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Barriers and pathways to informed consent for ionising radiation imaging examinations: A qualitative study

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ABSTRACT

Introduction: Informed consent for ionising radiation medical imaging examinations represents a recent change to medical imaging practice. This practice has not had a definitive and authoritative integration into clinical practice, and lack of direction has caused many health care professionals to be unsure of an appropriate consent methodology. Consent practices have been undertaken inconsistently and sometimes poorly. This research sought to investigate what barriers exist to meaningful informed consent, and what pathways are suggested to overcome these barriers. These views are then discussed in the context of practical health care consent practices.

Methods: A semi-structured interview explored the views of radiographers and radiologists on the practice of disclosing the ionising radiation risk of a clinical medical imaging examination. Qualitative data was analysed using a nominal method of quantitative transformation. Responses were reviewed, and a set of definitive themes constructed. Participants considered the influences, logistics and barriers to the informed consent process. Participants were then asked what pathways might be developed that would improve the process.

Results: Twenty-one (21) radiographer participants and nine (9) radiologists were interviewed. The barriers to consent identified issues of time constraints, lack of a unified message, and patient presentations. Pathways suggested included limiting the scope of the consent practice, sharing the consent responsibility, and formulation of definitive consent guidelines.

Conclusion: A unified, definitive series of guidelines for informed consent for ionising radiation examinations would alleviate many of the identified barriers. Having the consent process consistently begin with the referring doctor would facilitate more meaningful consent.

Introduction

Informed consent for ionising radiation medical imaging examinations represents a relatively recent change to the practice of radiographers[1] and radiologists.[2] This practice has not had a definitive and authoritative integration into clinical practice, and this lack of direction has caused many health care professionals to be unsure of an appropriate and robust methodology for this practice.[3,4]

Informed consent practices may vary between radiographers, radiologists and referrers,[5] leading to a practice that has been shown to be undertaken inconsistently,[4] and sometimes poorly.[6] Some variation in practice is to be expected, as there is considerable variation between different nations' approaches toward regulatory practice.[7,8] However, lack of consent education,[4] and time commitments[9] have been identified as widespread negative influences on the practice.

This research follows on from a survey investigating the process of informed consent for ionising radiation medical imaging examinations,[10] which highlighted these negative influences. The survey identified a wide range of practices, a resistance to the informed consent process, and a common theme of lack of direction in the practice.

This research sought to investigate what barriers exist to an informed consent process for ionising radiation medical imaging examinations that is practical for the health care professional, and meaningful for the patient, and to investigate what pathways are suggested to overcome many of these barriers. The viability of these

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views are then discussed in the context of contemporary health care practice.

Methods

Study design

A systematic review of literature was undertaken by the authors investigating the advocated processes and methodologies in the informed consent process.[11] This review identified a number of themes, most particularly the barriers to consent such as time commitment,[11] patient limitations,[11–13] referrer limitations,[13] unclear roles[12,13] and professional considerations.[13] These identified barriers (and some suggested pathways) and the results from a previous survey[10] led to the development of the interview questions. A semi-structured interview was designed to explore the views of radiographers and radiologists on the practice of disclosing the ionising radiation risk of a clinical medical imaging examination. The interview questions were reviewed by a panel of academics to ensure face and construct validity prior to implementation.

The *reliability* of the process[14] is difficult to assess, given the number of variables, however the consistency of interview technique was recognised (one interviewer and prepared interview script), and adhered to insofar as this did not compromise the organic nature of the interview process. The *validity* of the process[14] is considered to be good, in that the qualities measured (specifically, barriers and pathways) were those intended for measurement. There was good disclosure of personal influence from the respondents. Reflection on the linear study design and implementation suggest an appropriate level of robustness and rigour.[14,15]

Participants

The target populations were practicing radiographers and radiologists (including accredited radiology registrars) from both private and public settings and general practitioners (representing referrers) working in all Australian States and Territories. Accredited radiology registrars were included in this group, as they would have undertaken the *Patient Safety* and *Advanced Imaging Training* components of the Royal Australian and New Zealand College of Radiologists' *Radiodiagnosis Training Program Curriculum*,[16] and should be knowledgeable about both radiobiology and the informed consent process. One radiologist and two radiographers received their training in the United Kingdom; the rest were Australian trained.

Recruitment

Participants were recruited through professional groups, postgraduate professional education groups, and through social networks, primarily Facebook. This wide recruitment process was undertaken to maximise volunteers. Volunteer participants were provided with information statements and gave their consent to the interview process. Each participant had at least three years' experience from their undergraduate training, and were regular users of ionising radiation, including fluoroscopic and CT imaging.

Survey tool

Participants were asked to consider the influences, logistics and barriers to the informed consent process as well as professional and educational influences. Participants were then asked to consider and discuss potential pathways to facilitate the informed consent process. There were twenty questions in total (Appendix).

Procedures

The study received approval from the [redacted] Human Research Ethics Committee (Approval No. H-2013-0433). The interview (conducted either face—face or via telephone) was digitally recorded. Privacy, quiet and available time were emphasised when organising interviews, particularly for phone interviews. While non-verbal cues could be missed with the telephone interview, this was not considered important given the phrasing of the questions. The resultant recording was transcribed using automated audio transcription (www.trint.com). The transcription was then reviewed and proofread against the audio file. The transcription was then sent to the individual participant, who had the opportunity to retract their involvement, and to amend, edit or retract any comments before a final authorised transcription was analysed.

Data analysis

Qualitative data was analysed using a nominal method of quantitative transformation,[17] as the nominal variables cannot be organised hierarchically based on importance.[18] Key words, phrases (and their synonyms) were recorded by frequency. Frequency is considered the most appropriate statistic for describing nominal variables.[18,19] The frequency was considered to correlate to the importance the participant placed on the word or phrase, not necessarily on the process being investigated. Two researchers independently reviewed the articles, constructed their own theme titles, and recorded frequencies.

The two researchers then discussed, and agreed upon definitive minor theme titles (e.g. *Referrer Knowledge*). These minor themes were then inductively codified into the major themes. The responses were then reviewed using these definitive major theme titles, and the theme frequency counted. Examples of some quotes and assignment to themes are given in Table 2.

Results

Thirty participants responded to the invitation to be interviewed and all were interviewed. This comprised twenty-one radiographers and nine radiologists. Interviews ranged from 11 min to 26 min, and averaged 19 min.

Summary demographics are presented in Table 1. General practitioners were invited as a target population, but none accepted the invitation to participate.

Table 1
Demographic characteristics of the participants.

Characteristic	Radiographer		Radiologist		TOTAL	
	n (21)	%	n (9)	%	n (30)	%
Age						
18–30	13	62	2	22	15	50
31–40	3	14	2	22	5	17
41–50	2	10	2	22	4	13
51–60	3	14	3	33	6	20
Gender						
Male	6	29	6	66	12	40
Female	15	71	3	33	18	60
Majority Employment						
Public Health	7	33	2	22	9	30
Private Health	14	66	7	77	21	70

Over all questions, the theme count agreement between the researchers ranged between 98.2% and 100%. The reviewers then reviewed all disagreements to reach consensus.

Table 2
Frequency of themes.

Major Theme (frequency)	Minor Theme (frequency, percentage)	Example Quote
Scope of Practice (90)	Patient Presentation (n = 37, 41%)	“Pregnant women and paediatrics are an important consideration”
	Clinical History (n = 24, 27%)	“It mostly depends on the clinical history [as to the viability of consent]"
	Stratification of Consent (n = 29, 32%)	“I think screening would be a good line in the sand [as a threshold of consent]”
Barriers to Consent (75)	Patient Knowledge & Capacity (n = 22, 29%)	“not every [patient] is going to be able to understand what you're saying”
	Time Commitment (n = 53, 71%)	[Active Informed Consent] “…would just take up too much time”.
Ethical Care (51)	Autonomy (n = 47, 92%)	“If a patient wants to know, they have every right to know”.
	Ethics vs. Logic (n = 4, 8%)	“After a certain age, do we just not worry?”
Professional Roles (48)	Medical Portfolio (n = 40, 83%)	[Considerations of informed consent] are above my pay grade”.
	Message Reinforcement (n = 5, 10%)	“…back up the doctor and tell the patient that the benefit outweighs the risk”.
	Professional Hierarchy (n = 3, 7%)	“I believe patients are sent to us for an x-ray for justified reasons. And who am I to question that?”
Education and Training (42)	Education and Training (42, 100%)	“I don't think we're taught well enough, at all”
Paternalism vs Autonomy (31)	Examination Priority (n = 24, 77%)	“Just do what the referring GP has asked without any other considerations”
	Patient discharging responsibility (n = 4, 13%)	[In such circumstances] “I'd probably just do it and say "There you go".”
	Risk/Benefit already factored (n = 3, 10%)	“I assume that the referring doctor, that they've weighed up the risk versus benefit already”.
Referrer Relationship (27)	Referrer Relationship (20)	“If a physician refers for something, whether we think it is insane or not, most of the time, they'll get what they want”.
	Referrer Knowledge (7)	“The referring doctor should be more knowledgeable on radiation”
Information Delivery (21)	Pamphlets (14)	Pamphlets have great potential value … I think especially average doses for each examination”
	Consistency of Message (7)	“It would need to be a standardised message, from the top, down.”

Qualitative analysis

Quotes from radiographers are noted with [T], and radiologists with a [D].

Table 2 shows eighteen minor themes (and example quotes) and eight subsequent major themes. A phrase with high frequency might represent importance to the individual respondent, but this does not guarantee that it is necessarily impactful to the process being investigated. Ethical care (for example) was frequently mentioned, but may not heavily influence the logistics of the informed consent process.

Theme 1: Scope of practice

The most common theme was that the informed consent process should be limited in scope, and only undertaken for specific patient presentations (with paediatrics and pregnant patients frequently cited as radiosensitive populations) or for higher dose examinations. Many radiologist participants indicated that “*CT, fluoroscopy, DSA, and any [interventional] fluoroscopic procedures … should be consented. Standard x-rays … I don't believe they should be consented*” (D07). Many radiographers agreed: “*I don't think it's necessary for plain radiography, full stop… I just fail to see the logic of it*” (T01).

Fig. 1 shows the responses of both groups when asked if an ionising radiation dose could be low enough that it did not require disclosure to the patient. The majority of radiographers (52%, n = 11) and radiologists (89%, n = 8) responded that radiation doses below those normally encountered in fluoroscopic examinations did not need to be disclosed to the patient (assuming an appropriate examination, and that the patient was not specifically radiosensitive). The threshold was lower for radiographers, with one-third of the radiographer participants indicating that all radiation doses required disclosure.

Theme 2: Barriers to consent

Many participants recognised that meaningful informed consent for ionising radiation in the clinical environment had many barriers, with time constraints being the most frequently cited: “*How much time would be allocated if every patient wanted informed consent? It wouldn't happen. So what we end up with then is … having to pick and choose*” (D06).

However, patient knowledge and cognition (and the subjective recognition of poor cognition) was also recognised as a challenge: “*a patient is … by definition, they are unwell. You can't judge their level of mental status, their level of knowledge, or … their capacity to understand*” (D01). Some participants gave the opinion that in the modern era of information availability, a patient can readily be informed, but information doesn't necessarily lead to constructive knowledge, but may lead to escalating undue concern: “*They've just got enough knowledge to be dangerous to you professionally. You can just tell they know just enough to be dangerous but not really enough to actually know*” (T01).

Conversely, some radiologist participants recognised that patients may wish to discharge the responsibility for their care: “*They say ‘Doctor, I trust you. If you think that's the right thing to do, please go ahead, I trust you*’” (D09). In light of this, some participants suggested that the practice of risk disclosure be undertaken only if the patient requests such information: “*…only if they bring it up, if they have a question. You would never bring it up with a patient unless they had that query first off*” (T16).

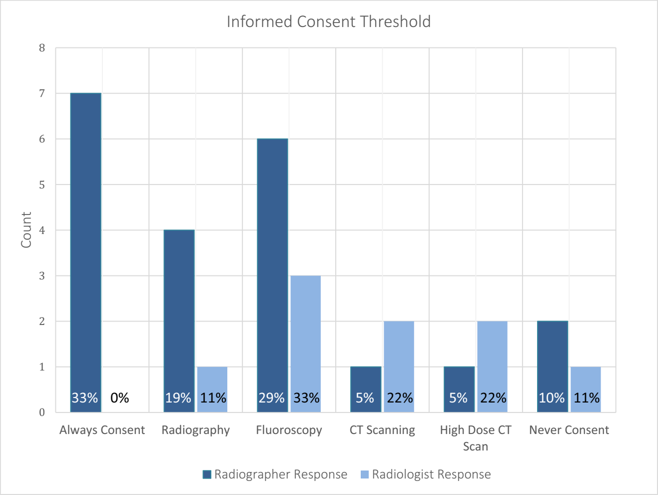

Figure 1. The informed consent dose threshold in response to the question “When should consent be sought?”.

Theme 3: Ethical care

Many of the interview questions were centred on informed consent and patient autonomy. Predictably, ethical considerations were referred to frequently, making ‘ethical care’ the third most cited theme. Within this theme, recognising patient autonomy was frequently emphasised. Ethical care of the patient was recognised as being the driving force behind the informed consent process: “*Every patient has a right to know what they're doing and why they're doing it*” (T14). Respondents indicated that ethical care represented the reason *why* the process was undertaken, not *how*; simply, that it was important that an ethical standard was met for any consenting process.

However, many participants gave the opinion that disclosing risk might not have any impact for the patient, but that it was undertaken because it was ethically correct, rather than being driven by logic.

Theme 4: Professional roles

The topic of professional roles and hierarchies were discussed by many participants: “*I feel like we are just radiographers*. *There's this hierarchy … because they're doctors*, *and* of course *they know more*” (T09). Discussing alternate examinations, for example, was seen as “*undermining the physician who has sent the patient in the first place*” (T01). This view was shared by the radiologists: Informed consent being “*in the portfolio of the physician*” (D01). “[*Discussing the validity of a scan] is more in the sphere of the medical… what is the risk of* not *making a diagnosis?*” (D06) and that “*It is better coming from [a radiologist]*, *who might understand why the patient has to have that particular scan … understanding the alternatives*, *explaining what the clinical entity it is that they are looking for*” (D03).

Both groups strongly advocated informed consent beginning with the referrer. “*I believe [informed consent] is only effectively done by a practitioner who can do so accurately*, *and … who can also [discuss] the risks if they don't have the study*, *like the potential for things to be undiagnosed … I'm mindful of potentially making a patient not have a study that they possibly should*” (T11), but that “*It's safest to assume they haven't had anything*” (D06). Many radiographers responded that they only felt comfortable reinforcing the opinions or values already given by the referrer: “*We [reiterate to patients] that the referring physician is acting in the best interests of the patient*” (T02).

Theme 5: Education and training

A common theme among participants was that they had concerns regarding their ability to provide information which was accurate, contemporary, and supported by their employer. Many participants felt frustration at the implementation of the informed consent process without training. “*If it is an institutional necessity that we have [informed consent] then it should be done properly*, *not this … hatchet job that's being done at the moment. If they want us to give informed consent then tell us what that informed consent* is *… then it's a uniform message from the whole staff*” (T01).

Theme 6: Paternalism vs. autonomy

Balancing the need for patient autonomy with the need to prioritise workflow and/or the patient's best care was emphasised by a number of participants. Some participants gave the opinion that a beneficent paternalistic approach (without informed consent) has merit: “*I think*, *given how low the doses are these days*, *I think probably enough thinking happens at the ordering physician's level*” (D02).

Some radiographer participants had similar views: “*If the health care professional has decided that they need this test … they have decided that the benefit outweighs the risk. I don't see it's for us to … go against the doctor's wishes. He needs that information for the patient management*; *you should go ahead and do it*” (T01).

Theme 7: The referrer quandary

A common theme was the importance of the relationship between the referrer and the imaging provider: “*We don't want to stop the relationship between the [referrer and imaging provider]*” (D04). The ongoing relationship was described by radiographer participants as “*very big*” (T23) and “*important*” (T18).

When asked whether the informed consent process should have taken place by the time the patient arrives for their examination, no participant from either group disagreed; “*responsibility (for the informed consent process) comes from the GP referring the patient*” (T12), and that “*It has to be done by the referring doctor … (but that) I don't think it ever has*” (D08).

A recurring theme was that referring physicians (being a key figure in the process of informed consent) may not have a good knowledge base on the risk involved in ionising radiation examinations “*I don't think [referring physicians] know about radiation safety*, *about how much radiation an abdomen CT will give*” (D09), and that referrers may not appreciate alternate studies that might be available or suitable. Thus, there is a desire to improve referrer knowledge, but not compromise the referrer–provider relationship. Of particular interest is the finding that all three United Kingdom trained radiographers espoused the virtues of The United Kingdom's *Ionising Radiation (Medical Exposure) Regulations* (IR(ME)R),[20] citing that the referrer had a greater regulatory answerability to examination justification, which may lead to a greater knowledge base.

Theme 8: Information delivery

A frequent theme when discussing communication and risk information provision was that the information should be provided by an appropriate authority, supported by the professional bodies of the participating stakeholders (radiographers, radiologists and referrers). This was supported by radiographers: “*I'd feel more comfortable if there was something from [an authorising body] stating the facts*” (T10), and that “*a [statement] that's in print would give [the patient] more confidence that I'm not making it up*” (T02).

Radiologists were similarly supportive: “*I think some extra resources could be really useful… having some sort of information sheet that's generally agreed upon by countrywide or state-wide would be really useful. Because they know they're getting genuine information*” (D08), and that “*You cannot have enough material in terms of radiation safety*” (D09).

The need for patients to be given time to process the risk and benefit information provided was also emphasised by some participants: “*A lot of the stuff they actually need to think about for a bit longer than thirty seconds. It needs to be at … point of referral*”; “*informed consent actually means not only do you have to give them information*; *you have to give them time to actually process and think about it. A lot of time we don't give them enough time for that*” (D06).

Discussion

Barriers to informed consent

Radiographers and radiologists have clearly indicated that there are barriers to the informed consent process.

The most emphasised barrier is the time commitment. Time is an important resource in health care. In the opinions of participants, providing active informed consent (including risk disclosure) for all ionising radiation medical imaging examinations represents a significant time commitment, impacting on efficient throughput of patients. Studies have agreed that such a time commitment would be prohibitively long.[9]

Many radiographers and radiologists have little confidence in the correctness of their information. This lack of confidence is exacerbated by a lack of knowledge regarding *who* should provide what information, *how* and *when* it should be provided, and *how much* information to provide.

Many radiographers and radiologists are keenly aware of the need to maintain a healthy relationship with their referrer. However, participants expressed concerns about the referrer knowledge base regarding ionising radiation risk, or potential alternative studies; this concern is echoed in a number of studies.[3,21–26] Thus placing the imaging provider in a quandary; what might be *good for business* might not be the best ethical care of the patient.

Consequently, radiographers and radiologists indicated that in their own practice, they deliver risk information to the patient carefully and conservatively. Participants are concerned that they might compromise a necessary examination, undermine the referrer relationship, upset the professional hierarchy, or make themselves vulnerable for some medicolegal reprisal.

Pathways toward informed consent

Within this framework, is there a way to provide ionising radiation risk information that is meaningful for the patient? Based on the comments of the participants, three suggested pathways are suggested to overcome the barriers to informed consent[1]: Development and dissemination of authoritative information[2]; Initiating the informed consent process at referral; and[3] Considering a limited scope of ionising radiation consent.

In Australia, the regulatory agency for radiation protection is the Australian Radiation Protection and Nuclear Safety Agency (ARPANSA), a Federal Government agency. ARPANSA's *Protection of the Patient* module, and the associated *Guide for Medical Imaging*[27] could form the foundation of a stakeholder-friendly and/or patient-friendly resource for patients.

Stakeholder bodies such as the Australian Health Practitioner Regulation Agency, the Royal Australian and New Zealand College of Radiologists, the Australian and New Zealand Society of Nuclear Medicine and the Australasian College of Physical Scientists & Engineers in Medicine might be appropriate contributors.

A unified message, particularly on ionising radiation risk disclosure methodology[28] would greatly empower the information provision process. A patient-friendly document would empower the patient, and increase their confidence in the quality of care being provided to them.

Participants expressed the view that the referrer should initiate the informed consent conversation, by providing contextualised risk and benefit information, but that this rarely happens. If the role of the referrer as the initiator of consent were recognised as an essential component of care (and formalised in their practice), this might eliminate many of the expressed participant concerns of role responsibility and time management. Such a pathway is supported in the literature.[4,25,29]

On referring a patient for a medical imaging examination, the referrer might contextualise the risk and benefit scenario (with increased confidence and knowledge from utilising the previously mentioned authoritative document), and then provide the patient with a suitable materials (or an online link to such materials). This seems a reasonable pathway of care, as this practice probably should already happen.[6,30] Regulatory control of practice, such as the United Kingdom's IR(ME)R protocols, may also be a pathway here.

The patient, as a health care consumer, has a right to authoritative information and enough time to process such information, and to formulate any questions that might arise from it.[31,32] Based on the participant responses, patients tend to be a passive, accepting participant in their care, and may suffer from poor information quality (or the time needed to process the information). By empowering the patient to be an active participant in their care, and by providing quality information early in the process, patients might be given greater autonomy and have the best chance to be an educated consumer.[31]

At the time of the examination, if there is confidence that the patient has been given adequate information (“Did your doctor discuss this examination with you?”), and that the patient is satisfied (“Do you have any questions about this test?”), then if the patient consents to the examination (or unquestionably implies consent), it is probably reasonable to conclude that the patient has given their *informed* consent.

Is there a minimum threshold of dose before ionising radiation risk needs to be disclosed? The majority of radiographer and radiologist participants gave the opinion that fluoroscopic examination dose levels (and above) represented a significant enough dose to disclose to the patient (assuming that the examination was appropriate, and that the patient was not specifically radiosensitive). The dose of plain radiographs was not considered to be significant.

In previous studies, considering a *hypothetical* medical imaging examination, patients reported *all* doses to be potentially significant[10] (essentially, a zero threshold). Obviously, a zero threshold represents the greatest time commitment on health care professionals. Such a threshold also has the potential to create concern or suspicion in patients that might question *why* a risk is being disclosed to them (potentially delaying or compromising their care).

Conversely, higher dose ionising radiation medical imaging examinations represent a risk (averaged over a population) that a reasonable patient might consider significant in the context of their proposed treatment. While some studies have shown that “not all patients wanted to have information about radiation, and some [are] happy to adopt a more passive role”,[33] this is not in line with the principle of the proactive duty to disclose risk.[34] Not disclosing risk does not represent ethical care.

The threshold lies somewhere between these points

A single posteroanterior chest radiograph has a dose of 0.02 mSv,[35] which equates to a one in one million risk (averaged over a population), using the International Commission on Radiological Protection risk model estimates.[20] Some authors have suggested that “a risk of death of one in one million is generally ignored, since we face many risks of such magnitude every day”,[3] and that “the principle of patient autonomy in current radiological practice might be reinforced by making it mandatory to obtain informed consent for all [examinations] with an associated risk of 1 in 10000 or higher”.[3]

A risk of one in ten thousand represents a (population averaged) dose of 2 mSv. This is the dose of a CT scan of the head, and approximates that of lower-dose fluoroscopic procedures.[35] The highest reported dose for a lumbar spine (representing high dose plain radiography), by comparison, is 1.8 mSv.[35] Fluoroscopy, as a threshold, has been supported by some authors.[9,29,31]

Is this a defensible threshold of dose? This is a very difficult question. It is a multi-factorial consideration that essentially involves placing one's self in the position of the patient. A threshold of risk significance is a statement of best-fit. Recognising these considerations, however, it seems reasonable to support the notion that a (non-radiosensitive) patient does not need to have the ionising radiation risk of a plain radiograph disclosed. This pathway alone would represent an ethically defensible change to informed consent practice that could greatly reduce the time commitment.

Limitations

The greatest limitation of this study was that one potential response group did not provide any participants. The views of General Practitioners (representing the referrer base) would have added great value to this research, as this group represents the start of the medical imaging process, and it is presumptuous to suggest how the referrer group can improve the patient journey without consultation. Attempts were made to include this participant group through various avenues, and the views of this group represent a worthwhile avenue for future investigation.

Patients (or members of the public) have not been included in this study. There would be value in assessing if the attitudes of patients reflect those suggested by respondents. There would be further value in assessing the acceptance of patients to the proposed pathways. This forms an avenue of potential future research.

It should also be noted that differences between national regulatory practices may vary the efficacy of some of the pathways suggested. Nations with stricter guidelines on the use of ionising radiation may have less need to consider factors such as time commitments when considering changes to practice.

Conclusion

Barriers to informed consent have been identified by participants. Lack of definition of this practice has led most participants to be unsure of the scope, nature, and requirements of informed consent. Unified, authoritative definition of the risks involved in ionising radiation examinations (ideally developed by the stakeholder regulatory bodies) has the potential to greatly reduce these concerns, and to provide a unified message to the patient.

The patient has a right to be informed about significant risk. If informed consent is initiated at the time of the examination, patient information and autonomy can be greatly improved. This has the potential to greatly reduce the time commitment involved in consent. Radiographers and radiologists believe that plain radiographs do not represent a significant risk, and do not need to be disclosed to the patient.

Conflicts of interest

None.

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Appendix A. Supplementary data

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