TOWARDS POTENTIAL HARM ASSESSMENT FROM THE INDIVIDUAL PATIENT RADIATION DOSES IN IMAGING PROCEDURES: A PROPOSAL FOR A NEW QUANTITY

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Abstract — **Imaging procedures continue to advance rapidly and offer unprecedented benefits in health care. Even so, the potential harm from the associated radiation exposure has remained relevant and subject to strong public scrutiny. This necessitates a quantity to gauge this potential harm in such a way that it is reflective of the attributes of the patient, the imaging procedure, and the latest science on radiation effects. The current metrics fall short of such objectives, as they are either procedure-centric (not relatable across imaging modalities), or negligent of the patient attributes, such as size, sex and age that are known to strongly influence the potential harm. Without a relevant quantity, the (often minor) potential risk associated with imaging procedures cannot be reliably put into perspective with the (often significant) benefit from the procedures, nor can that potential be properly monitored, communicated, or researched.**

In this white paper, we propose a new quantity that alleviates some of the shortcomings of existing measures. The quantity, which may be termed potential radiation harm or detriment, builds upon the foundation of effective dose and its numerical quantification with additional inclusion of patient and exam attributes. The new quantity is devised to enhance the assessment, optimization, and communication related to medical imaging procedures, with potential for extension to other conditions or practices where individualizations of irradiation is needed.

I. Introduction

Imaging procedures continue to advance rapidly and offer unprecedented benefits in health care. Even so, the potential harm from the associated radiation exposure has remained relevant and subject to strong public scrutiny. This necessitates a quantity to gauge this potential harm in such a way that it is reflective of the attributes of the patient, the imaging procedure, and the latest science on radiation effects. The current metrics fall short of such objectives, as they are either procedure-centric (not relatable across imaging modalities), or negligent of the patient attributes, such as size, sex and age that are known to strongly influence the potential harm. Without a relevant quantity, the (often minor) potential risk associated with imaging procedures cannot be reliably put into perspective with the (often significant) benefit from the procedures, nor can that potential be properly monitored, communicated, or researched.

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II. Why should we quantify patient radiation dose in medical imaging?

There is a prevailing assumption in the scientific community, anchored to the de facto linear no threshold (LNT) model of stochastic radiation risk (NCRP 2018, ICRP 2021), that any radiation dose may involve a non-negligible likelihood of harm. This includes likelihood of harm to patients undergoing medical imaging. At low doses associated with the vast majority of imaging exams, this likelihood is small and stochastic. While the magnitude of this harm remains debatable, its likelihood cannot be dismissed. As patient safety is an integral mandate of healthcare – *First Do No Harm*, the very *likelihood* of harm necessitates a system by which it should be quantified, minimized, and put in perspective with the substantial benefit associated with medical imaging. Patients, families, and clinicians who care for them want to know – and do ask – radiological professionals for the magnitude of doses associated with their imaging exams and the associated risk. Stating there is no risk is not scientific and avoiding a proper quantification only leads to the presumption of higher risk than actual reality.

III. What have we used thus far to quantify patient dose in medical imaging?

Over the years, various quantities have been developed to gauge the magnitude of patient radiation dose in medical imaging. Common among them are those that reflect the standard radiation absorbed dose in a phantom associated with a particular imaging condition: e.g., CT Dose Index (CTDI) and Dose Length Product (DLP) for CT imaging (ICRP 2012). While practical, these metrics do not reflect the likelihood of harm to the patient and cannot be compared across modalities, clinical indications, or patients.

Alternatively, Effective Dose, typically expressed in millisievert, has been used as a way to evaluate individual patient dose in a way that is independent of the modality for specific imaging exams. Effective dose has been developed by the International Commission of Radiological Protection (ICRP) as a dose quantity with a link to risks of health detriment from stochastic effects, for quantifying occupational and public doses, with the main objective of exposure limitation and risk management (ICRP, 2007). However, it has become a common metric for quantifying patient radiation doses across populations and medical imaging modalities in practice and publications with over 20,000 publications in the last 10 years alone (Zhang 2012, Brindhaban 2020, Casiraghi 2021, Fu 2021a).

This use has in fact significantly enhanced the reach and prevalence of Effective Dose, well beyond its originally designed purpose. However, this use of Effective Dose is 'off-label'. Effective Dose was never intended to capture potential harm to individual patients as it intentionally averages the effect of age, sex, size, and genetic radiosensitivity. Its original definition in fact emphasized that use of Effective Dose not as a substitute for specific risk analysis for individual cancer types using organ/tissue doses. Further, Effective Dose is calculated as a whole-body exposure estimate whereas patient imaging exposures are almost always only to a part of the body. Moreover, the non-commissioned and unguided use or Effective Dose for patient examinations has led to different calculations and implementations of Effective Dose across medicine, causing major confusion and inconsistences – no two millisieverts are created equal!

IV. WHY WE NEED TO DEFINE A NEW QUANTITY FOR AN IMAGING PATIENT'S RADIATION DOSE?

The non-orthodox, unrepresentative, and variable application of Effective Dose for assigning patient radiation doses is not mal-intentioned; it is rather a consequence of a lack of clear guidance for a better alternative. Medical exposures remain by far the leading source of artificial radiation exposure in the world (UNSCEAR 2022). As the community of radiation scientists, we have the opportunity and the responsibility to define a quantity that can better gauge the radiation dose associated with medical imaging.

V. WHAT SHOULD BE THE KEY INGREDIENTS OF THIS NEW QUANTITY?

The reason for assessing imaging radiation dose in the first place is its potential for harm to the patient. This is the only way that an imaging examination can be properly optimized, any shared decision-making to proceed with medical imaging can be communicated ethically, and dose benchmarking and management can have validity. As such, a proper quantity should be reflective of patient harm taking into consideration the unique attributes of the patient that contribute to this likelihood of harm. Any potential harm takes place within an organ or tissue. Therefore, the quantity should be informed by doses within and across organs, similar to the approach used for Effective Dose. These doses across organs should likewise be reflective of the attributes of the individual patient.

The quantification should further take into consideration other risk factors, such as age, sex, and patient body habitus, factors that are well recognized to influence dose and radiation risk. The quantity should also accommodate other factors once their influence has been well documented, such as the genetic disposition to radiation risk and the non-uniformity of the distribution of radiation dose across organs. There has been substantial formational work in patient- and exam-specific organ dose estimation that can be adapted in defining a standard methodology for patient-specific organ dosimetry (Li 2011, Choi 2020, Peng 2020, Samei 2020, Fu 2021b). Integrated with known age and sex weighted radiation risk factors, a quantity can likewise be defined to capture a supra-organ metric of radiation dose in imaging (Ria 2021).

VI. IS USING RISK AND AN ASSOCIATED UNIT A GOOD APPROACH TO QUANTIFY IMAGING RADIATION DOSE?

A quantity to reflect imaging radiation dose should provide an improved estimate of the potential harm from a patient's associated exposure to radiation (Ria et al., 2021). One thus may wish to capture that harm in terms of risk or a risk index (e.g., the likelihood of a cancer in 20 years). This approach, while used by many including principal authors of this article, is not ideal on five grounds:

1) A risk by definition assumes a likelihood of harm within a population identical to the patient. No two patients are created equal; therefore the quantity becomes hypothetical and not *patient*-specific as intended.
2) The method implies, by the virtue of ascribing a likelihood of harm to the patient, too much certainty on the science of radiation biology – there are still many unknowns and we should be careful not to project unwarranted certainty.

3) Any likelihood of harm depends, in a large part, on many factors that the patient will experience *in the future*. Ascribing a futuristic likelihood of harm is speculative.

4) A likelihood of harm estimated for some decades later has little practical value when compared with often immediate likelihood of benefit that will come from the examination. The two likelihoods have dramatically *different perceived values due to the times scales* and cannot readily be compared or put in balance with one another (so-called discounting in economic theory).

5) A likelihood of harm in terms of quantitative assessments such as micromort qualifications (Howard 1980), are overly terrifying to many patients that may have difficulty understanding the stochastic nature of the harm, are already concerned with morbidity and mortality, and cannot readily differentiate between milli or micro qualifiers, e.g., 1000 of something is perceived as a big value regardless of the units.

VII. WHAT QUANTITY AND AN ASSOCIATED UNIT SHOULD BE THE GAUGE OF IMAGING PATIENT RADIATION DOSE?

It seems prudent that an ideal quantity should take advantage of the prevalence, familiarity, and quantitative values of similar magnitude to those of Effective Dose to facilitate its adoption. Such a quantity may also be relatable to potential radiation risk, if so desired, but not be a direct reflection of risk – per points above – echoing the philosophy that led to the definition of Effective Dose in the first place. To avoid confusion, we do not recommend the use of the term "effective dose" in the nomenclature for the new quantity.

Informed by the rationales detailed above, we suggest this quantity should be described in a more generic manner relating to potential harm or detriment from radiation exposure. We have in fact considered the term *potential radiation harm* as a possible candidate for such a quantity. Such a term, in addition to alleviating the limitations of existing alternative quantities, offers unique advantages:

1) A quantity characterized as a *harm* or detriment can encapsulate (if needed) other effects of radiation exposure beyond stochastic risk and cancer induction.

2) A quantity characterized as a *radiation* harm can reflect directly what the patient would understand, the burden of radiation, beyond technical terms such as risk or dose.

3) A quantity characterized as a *potential* radiation harm can more authentically reflect the state of the underlying science of harm from radiation exposure, not all of which is fully known.

4) A quantity based on the best available data on radiation risk, will provide a more science-based quantity than effective dose, which used approximate weighting factors to facilitate simple calculations. This will allow more realistic and valid assessments of uncertainties in the characterization of radiation harm.

VIII. HOW CAN *POTENTIAL RADIATION HARM* BE DEFINED?

We propose the new quantity to follow the general framework of Effective Dose with the additional inclusion of patient and exam attributes. This approach echoes the formulation of ICRP Publication 147 (ICRP, 2021) to incorporate "approximate indicator of possible risk." The definition is based on estimation of organ doses and the exact irradiation condition of the patient. The approach follows these broad steps, exemplified for CT imaging but meant to extend to other modalities:

1) Modeling the patient geometry into a virtual form that captures the body habitus and organ locations of the patient. This will be done through matching patients to phantom libraries initially, but in time it should be possible to assess the components of the radiation dose to organs within the scan field directly (Choi et al., 2020, Fu et al., 2021).

2) Estimating dose to the individual organs of the patient via Monte Carlo-based methods or their derivatives taking into account all available information about the irradiation condition of the exam.

3) Estimating an overall level of radiation risk by summing individual organ doses multiplied by x_n-factored sensitivities, where x_n reflects numerous known radiation sensitivities (e.g., starting with age and sex, with additional personal factors such as smoking and patient size, progressively considered in the future extension of the methodology).

4) Scaling the estimated risk such that its numerical value matches to that of conventional Effective Dose (delivered to a 35 years-old adult) when the method is applied to the Effective Dose standard anatomical model and irradiation. In that way, the unit of the new quantity will not be sievert, but the quantity will have values in the same order of magnitude and scale as sievert.

IX. SHALL WE EXTEND THIS INDIVIDUAL QUANTITY TO WORKERS AND THE PUBLIC?

We propose this quantity to be applied initially to medical imaging, where a new quantity and guidelines are of current need (Ruehm 2022). However, the new quantity may as well be extended beyond patient imaging. Case in point, there are already individual dose limits in use, based on Effective Dose, set separately for female and for male astronauts (NAS 2021). Thus, there is a rationale to upgrade all such efforts to the new quantity.

X. WHAT ARE THE CRUCIAL REQUIREMENTS TO ENABLE THE CHARACTERIZATION OF *POTENTIAL RADIATION HARM*?

To enable the medical imaging community to compute and use a new measure of potential radiation harm proficiently and practically, we encourage a process to explicitly meet the following requirements:

1) Accuracy in modeling the patient
2) Accuracy in modeling the irradiation condition – first applied to CT imaging, and then to other modalities including nuclear medicine
3) Standardized description of the methodologies deployed
4) Benchmarking process
5) Incorporation of uncertainty in the quantity and its derivation (e.g., confidence interval)
6) Practical approximation strategies that accommodate resource-limited countries and settings

XI. CONCLUSIONS

The existing measures to gauge the potential radiation harm associated with medical imaging are inadequate to provide a quantitative account that is patient-relevant, technology-agnostic, and reflective of known factors of radiation risk. Currently the best candidate quantity for this purpose, Effective Dose, is a relatively poor discriminator, despite the considerable efforts to convey the link to stochastic effects. Consequently, efforts to justify and optimize medical imaging procedures and to communicate regarding benefit/risk are negatively influenced. In this article, we offer a proposal for a new quantity and metrology with the hope to enhance the assessment, optimization, and communication about medical imaging exposures to the benefit of all patients and the practices.

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