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Review of Radiation Dose Metric Tracking for Patients: Ethical Implications of the "Do Not Disclose" Standard

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Les tests d'imagerie diagnostique médicale qui produisent des rayonnements ionisants utilisent désormais une technologie qui permet de connaître la dose de rayonnement cumulée d'un patient. Cela soulève la question de savoir s'il est impératif que les autorités sanitaires régionales divulguent ces informations aux médecins, qui peuvent alors faire participer leurs patients à la décision de savoir si les inconvénients potentiels valent les avantages de l'imagerie diagnostique ultérieure. Actuellement, les organismes professionnels qui fournissent des normes de pratique pour l'imagerie diagnostique médicale conseillent de ne pas divulguer ces informations aux médecins. Ils craignent que les informations sur les doses cumulées soient difficiles à évaluer en termes de risque pour les patients individuels, qu'elles ne soient pas facilement applicables à la prise de décision clinique sur l'opportunité d'un examen d'imagerie ultérieur, et que les cliniciens référents se sentent obligés de proposer à un patient un test non ionisant moins efficace, ce qui pourrait avoir un impact négatif sur les soins prodigués au patient. Nous présentons une analyse critique de plusieurs hypothèses qui sous-tendent la position de non-divulgation. Travaillant à l'intersection de la physique médicale, de l'anthropologie médicale et de l'éthique clinique, nous proposons une autre formulation du discours sur le risque qui a façonné le récent débat scientifique sur la divulgation de la dose de rayonnement cumulée individuelle. Nous postulons qu'il est possible de présenter un argument convaincant contre la position des organismes professionnels et en faveur d'une politique de divulgation – à condition qu'une telle politique donne la priorité à la décision partagée centrée sur le patient.

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Review of Radiation Dose Metric Tracking for Patients: Ethical Implications of the "Do Not Disclose" Standard

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Résumé

Les tests d'imagerie diagnostique médicale qui produisent des rayonnements ionisants utilisent désormais une technologie qui permet de connaître la dose de rayonnement cumulée d'un patient. Cela soulève la question de savoir s'il est impératif que les autorités sanitaires régionales divulguent ces informations aux médecins, qui peuvent alors faire participer leurs patients à la décision de savoir si les inconvénients potentiels valent les avantages de l'imagerie diagnostique ultérieure. Actuellement, les organismes professionnels qui fournissent des normes de pratique pour l'imagerie diagnostique médicale conseillent de ne pas divulguer ces informations aux médecins. Ils craignent que les informations sur les doses cumulées soient difficiles à évaluer en termes de risque pour les patients individuels, qu'elles ne soient pas facilement applicables à la prise de décision clinique sur l'opportunité d'un examen d'imagerie ultérieur, et que les cliniciens référents se sentent obligés de proposer à un patient un test non ionisant moins efficace, ce qui pourrait avoir un impact négatif sur les soins prodigués au patient. Nous présentons une analyse critique de plusieurs hypothèses qui sous-tendent la position de non-divulgation. Travaillant à l'intersection de la physique médicale, de l'anthropologie médicale et de l'éthique clinique, nous proposons une autre formulation du discours sur le risque qui a façonné le récent débat scientifique sur la divulgation de la dose de rayonnement cumulée individuelle. Nous postulons qu'il est decision making, radiologists as risk-interpretation experts, and possible de présenter un argument convaincant contre la the authority of the prescribing physician. position des organismes professionnels et en faveur d'une politique de divulgation - à condition qu'une telle politique donne la priorité à la décision partagée centrée sur le patient.

Mots-clés

rayonnement, risque, consentement éclairé, politique de radiation, risk, informed consent, disclosure policy, medical divulgation, imagerie médicale

Abstract

Medical diagnostic imaging tests that produce ionizing radiation now deploy technology that captures an individual patient's cumulative radiation dose. This raises the question of whether there is an imperative for regional health authorities to disclose this information to physicians who may then engage their patients in decisions about whether the potential harms are worth the benefits of subsequent diagnostic imaging. Currently, the advice of the professional bodies providing standards of practice for medical diagnostic imaging is to withhold this information from physicians. Their concern is that cumulative dose information is difficult to evaluate in terms of risk to individual patients; it is not easily applicable to clinical decision making about the appropriateness of a subsequent imaging exam; and referring clinicians will feel compelled to offer a patient a less efficacious non-ionizing test, which could negatively affect patient care. We present a critical analysis of several assumptions underlying the stance of non-disclosure. Working at the intersection of medical physics, medical anthropology, and clinical ethics, we offer an alternative framing of the discourse of risk that has shaped the recent scholarly debate on disclosure of individual cumulative radiation dose. We posit that a persuasive argument can be made against the stance of the professional bodies and for a policy of disclosure - provided that such a policy prioritizes patient-centred shared

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INTRODUCTION

It is well established that medical diagnostic imaging producing ionizing radiation can have adverse health effects on patients as well as radiology technicians. Studies examining those risks have contributed to changes in practice, particularly since the late 2000s, with prescribing physicians becoming more reflective over whether to request medical imaging tests, institutions implementing new protocols to ensure that tests producing ionizing radiation are not being over-used, and industry developing technologies to lower radiation doses (1-11).

As part of this increased scrutiny over risks, the technology has advanced, and data archiving systems are now able to provide a numerical value for the amount of radiation that has been used for each ionizing radiation examination and from these values compute a patient dose estimate using a priori knowledge and simulations (12). One value generated over time is "cumulative dose", that is, the sum of the individual estimated doses the patient has received over time. This ability to track and monitor each patient's cumulative dose raises the question of whether there is an imperative to disclose this information to physicians, who might then engage in discussion with their patients to determine whether the potential harms are worth the benefits of subsequent diagnostic imaging.

On one hand, some clinicians argue that there are advantages to providing risk statistics. Doing so supports the principle of informed consent to treatment: prescribing physicians and patients can weigh the future risk of harm related to overall radiation load against the potential health effects of not receiving a CT scan (for example) to inform a treatment decision. Physicians who argue for disclosure believe that knowledge of patient radiation history would be helpful for facilitating patient decisionmaking and discussions regarding the risks and benefits of imaging (13-16). On the other hand, there are those who argue against the release of a cumulative dose estimate. These scholars note that the risk of radiation exposure from diagnostic imaging is stochastic (that is, random, like the roll of dice), and therefore an individual's cumulative dose exposure cannot be used in a predictive sense (6,17-21). The concern is that prescribing physicians will use the information to decide against a subsequent diagnostic imaging exam, inadvertently to the detriment of that patient's health.

In the United States, professional oversight organizations agree with those recommending a policy of non-disclosure. In August 2021, the American Association of Physicists in Medicine (AAPM), the American College of Radiology (ACR), and the Health Physics Society (HPS) jointly released a position statement advising against using information about a patient's cumulative radiation dose from medical imaging in determining the appropriateness of a subsequent imaging exam (22). Similarly, Canada's Association of Radiologists Radiation Protection Working Group has come out strongly in support of a policy of non-disclosure (20). Its members argue that a cumulative dose history provides no clinical decision-making benefit to an individual patient, and the frequency and number of previous diagnostic exams should not discourage a clinician from requesting a subsequent exam.

We critically examine the assumptions that shape this advice. We begin with the premise that recent international ethics frameworks for radiological protection – which emphasize the importance of the values of accountability, transparency and inclusiveness in the practical implementation of radiological protection (9,10,11) – are well conceived and unproblematic. We concur that these procedural values are key for supporting the aims of the system of radiological protection and its fundamental principles of justification, optimization, and individual dose limitation (9,10,11). We question why, given the emphasis on transparency and inclusiveness in the international ethics framework, the scholarly debate over the merits of disclosure versus nondisclosure of risk has been translated into a professional standard of nondisclosure.

Working at the intersection of medical physics, medical anthropology, and clinical ethics, we offer an alternative framing of the discourse of risk that has shaped the scholarly debate on disclosure of individual cumulative radiation dose. Our intent, with this gentle prod at the normative assumptions that underlie concerns related to disclosure, is to advance scholarly debate on this important issue. We posit that a persuasive argument can be made against the stance of these professional bodies and thus in favour of a policy of disclosure, provided that such a policy prioritizes patient-centred decision making, radiologists as risk-interpretation experts, and the authority of the prescribing physician.

IONIZING RADIATION AND THE COMPLEXITIES OF RISK

Diagnostic imaging is central to patient care and generally is non-invasive. By far the most commonly used imaging method involves the use of x-rays generating electromagnetic radiation in the 30 PHz to 30 EHz frequency range. This radiation has enough energy to break chemical bonds forming ions. These ions may initiate chain reactions, breaking chemical bonds and so disrupting cellular function. Ionizing radiation may also have long term effects, such as targeting cellular DNA and thus causing uncontrolled cell growth. These types of changes happen by chance; they are not predictable, and while the likelihood increases with dose, the severity is deemed to be independent of dose in the low dose regime. It is these stochastic effects that concern occupational and patient protection programs.

Health care staff who perform diagnostic imaging have their radiation doses monitored and receive regular reports on their status. By contrast, for patient monitoring, there is no equivalent reporting. The process involves a quality assurance team ensuring that the equipment is functioning as efficiently as possible. The team follows guidelines based on cohort studies, which set standards for the amount of radiation per exam, the integrity of the imaging system, and the performance of the imaging chain. These standards apply the ALARA ("as low as reasonably achievable") guideline that states that the goal is to use the lowest level of radiation that is reasonably achievable while ensuring the images are sufficiently diagnostic (6).

A key concern presented in the radiology literature cautioning against disclosure of a patient's radiation exposure history is that referring physicians will feel compelled to alter a patient's imaging pathway to a less efficacious non-ionizing test, based on the patient's cumulative exposure, which could unintentionally negatively affect the patient's medical care. The concern is that since stochastic risk cannot be used in a predictive sense it will not contribute to patient care (18-20). This position appears to stem from the most widely accepted model linking radiation exposure to cancer risk, i.e., the Linear No-Threshold (LNT) model (23). This model is used in radiation protection to estimate stochastic health effects of exposure. According to the LNT model, each incremental dose unit in a patient's history has an *equal* and *independent* effect on a patient's risk for developing a radiation-induced cancer (18). Therefore, if two patients have identical benefits to be gained from CT-scanning, for example, and if these benefits are determined to exceed the risks of the proposed CT exam, but one patient has a history of multiple CTs and previous exposures, the two patients should still be treated the same – the history of multiple exposures should not factor into the decision making.

One explanation offered for the (assumed) physician misuse of stochastic risk statistics is the "sunk cost bias" (or "gambler's fallacy"), whereby the perception of irrecoverable losses then influences decision making (6,13,18,19). Those who support a policy of non-disclosure argue that physicians may hesitate to order a CT exam for a patient with a history of multiple radiation exposures, weighing the patient's cumulative radiation-induced cancer risks (past and present) against the benefits of an additional CT exam. Such reasoning on the part of prescribing physicians would be fallacious because, proponents of non-disclosure argue, only the risk of the current CT examination should be considered in the risk-benefit analysis. A decision

against an additional CT exam will not reduce the cancer risks (sunk costs) incurred with previous examinations, and to not order a CT scan because a patient has a history of cumulative radiation doses is illogical¹.

For those who argue for a policy of non-disclosure to physicians (6,17-22), the consensus is that while automated dose-history databases are useful for ensuring that doses being given are within the guidelines set for a specific cohort, cumulative dose history is not useful for establishing the specific risk of a future test to an individual patient². Moreover, they argue, information on cumulative risk is deemed unnecessary to provide because other safety measures are effective. The stance of those who advocate for non-disclosure is that patient safety is best assured by attending to the ALARA principles, setting appropriate criteria and referral guidelines for those cohorts of patients who require recurrent imaging ("frequent flyers"), and developing CT machines with lower radiation doses: the emphasis is placed on cohort identification and standard setting, rather than on individual patient history (5,21). For example, Sodickson (21), discussing the question of how cumulative dose history can be incorporated into clinical decision making, argues that it is inappropriate to balance cumulative risk against incremental benefit (and that doing so biases against a decision to re-image the patient), because imaging benefit is not easily quantifiable, and radiation risk estimates are inherently error prone and reliant on a number of unproven assumptions (21). However, he argues, it is equally problematic to dismiss outright the incremental risk of each new scan. For Sodickson, the solution is to focus on the cohorts of frequent flyers and strive for solutions to avert unneeded radiation exposures on a collective rather than individual level.

TROUBLING THE ARGUMENTS FOR NON-DISCLOSURE

The argument in support of not providing cumulative dose information to prescribing physicians can be scrutinized and critiqued on several points: 1) the emphasis on the LNT model and its specific framing of stochastic risk assumes an independence of events and does not take into account accrued (posterior) probability; 2) the argument that physicians will misuse risk statistics and under-prescribe medical imaging exams has not been supported by evidence; 3) a policy of non-disclosure to physicians conflates the logistical challenges of communicating risk information with the question of whether patients should be informed of the risk; 4) non-disclosure to prescribing physicians results in a situation where the main professionals who have authority to requisition the tests do not have access to the information required to make an informed decision and to engage the patient in fully informed consent; and finally, 5) a policy of non-disclosure ignores the important role that radiologists (or other radiation counsellors) can play in inter-professional and collaborative decision making.

Accrued Probability Does Matter

The nature of low-dose stochastic injury is complex to translate into risk because each time a patient receives an individual dose of radiation it is like rolling the dice as to whether cellular damage will occur. The analogy of regularly driving to work can be used to explain this situation. When evaluating the risk of having a traffic accident while driving to work, each trip is associated with a small but significant risk level. While it may be true that, over time, the likelihood of an accident occurring will be accrued, for any given trip the chances of an accident occurring are no greater than they were on the previous trip. Using cumulative dose history to make a decision about a future medical test would be the equivalent of stopping someone from driving once they pass a certain threshold of kilometers driven. However, the fact remains that, over time, there is an accrual of risk.

Reviews of the published data on cumulative exposure to radiation due to nuclear medicine examinations reveal that the cumulated exposure to radiation may be of significant concern, particularly in certain groups of "frequent flyer" patients (3,5,8,25,26). Brower and Rehani (7) argue that there is a need to have a critical look at the fundamental principles of radiation protection as cumulative doses are likely to increase in the coming years. The ALARA standard is instrument-based and is intended to protect diagnostic quality. It does not address exam frequency; for a variety of reasons, some patients will accumulate significant doses. Although the discrete exposures are small the stochastic effect may have no threshold, so these doses may have a future impact. Viewed solely from an events perspective, increasing the number of risky events increases lifetime risk. It is not possible to establish a causal relationship, but population statistics point to a non-zero risk paradigm.

Moreover, we are concerned that the LNT model, which tells us that previous exposures do not affect subsequent exposures, inappropriately assumes an independence of events and does not take into account the complexity of accrued probability of cancer induction through radiation exposure. According to the LNT model, any exposure to ionizing radiation may induce cancer. However, the utility of the model can be and has been questioned (cf. 6,27-29), since it is hypothetical and based on extrapolation of data related to much higher ionizing radiation doses than encountered in diagnostic imaging, and because other factors are at play that alter a given individual's accrued probability of cancer induction through radiation exposure.

To clarify this concern, it is useful to reflect on the risk significance of "cumulative dose", that is, the sum of the individual doses the patient has received over time. Cumulative dose brings together the amount and rate at which the dose was accumulated as well as the number of events that contributed to that dose. Unfortunately, the dose registry approach is a limited means of accounting for cumulative dose. To be a complete cumulative dose, the dose history would need to include all aspects of daily life that can lead to radiation exposure (including, for example, dental exams and chiropractic x-rays). Moreover, it is unknown

¹ Beyond the issue of stochastic risk, a further complexity is that the automated patient-specific dose history databases are in fact not 'complete' in terms of the dose history, because they do not include all aspects of daily life that can lead to radiation exposure (e.g., dental exams, chiropractic x-rays).

² Cumulative dose history *is* relevant to an individual patient if the potential for tissue injury is a concern. Then, there is a clear clinical course of action that can be applied. Indeed, withholding information about the potential for tissue damage would be unethical – but this concern is only applicable to the context of a radiological intervention, which is a small subset of those referred for radiological imaging.

whether a patient's inherent resistance to radiation is in some way weakened by a single radiological exposure – it may very well be that a patient is left more susceptible to cancer from future radiological examinations (i.e., that repeat exposure to low levels of ionizing radiation weakens healthy cells, predisposing them to future malignancy). On the other hand, it could be that exposure promotes resistance; or it might be that exposure produces vulnerability in one patient and promotes resistance in another (6).

In short, the way in which the notion of cumulative risk has been constructed and purveyed through the LNT model is misleading. First, given that cellular repair is thought to be able to correct radiation damage, the timing between independent doses potentially alters one's risk status – a complexity that the notion of "cumulative risk" fails to capture. Second, individual risk factors (both genetic and physiological) are necessarily part of "cumulative" risk and are not accounted for in the accrued probability statistics. We suggest, therefore, that the LNT model is insufficient for basing a policy of non-disclosure of individual cumulative dose for patient decision-making. That is, relying on the LNT model to justify a policy of non-disclosure is ineffective. Moreover, we argue that the notion of "cumulative risk" should, rather, be conceived as "accrued probability," for all of the reasons outlined above.

Would Physicians Under-Prescribe?

Arguments in support of non-disclosure assume that physicians who order medical imaging exams are unable to fully appreciate the complexities of stochastic risk, and will interpret the risk-benefit ratio inappropriately, erring on the side of underprescribing a potentially beneficial medical test. Specifically, the postulate is that if a patient has accumulated a significant or arbitrary threshold dose, a physician may opt for a less suitable but lower dose alternative for the next dose, placing the patient at a disadvantage (6,13,18,21,30-32).

It may be the case that providing this information will alter prescribing practices. But the evidence is that when physicians had access to stochastic risk (and cost) information, their prescribing practices improved (14,33). Gimbel and colleagues (33) found a significant reduction (56.3%) in CT ordering when physicians were given information about radiation exposure and health risks. This is not to suggest that forgoing the CT exams decreased the quality of patient care, rather that over-prescribing had not been considered problematic.

We were unable to find evidence supporting the argument that physicians will under-prescribe necessary medical tests if provided with patient cumulative dose histories. For example, the American Association of Physicists in Medicine position paper does not provide evidence that cumulative dose information would negatively affect uptake or diagnostic accuracy, yet this is a fundamental premise of their position on non-disclosure. We are concerned that the idea that physicians will under-prescribe is an un-tested assumption held by non-clinical specialists.

Consider, for example, that the U.S.-led international "Choosing Wisely" campaign supports the opposite contention, that doctors will over-prescribe rather than under-prescribe. A key purpose of the Choosing Wisely Campaign was to improve patient care by encouraging a conversation between professionals and patients at the point of care about not providing an unnecessary test or procedure (34). The literature informing that movement indicates that prescribing behaviours tend to be overly cautious, going for more invasive procedures and more expensive tests, despite harms to the system and despite the futility of certain tests. This stance has also informed the Canadian Choosing Wisely movement (35-37).

Consider also that the reason for monitoring radiation dose in the first place is that there is a concern with physicians overprescribing tests (2,4). In other words, the assumption that physicians will under-prescribe needed tests contradicts the primary concern driving the literature on radiation risk of medical imaging exams – that such tests are and will be routinely overprescribed (33,38).

Conflating the Logistical Challenges of Communicating Risk with the Question of Whether Patients Should be Informed About Risks

Informed consent is grounded in the ethical principles of autonomy and respect for persons (39). One of the cornerstones is the disclosure of information about the choice to be made. Patients have the right to be as fully informed as possible of the medical facts about their condition, the proposed medical procedure, and the potential risks and benefits of the procedure and its alternatives, as well as the diagnosis, prognosis, and progress of treatment. A patient-centred informed consent model means that meaningful information that can be used to shape decision making is provided to patients. Disclosure of the information requires a discussion and verification of the patient's understanding of the disclosed information (39,40,41).

In practice, the amount of information to disclose varies. The reasonable-patient standard views the informed consent communication process from the patient's perspective (42). This means that disclosure must include all *relevant* information about risks, benefits, and alternatives that an objective patient would find material in making an intelligent decision as to whether to agree to the proposed procedure.

The question at hand is the following: is information about cumulative radiation risk relevant to disclose, despite its uncertainty? The conundrum is that there is always the possibility of stochastic occurrence of injury, even at the smallest dose; and this creates a significant problem for physicians, who have an ethical duty to inform their patients of the risks involved in undergoing a medical procedure. Many argue that prescribing physicians do have a moral duty to inform their patients of the risks involved in undergoing diagnostic imaging procedures such as CT scans (13,14,16,43-50). For those who adhere to the argument that

there is a moral duty to inform patients of medical imaging risks, the process of informed consent is conceived as "informed decision making" rather than a legalistic conception of "informed consent" (44,50,51).

In contrast, proponents of a policy of non-disclosure present a compelling reason for *not* having patients involved in decision making around their individual risk in relation to medical imaging. They argue that informed consent to medical imaging is inherently flawed, since it is impossible to describe precisely the risk of a medical imaging procedure, thus this information cannot be communicated to patients and informed consent cannot be obtained (50,53,54). Harvey, Brink, and Frush argue that "cloaking uncertain radiation risks with the credibility suggested by an informed consent process does not further patient autonomy or protect patient interests" (51). They, like others who support a policy of non-disclosure, argue that given that stochastic risks cannot be predictive, a genuine informed consent process would need to state that "there is an unproved possibility that the CT study could increase the risk for cancer" (51). Similarly, Mendelson (27) points out that there are practical limitations to communicating risks of cumulative radiation, so that even if theoretically informed consent and shared decision making should be the standard, this would be difficult to operationalize.

We concur with Davies et al. (49,55) that such barriers to the processes must be identified and tackled but cannot be used to argue that informed consent is not necessary. Davies and colleagues have highlighted the problematic either-or nature of the debate around informed consent to medical diagnostic imaging. As they note, there has been a blurring of the *need to disclose* relevant information (about the unknown risk of the potential for damage) and the *logistical challenges of* presenting complex risk information (about stochastic risk being present, yet available individual dose statistics non-predictive). Like Davies et al., we are critical of a stance that implies that consent is only obtained where the choice is easy and information is clear (49,55). In fact, a patient-centred process of informed consent can and should include discussions about unknowns. Just because information is messy and complicated does not mean that patients cannot engage in discussion about and understand the uncertainty of the risks as part of their decision making.

There is an obvious way to honour the principles of informed consent, while navigating the logistical challenges with translating stochastic risk – that is, in the form of a patient-centred consent model of "informed decision making" rather than traditional "informed consent". This approach distinguishes between patient-oriented collaborative discussion and negotiation related to risks and decision making about medical treatment, compared to a contractual, written consent in light of known risks and benefits (29,51,52). That is, patients and providers can (and, we argue, should) jointly practice informed decision making when contemplating an imaging examination.

The Professionals with the Authority to Request the Tests do not Have Access to the Information Required to Make an Informed Decision

In Canada, the privilege to requisition diagnostic tests used to be primarily limited to specialists but increasingly has been extended to general practitioners/family physicians, chiropractors, and nurse practitioners among others, depending on the jurisdiction (55). When a test is completed, these health professionals receive an interpretive report of clinical findings, but rarely any information on dose. Considering that all x-ray exams entail exposure to ionizing radiation, it is reasonable to ask: should radiation dose and in particular cumulative dose be provided to the referring medical professional?

The evidence is clear that some health care professionals lack knowledge and will require support to carry out informed consent discussions and shared decision making (54,57). But that need for support in understanding the complexities of radiation risk should not be interpreted to mean that they should not have this information or discuss it with their patients. Normally, health care professionals have all of the relevant facts before them when considering a medical intervention, including a diagnostic procedure; and normally, when a health authority responsible for the tests has relevant information, including contextual information, they have a responsibility to provide it to the relevant medical professionals. If referring medical professionals need additional education on how to understand and communicate these risks, that is an issue separate from providing information regarding patient status.

Moreover, we find that there is an inherent contradiction in the stance that physicians do not have the education in risk assessment necessary to prescribe imaging based on patient cumulative dose history, considering they have the authority to prescribe medical imaging. Prescribing medical professionals are solely responsible for harms that may eventually accrue to patients; yet they are unable to access the information needed for them to assess whether it is advisable to prescribe a medical exam and to negotiate shared decision making around treatment with their patient. In Canada, physicians receive some training in radiation safety and learn to recognize the "dose report" information that accompanies each x-ray exam. They are, at a minimum, aware that the information exists and where it can be accessed. But currently, they, along with other authorized professionals, are not sufficiently trained in risk analysis to engage in a meaningful informed consent discussion with patients, and as such are unlikely to pursue further training given their competing priorities, particularly if working in a resource-strained context. By contrast, certain specialties, such as radiology and nuclear medicine, receive additional training in radiation safety and dose management. This leads us to our final point – that a policy of non-disclosure ignores the important role that radiologists (or other experts in interpreting radiation associated risk) can play in inter-professional and collaborative decision making and in the consent process.

A Policy of Non-Disclosure Ignores the Important Role for Radiologists in Inter-Professional and **Collaborative Decision Making**

Concerns that physicians might avoid prescribing a necessary imaging test because of their misunderstanding of cumulative radiation risk tend to overlook the possible role of Radiology. The potential harms of under-prescribing can be mitigated by actively engaging radiologists in the consent process or, at the very least, engaging them as consultants to those responsible for ordering the tests. Radiologists are already part of interdisciplinary teams that triage diagnostic imaging requests, including determination of inappropriate requests (56). Further, radiologists already have a consulting role in describing test performance, prescribing acquisition methods to mitigate risk, and describing risks relevant to specific cohorts (21).

Beyond that role, we argue that radiologists can and should be actively engaged in patient-centred decision making around testing. These reviewing radiologists, who have access to patient radiological history, can play an important role in the informed consent process. Radiologists may not currently be considered risk-interpretation experts. But, if necessary, they can gain that expertise with some additional training. Indeed, several scholars have put forth persuasive arguments that it is best to have a collaborative approach between physicians and radiologists, particularly where providers may not feel comfortable talking about risks of radiation exposure because they are unfamiliar with the doses that are imparted by the imaging test and how they relate to cancer risk (32,38,58,59).

Importantly for us, this kind of collaborative process should not be construed as replacing the authority of the prescribing medical professional - the responsible physician or nurse practitioner is in the best position to weigh the risks and benefits based on their knowledge of the patient and should convey this information to the patient at the time an imaging exam is ordered. However, the role of the radiologist can go much further than assisting the referring clinician in making the assessment and ensuring that the dose is appropriate. As experts in understanding and conveying the complexity of risk, they can be directly involved in the consent process.

CONCLUSION

We have offered a critical analysis of several assumptions underlying the stance of non-disclosure: 1) the emphasis on the LNT model and its specific framing of stochastic risk assumes an independence of events and does not take into account accrued probability; 2) the fear that physicians will misuse risk statistics and under-prescribe medical imaging exams appears to be an un-tested assumption held by non-clinical specialists; 3) a policy of non-disclosure to physicians conflates the logistical challenges of communicating about risk with the question of whether patients should be informed of the risk; 4) non-disclosure to prescribing physicians results in a situation where the only professionals with the authority to order the tests do not have access to the information required to make an informed decision and to engage the patient in fully informed consent; and finally 5) a policy of non-disclosure ignores the important role that radiologists (or other radiation counsellors) can play in interprofessional and collaborative decision making.

We argue against the stance of the professional bodies and for a policy of disclosure, provided that such a policy prioritizes patient-centred decision making, the authority of the prescribing physician, and the engagement of radiologists or other experts in radiation associated risk. Specifically, we call for an expansion of the circle of care to include radiologists or other radiation counsellors. This individual would be a resource for the patient and referring physician to help them to better understand the additional risk that may accrue as a result of a planned examination. Not every department will have a radiologist available to fill this role; and not all radiologists will be versed in radiation associated risk (for example, if their role is limited to nonionizing radiation); but most departments will have someone who is able to interpret radiation associated risk. Having access to information is a cornerstone of consent, and our proposed approach for disclosure - with an expert available to interpret the radiation associated risk - is key to enabling fully informed consent.

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REFERENCES

- Sodickson A, Baeyens P, Andriole K, et al. Recurrent CT, cumulative radiation exposure, and associated radiation-1. induced cancer risks from CT of adults. Radiology. 2009; 251(1):175-84.
- Armao D, Semelka R, Elias J. Radiology's ethical responsibility for healthcare reform: tempering the overutilization of 2 medical imaging and trimming down a heavyweight. Journal of Magnetic Resonance Imaging. 2012;35(3):512-17.
- 3. Rehani M. Looking into future: challenges in radiation protection in medicine. Radiation Protection Dosimetry. 2015;165(1-4):3-6.
- 4. Salerno S, Laghi A, Cantone M-C, Sartori P, Pinto A, Frija G. Overdiagnosis and over imaging: an ethical issue for radiological protection. La radiologia medica. 2019;124(8):714-20.
- Brambilla M, Vassileva J, Kuchcinska A, Rehani M. Multinational data on cumulative radiation exposure of patients 5. from recurrent radiological procedures: call for action. European Radiology. 2020;30(5):2493-2501.
- Walsh C, O'Reilly G, Murphy D. Patient cumulative radiation exposure-the potential for unintended consequences. 6. European Radiology. 2020;30(8):4434-37.
- 7. Brower C. Rehani M. Radiation risk issues in recurrent imaging. British Journal of Radiology. 2021;94(1126):20210389.
- Vassileva J, Holmberg, O. Radiation protection perspective to recurrent medical imaging: what is known and what 8. more is needed? British Journal of Radiology. 2021;94(1126): 20210477.
- 9 World Health Organization. Ethics and medical radiological imaging: a policy brief for health-care providers. 2022.
- 10. Malone J, Zölzer F, Meskens G, Skourou C. Ethics for Radiation Protection in Medicine. Taylor & Francis; 2018.
- 11. Bochud F, Cantone M-C, Applegate K, et al. Ethical aspects in the use of radiation in medicine: update from ICRP task group 109. Annals of the ICRP. 2020;49(1 suppl):143-53.
- 12. Bernier M, Baysson H, Pearce M, et al. Cohort profile: the EPI-CT study: a European pooled epidemiological study to quantify the risk of radiation-induced cancer from paediatric CT. International Journal of Epidemiology. 2019;48(2):379-81g.
- 13. Rehani M, Berris T. International Atomic Energy Agency study with referring physicians on patient radiation exposure and its tracking: a prospective survey using a web-based questionnaire. BMJ Open. 2012;2(5):e001425.
- 14. Kruger J, Chen A, Rybkin A, Leeds K, Frosch D, Goldman L. Clinician perspectives on considering radiation exposure to patients when ordering imaging tests: a qualitative study. BMJ Quality & Safety. 2014;23(11):893-901.
- 15. Griffey R, Jeffe D, and Bailey T. Emergency physicians' attitudes and preferences regarding computed tomography, radiation exposure, and imaging decision support. Academic Emergency Medicine. 2014;21(7):768-77.
- 16. Einstein A, Berman D, Min J, et al. Patient-centered imaging: shared decision making for cardiac imaging procedures with exposure to ionizing radiation. Journal of the American College of Cardiology. 2014;63(15):1480-89.
- 17. Durand D, Dixon R, Morin R. Utilization strategies for cumulative dose estimates: A review and rational assessment. Journal of the American College of Radiology. 2012;9(7):480-85.
- 18. Eisenberg J, Harvey H, Moore D, Gazelle G, Pandharipande P. Falling prey to the sunk cost bias: a potential harm of patient radiation dose histories. Radiology. 2012;263(3):626-28.
- 19. Eisenberg J, Lewin S, Pandharipande P. The fisherman's cards: How to address past and future radiation exposures in clinical decision-making. American Journal of Roentgenology. 2014;202(2):362-67.
- 20. Pandharipande P, Eisenberg J, Avery L, et al. Journal club: How radiation exposure histories influence physician imaging decisions: a multicenter radiologist survey study. American Journal of Roentgenology. 2013;200(6):1275-83.
- 21. Sodickson A. Radiation concerns in frequent flyer patients: should imaging history influence decisions about recurrent imaging? British Journal of Radiology. 2021;94(1126): 20210543.
- 22. American Association of Physicists in Medicine. AAPM/ACR/HPS Joint statement on proper use of radiation dose metric tracking for patients undergoing medical imaging exams. 6 Aug 2021.
- International Commission on Radiological Protection (ICRP). Low-dose Extrapolation of Radiation-related Cancer 23. Risk. Annals of the ICRP. 2005;35(4):99.
- 24. Bjarnason T, Thakur Y, Chakraborty S, et al. Canadian Association of Radiologists Radiation Protection Working Group: Automated patient-specific dose registries—What are they and what are they good for? Canadian Association of Radiologists Journal. 2015; 66(3):192-97.
- 25. Rehani M, Frush D, Berris T, Einstein A. Patient radiation exposure tracking: Worldwide programs and needs -Results from the first IAEA survey. European Journal of Radiology. 2012;81(10):e968-76.
- 26. Rehani M. Patient radiation exposure and dose tracking: a perspective. Journal of Medical Imaging. 2017;4(3):031206.
- 27. Mendelson R. Informed consent for stochastic effects of ionising radiation in diagnostic imaging. British Journal of Radiology. 2022;95(1132):20211265.

- 28. Charles M. LNT-an apparent rather than a real controversy? Journal of Radiological Protection. 2006;26(3):325.
- 29. Brink J, Goske M, Patti J. Informed decision-making trumps informed consent for medical imaging with ionizing radiation. Radiology. 2012;262(1):11-14.
- 30. Lee C, Haims A, Monico E, Brink J, Forman H. <u>Diagnostic CT scans: Assessment of patient, physician, and radiologist awareness of radiation dose and possible risks</u>. Radiology. 2004;231(2):393-98.
- 31. Walsh C, Murphy D. <u>Should the justification of medical exposures take account of radiation risks from previous examinations?</u> British Journal of Radiology. 2014;87(1037):20130682.
- 32. Shyu J, Sodickson A. <u>Communicating radiation risk to patients and referring physicians in the emergency department setting</u>. British Journal of Radiology. 2016;89(1061):20150868.
- Gimbel R, Fontelo P, Stephens M, et al. <u>Radiation exposure and cost influence physician medical image decision</u> <u>making: a randomized controlled trial</u>. Medical Care. 2013;628-32.
- 34. Levinson W, Huynh, T. Engaging physicians and patients in conversations about unnecessary tests and procedures: Choosing Wisely Canada. CMAJ. 2014;186(5):325-26.
- 35. Embrett M, Randall G. <u>Physician perspectives on Choosing Wisely Canada as an approach to reduce unnecessary</u> medical care: a qualitative study. Health Research Policy and Systems. 2018;16:95.
- 36. Silverstein W, Lass E, Born K, Morinville A, Levinson W, Tannenbaum C. <u>A survey of primary care patients'</u> readiness to engage in the de-adoption practices recommended by Choosing Wisely Canada. BMC Research Notes. 2016;9:301.
- Patey A, Fontaine G, Francis J, McCleary N, Presseau J, Grimshaw J. <u>Healthcare professional behaviour: health</u> <u>impact, prevalence of evidence-based behaviours, correlates and interventions</u>. Psychology & Health. 2023;38(6):766-94.
- 38. McBride J, Wardrop R, Paxton B, Mandrekar J, Fletcher J. <u>Effect on examination ordering by physician attitude</u>, <u>common knowledge</u>, and practice behavior regarding CT radiation exposure. Clinical Imaging. 2012;36(5):455-61.
- 39. Beauchamp T, Childress J. Principles of Biomedical Ethics, 8th Edition. Oxford University Press; 2019.
- 40. Beauchamp T. Informed consent: its history, meaning, and present challenges. Cambridge Quarterly of Healthcare Ethics. 2011;20(4):515-23.
- 41. Etchells E, Sharpe G, Walsh P, Williams J, Singer P. Bioethics for clinicians: 1. Consent. CMAJ. 1996;155(2):177-80.
- 42. Spatz E, Krumholz H, Moulton B. The new era of informed consent: getting to a reasonable-patient standard through shared decision making. JAMA. 2016;315(19):2063-64.
- 43. Baerlocher M, Detsky, A. <u>Discussing radiation risks associated with CT scans with patients</u>. JAMA. 2010;304(19):2170-71.
- 44. Nievelstein R, Frush D. <u>Should we obtain informed consent for examinations that expose patients to radiation?</u> American Journal of Roentgenology. 2012;199(3):664-69.
- 45. Paterick T, Jan M, Paterick Z, Tajik J, Gerber T. <u>Cardiac imaging modalities with ionizing radiation: The role of informed consent</u>. JACC Cardiovascular Imaging. 2012;5(6):634-40.
- Ricketts M, Baerlocher M, Asch M, Myers M. <u>Perception of radiation exposure and risk among patients, medical students, and referring physicians at a tertiary care community hospital</u>. Canadian Association of Radiology. 2013;64(3):208-12.
- 47. Berlin L. <u>Shared decision-making: is it time to obtain informed consent before radiologic examinations utilizing</u> ionizing radiation? Legal and ethical implications. Journal of the American College of Radiology. 2014;11(3):246-51.
- 48. Doudenkova V, Bélisle Pipon JC. <u>Duty to inform and informed consent in diagnostic radiology: how ethics and law</u> <u>can better guide practice</u>. HEC Forum. 2016;28(1):75-94.
- 49. Davies E, Bridges A, Chung E. <u>Does radiology require informed consent for radiation risk?</u> British Journal of Radiology. 2021; 94(1127):20210620.
- 50. Gutiontov S, Golden D, McCloskey S, et al. <u>Informed consent in radiation oncology</u>. International Journal of Radiation Oncology, Biology, Physics. 2021;109(1):29-35.
- 51. Harvey H, Brink J, Frush D. Informed consent for radiation risk from CT is unjustified based on the current scientific evidence. Radiology. 2015;275(2):321-25.
- 52. Goske M, Bulas D. Improving health literacy: informed decision-making rather than informed consent for CT scans in children. Pediatric Radiology. 2009;39(9):901-3.
- Lam D, Larson D, Eisenberg J, Forman H, Lee C. <u>Communicating potential radiation-induced cancer risks from</u> medical imaging directly to patients. American Journal of Roentgenology. 2015;205(5):962-70.
- 54. Vassileva J, Zewde N, Reim M, Holmberg O, Rehani M. <u>Communication of radiation risk from imaging studies: an</u> <u>IAEA-coordinated international survey</u>. Journal of Radiological Protection. 2022;42(2):021524.
- 55. Davies E, Peet D, Taylor M, Chung E. <u>Survey of the public's preferences for communication of medical radiation</u> risk. Journal of Radiological Protection. 2022;42(2):021506.
- 56. Canadian Agency for Drugs and Technologies in Health. <u>Appropriate utilization of advanced diagnostic imaging</u> procedures: CT, MRI, and PET/CT: Environmental Scan. Issue 39, February 2013.
- 57. Krille L, Hammer G, Merzenich H, Zeeb H. <u>Systematic review on physician's knowledge about radiation doses and</u> radiation risks of computed tomography. European Journal of Radiology. 2010;76(1):36-41.
- 58. Younger C, Moran C, Douglas C, Warren-Forward H. <u>Barriers and pathways to informed consent for ionising</u> radiation imaging examinations: A qualitative study. Radiography. 2019;25(4):e88-94.
- 59. Stewart C, Smith-Bindman R. It is time to inform patients of medical imaging risks. JAMA Network Open. 2021;4(10):e2129681.