests a pictograph that expresses a naturally-occurring lifetime fatal cancer risk, to which an additive risk of a proposed imaging examination can be added. This technique can be tailored to the patient presentation, easily modified, readily contextualised against other risks, include margins for error, and represents the information to the patient in a way that emphasises simplicity and understanding.

Clinical trials of such a technique may lead to a patient that is better informed about the risks of their proposed imaging examination. This, in turn, may bring medical imaging closer to the ethical ideal of a truly informed consent.

Conflict of interest statement

None.

Acknowledgements

The authors wish to thank Ms. Debbie Booth for valuable guidance and assistance. This research did not receive any specific grant from funding agencies in the public, commercial, or not-for-profit sectors.

References

1. Salgo v. Leland stanford etc. Bd. Trustees. In: *California court of appeals*; 1957. California.
2. Dauer LT, Thornton RH, Hay JL, Balter R, Williamson MJ, Germain St, et al. feelings, and facts: interactively communicating benefits and risks of medical radiation with patients. *Am J Roentgenol* 2011;196(4):756–61. Retrieved from: <https://www.ncbi.nlm.nih.gov/pubmed/21427321>. [Accessed 23 May 2018].

3. Picano E. Informed consent and communication of risk from radiological and nuclear medicine examinations: how to escape from a communication inferno. *BMJ* 2004;**329**(7470):849–51. Retrieved from: <https://www.ncbi.nlm.nih.gov/pubmed/15472270>. [Accessed 23 May 2018].
4. Slovic P, Fischhoff B, Lichtenstein S. Cognitive processes and societal risk taking. In: *Decision making and change in human affairs*. Springer; 1976. p. 7–36. Retrieved from: https://link.springer.com/chapter/10.1007/978-94-010-1276-8_2. [Accessed 23 May 2018].
5. Slovic P. Perception of risk from radiation. *Radiat Protect Dosim* 1996;**68**(3–4): 165–80. Retrieved from: <https://academic.oup.com/rpd/article-abstract/68/3-4/165/1614693?redirectedFrom=fulltext>. [Accessed 23 May 2018].
6. Karsli T, Kalra MK, Self JL, Rosenfeld JA, Butler S, Simoneaux S. What physicians think about the need for informed consent for communicating the risk of cancer from low-dose radiation. *Pediatr Radiol* 2009;**39**(9):917–25. 9pp. Retrieved from: <https://www.ncbi.nlm.nih.gov/pubmed/19557405>. [Accessed 23 May 2018].
7. Sasaki MS, Tachibana A, Takeda S. Cancer risk at low doses of ionizing radiation: artificial neural networks inference from atomic bomb survivors. *J Radiat Res* 2013;**55**(3):391–406. Retrieved from: <https://academic.oup.com/jrr/article/55/3/391/986945>. [Accessed 21 October 2018].
8. Brink JA, Goske MJ, Patti JA. Informed decision making trumps informed consent for medical imaging with ionizing radiation. *Radiology* 2012;**262**(1):11–4. Retrieved from: <https://pubs.rsna.org/doi/full/10.1148/radiol.11111421>. [Accessed 21 October 2018].
9. Einstein AJ, Berman DS, Min JK, Hendel RC, Gerber TC, Carr JJ, et al. Genotoxic damage in non-irradiated cells: contribution from the bystander effect. *Radiat Protect Dosim* 2002;**99**(1–4):227–32. Retrieved from: <https://academic.oup.com/rpd/article-abstract/99/1-4/227/1687780>. Accessed 21 October 2018.
10. National Research Council. *Committee to assess health risks from exposure to low levels of ionizing radiation, health risks from exposure to low levels of ionizing radiation: BEIR VII phase 2*. 2006. Retrieved from: <https://www.nap.edu/catalog/11340/health-risks-from-exposure-to-low-levels-of-ionizing-radiation>. [Accessed 21 October 2018].
11. VALENTIN J. *The 2007 recommendations of the International Commission on Radiological Protection*. 1955. Retrieved from: <http://www.icrp.org/publication.asp?id=ICRP%20Publication%20103>. Accessed 25 November 2018.
12. Jolly D, Meyer J. A brief review of radiation hormesis. *Australas Phys Eng Sci Med* 2009;**32**(4):180–7. Retrieved from: <https://link.springer.com/article/10.1007/BF03179237>. [Accessed 21 October 2018].
13. Mossman KL, Marchant GE. The precautionary principle and radiation protection. *RISK* 2002;**13**:137. Retrieved from: <https://scholars.unh.edu/cgi/viewcontent.cgi?article=1489&context=risk>. [Accessed 23 May 2018].
14. Joanna Briggs Institute. *Critical appraisal tools, in Checklist for qualitative research*. Adelaide: The University of Adelaide; 2017. Retrieved from: <http://joannabriggs.org/research/critical-appraisal-tools.html>. [Accessed 23 May 2018].
15. Bedetti G, Lore C. Radiological informed consent in cardiovascular imaging: towards the medico-legal perfect storm? *Cardiovasc Ultrasound* 2007;**5**:35. Retrieved from: <https://www.ncbi.nlm.nih.gov/pubmed/17916235>. [Accessed 23 May 2018].
16. Westra SJ. The communication of the radiation risk from CT in relation to its clinical benefit in the era of personalized medicine: part 2: benefits versus risk of CT. *Pediatr Radiol* 2014;**44**(Suppl. 3):S25–33. Retrieved from: <https://www.ncbi.nlm.nih.gov/pubmed/25304716>. [Accessed 23 May 2018].
17. Fahey FH, Treves ST, Adelstein SJ. Minimizing and communicating radiation risk in pediatric nuclear medicine. *J Nucl Med* 2011;**52**(8):1240–51. Retrieved from: <https://www.ncbi.nlm.nih.gov/pubmed/21764783>. [Accessed 23 May 2018].
18. Carpeggiani C, Picano E. The radiology informed consent form: recommendations from the European society of cardiology position paper. *J Radiol Prot* 2016;**36**(2):S175. Retrieved from: <http://iopscience.iop.org/article/10.1088/0952-4746/36/2/S175/meta>. [Accessed 21 October 2018].
19. Einstein AJ, Berman DS, Min JK, Hendel RC, Gerber TC, Carr JJ, et al. Patient-centered imaging: shared decision making for cardiac imaging procedures with exposure to ionizing radiation. *J Am Coll Cardiol* 2014;**63**(15):1480–9. Retrieved from: <https://www.ncbi.nlm.nih.gov/pubmed/24530677>. [Accessed 23 May 2018].
20. Perez M, Expert Working Group. *Communicating radiation risks in paediatric imaging - information to support healthcare discussions about benefit and risk*. Switzerland: World Health Organisation; 2016. Retrieved from: http://www.who.int/ionizing_radiation/pub_meet/radiation-risks-paediatric-imaging/en/. [Accessed 23 May 2018].
21. Boutis K, Fischer J, Freedman SB, Thomas KE. Radiation exposure from imaging tests in pediatric emergency medicine: a survey of physician knowledge and risk disclosure practices. *J Emerg Med* 2014;**47**(1):36–44. Retrieved from: <https://www.ncbi.nlm.nih.gov/pubmed/24698509>. [Accessed 23 May 2018].
22. Malone J, Rosario-Perez M, Van Bladel L, Jung SE, Holmberg O, Bettmann M. Clinical imaging guidelines part 2: risks, benefits, barriers, and solutions. *J Am Coll Radiol* 2015;**12**(2):158–65. Retrieved from: <https://www.sciencedirect.com/science/article/pii/S1546144014004116>. [Accessed 23 May 2018].
23. Merck LH, Ward LA, Applegate KE, Choo E, Lowery-North DW, Heilpern KL. Written informed consent for computed tomography of the abdomen/pelvis is associated with decreased CT utilization in low-risk emergency department patients. *West J Emerg Med* 2015;**16**(7):1014–24. Retrieved from: <https://www.ncbi.nlm.nih.gov/pubmed/26759646>. [Accessed 23 May 2018].
24. Ukkola L, Oikarinen H, Henner A, Haapea M, Tervonen O. Patient information regarding medical radiation exposure is inadequate: patients' experience in a university hospital. *Radiography* 2017;**23**(4):e114–9. Retrieved from: <https://www.ncbi.nlm.nih.gov/pubmed/28965905>. [Accessed 23 May 2018].
25. Carpeggiani C, Paterni M, Caramella D, Vano E, Semelka RC, Picano E. A novel tool for user-friendly estimation of natural, diagnostic and professional radiation risk: radio-Risk software. *Eur J Radiol* 2012;**81**(11):3563–7. Retrieved from: <https://www.ncbi.nlm.nih.gov/pubmed/21820256>. [Accessed 23 May 2018].
26. Lumbreras B, Vilar J, González-Álvarez I, Guilabert M, Pastor-Valero M, Parker JA, et al. Avoiding fears and promoting shared decision-making: how should physicians inform patients about radiation exposure from imaging tests? *PLoS One* [Electron Resour] 2017;**12**(7), e0180592. Retrieved from: <http://journals.plos.org/plosone/article?id=10.1371/journal.pone.0180592>. [Accessed 23 May 2018].
27. Younger C, Douglas C, Warren-Forward H. Medical imaging and informed consent—Can radiographers and patients agree upon a realistic best practice? *Radiography* 2018;**24**:204–10. Retrieved from: [https://www.radiographyonline.com/article/S1078-8174\(18\)30009-9/fulltext](https://www.radiographyonline.com/article/S1078-8174(18)30009-9/fulltext). [Accessed 23 May 2018].
28. Hoffman FO, Kocher DC, Apostoaei AI. Beyond dose assessment: using risk with full disclosure of uncertainty in public and scientific communication. *Health Phys* 2011;**101**(5):591–600. Retrieved from: https://journals.lww.com/health-physics/Abstract/2011/11000/BEYOND_DOSE_ASSESSMENT_USING_RISK_WITH_FULL.20.aspx?casa_token=sAW0ts0KtEkaAAAA:tBZVF3_DQv3rxqBzF0t7fLbXwi4mg80PrzSy60-0Sj7YvqSA0YCOodZlvuwx3P6xY0AF946_vlNF4HPKzA1OeQnNyx. [Accessed 21 October 2018].
29. Howard RA. On making life and death decisions. In: *Societal risk assessment*. Springer; 1980. p. 89–113.
30. Cameron J. A radiation unit for the public. *Phys Soc News* 1991;**20**:2.
31. Nickoloff EL, Lu ZF, Dutta AK, So JC. Radiation dose descriptors: BERT, COD, DAP, and other strange creatures. *Radiographics* 2008;**28**(5):1439–50. Retrieved from: <https://www.ncbi.nlm.nih.gov/pubmed/18794317>. [Accessed 23 May 2018].
32. Kimball RF. DNA repair and its relationship to mutagenesis, carcinogenesis, and cell death. *Cell Biol A Compr Treatise V2 Struct Replication Genet Mater* 2012;**2**:439.
33. Di Lorenzo L, Coco V, Forte F, Trinchese GF, Forte AM, Pappagallo M. The use of odds ratio in the large population-based studies: warning to readers. *Muscles Ligaments Tendons J* 2014;**4**(1):90. Retrieved from: <https://www.ncbi.nlm.nih.gov/pmc/articles/PMC4049657/>. [Accessed 21 October 2018].
34. Davies HTO, Crombie IK, Tavakoli M. When can odds ratios mislead? *BMJ* 1998;**316**(7136):989–91. Retrieved from: <https://www.bmj.com/content/316/7136/989.short>. [Accessed 21 October 2018].
35. Howard RA. *Readings on the principles and applications of decision analysis*, vol. 1. Strategic Decisions Group; 1983.
36. National Safety Council. *Odds of dying*. 2017. Retrieved from: <http://injuryfacts.nsc.org/all-injuries/preventable-death-overview/odds-of-dying/data-details/>. [Accessed 23 May 2018].
37. Australian Institute of Health and Welfare. *Cancer in Australia 2017*. Canberra: Australian Institute of Health and Welfare; 2017. Retrieved from: <https://www.aihw.gov.au/reports/cancer/cancer-in-australia-2017/contents/table-of-contents>. [Accessed 23 May 2018].
38. Malone J, Guleria R, Craven C, Horton P, Järvinen H, Mayo J, et al. Justification of diagnostic medical exposures: some practical issues. Report of an International Atomic Energy Agency Consultation. *Br J Radiol* 2012;**85**(1013):523–38. Retrieved from: <https://www.ncbi.nlm.nih.gov/pmc/articles/PMC3479887/>. [Accessed 23 May 2018].