Increasing the public awareness of justification

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ABSTRACT

One of the requirements of the UK Ionising Radiation (Medical Exposure) Regulations 2017 is that all medical exposures must be justified before the exposure can proceed. One of the main elements of justification is a determination that the medical benefits from the exposure will exceed the associated radiation detriment. The field of medical exposure to ionising radiation is in the rare position of having this explicit legal requirement for net benefit. In this article it is argued that, although separate information on benefit and detriment is also required for implied or explicit informed consent prior to exposure, justification comes first, is simple to explain, and is easily related to the commonly understood basis of medical ethics. It seems reasonable, therefore, to make patients and the public more aware of the protection that UK law already provides for them. A proposal for a single-sentence general statement on justification is made.

Introduction

One of the requirements of the UK Ionising Radiation (Medical Exposure) Regulations 2017 [1] (IR(ME)R 2017) and other European regulations [2] is that all medical exposures must be justified. Regulation 11(1)(b) requires that a medical exposure is justified 'as showing sufficient net benefit', which is clarified in 11(2)(b) and (c) as consideration of 'the total potential diagnostic or therapeutic benefits' against 'the individual detriment'. Although other elements must be considered for the special cases of clinical trials and non-medical imaging exposures, the main message for the patient undergoing a standard medical diagnostic procedure involving ionising radiation is simply that the benefit of the procedure must by law outweigh the detriment. This statement is essentially a rewording of the

philosophy of the Hippocratic oath, which in various forms dates back to AD 275 and is widely known to the general public in the form of the popular aphorism 'first do no harm'. Justification is consistent with the World Medical Association Declaration of Geneva [3]. A surgeon putting a knife into a patient is applauded, while outside of the healthcare field this is assault with a deadly weapon. This difference is, again, widely understood by the general public.

Justification of medical exposures is implemented on three levels [4]. At the first general level, the proper use of radiation in medicine must do more good than harm to society as a whole. At the second level, specific procedures must be justified as being beneficial to groups of patients with specific conditions. In the UK, the iRefer guidelines from the Royal College of Radiologists facilitate appropriate referrals to radiology departments. The guidelines make clear which x-ray and radionuclide examinations are indicated as appropriate for a range of clinical problems [5]. At the third level, the application of a procedure to an individual patient should be justified in advance, taking into account the objectives of the exposure and the patient's clinical condition. Within this level, variation is expected between standard relatively low dose examinations that can be adequately justified at the second level because of the very low risk from radiation exposure, and high dose complex examinations where justification of the individual case is expected [4]. Underlying all of this is an ethical framework in which respect for human dignity and beneficence is aligned with an implied or explicit requirement for informed consent for medical exposure [6,7]. The simple statement proposed below is intended to reinforce the three levels of justification already in place for a patient invited for a medical exposure, and to provide a starting place for informed consent [8,9]. It is, however, argued here that the justification process comes first and is independent of (although may inform) consent.

Explaining radiation benefits and risks to patients

An element introduced in IR(ME)R 2017 is a requirement that '..prior to an exposure taking place, the individual to be exposed or their representative is provided with adequate information relating to the benefits and risks associated with the radiation dose from the exposure'. This appears in part 1(i) of the Employer's Procedures given in Schedule 2 of the regulations. In order to help fulfill this requirement, a series of excellent posters has been produced by a collaboration of the Institute of Physics and Engineering in Medicine, The Royal College of Radiologists and the Society and College of Radiographers [10]. These explain the reason for a range of x-ray procedures and discuss radiation benefits, risks and optimization in an approachable and visually appealing way. The Society and College of Radiographers have also produced guidance on the best way to conduct conversations about benefits and risks directly with patients [11], and the World Health Organization have produced a detailed guide on communicating benefit and risk in paediatric imaging [12].

Information on radiation doses from medical exposure and comparison with background radiation etc. can be located by searching the internet, but it is relatively easy to be led to non-UK and non-mainstream views and information on radiation detriment which might not reassure the potential patient. Explaining benefits and risks separately to patients as IR(ME)R 2017 requires is not easy, as anyone who has ever tried to clarify the meaning of mSv to a skeptical layperson will know. It is suggested here that increased public awareness of justification would be a useful way of putting information relating to the relative benefits

and detriment of medical radiation exposure into context before starting the consent process.

Quantitative justification of benefit versus detriment

Despite the legislative requirement for justification, it is difficult to answer the patient who asks 'by how much does the benefit exceed the risk for this examination?' as justification is presently a judgment made by an expert, the IR(ME)R practitioner, rather than a quantitative calculation. Calculations on the ratio of benefit to detriment based on real morbidity and mortality data have been made for a small number of mostly high dose procedures [13, 14], with the low values of ratio reported for some of these bringing into question whether these specific examinations should be clinically indicated. Conversely, recent work attempting to align public health measures of health detriment with radiation detriment, both defined in terms of disability-adjusted life years [15], has suggested large values for the ratio of benefit to detriment for a range of more common examinations. The implication of these latter results could be that all clinically indicated [5] common examinations can be taken as quantitatively justified in terms of benefit versus detriment. If so, then this would reinforce the idea that the existing legal requirement for benefit to exceed detriment is a stronger general concept to be promoted to patients than the presentation of numbers related to radiation dose and detriment which are not directly comparable with medical benefit.

Promoting justification

The field of medical exposure to ionising radiation in the UK is in the rare position of having an explicit legal requirement for the benefit of a medical intervention to exceed the risk. (The only other legislation requiring a similar mandatory requirement for benefit to exceed risk found during the preparation of this article is that covering clinical trials [16].) The patient undergoing medical exposure to ionising radiation is therefore not only protected by the procedures of the healthcare organization performing the exposure, but by the UK Government in the form of IR(ME)R 2017. The proposal here is therefore to promote justification to the public separately from attempting to quantify benefit and risk, and to use the legal weight of IR(ME)R 2017 to amplify the message. This is consistent with the findings of a study on public preferences for the presentation of radiation risk information, which concluded that 'most patients' concerns could be addressed by a simple statement about justification and indication of the level of risk' [17]. The proposal is also in line with action 9 of the Bonn Call For action [18], which calls for improved awareness about radiation benefits and risks among health professionals, patients and the public. An appropriate mechanism might be to include a short statement on justification with the patient appointment letter, or with the equivalent information to in-patients, at which time the three elements of justification described above will already be in place.

The initial proposal for a simply worded statement on justification is:

'Under UK law*, medical procedures that use x-rays or radioactivity can proceed only after confirmation that the resulting health benefits will be greater than any associated risk from radiation.

***Ionising Radiation (Medical Exposure) regulations 2017.'**

The wording of the footnote applies in England, Wales and Scotland. For Northern Ireland the footnote would read '*Ionising Radiation (Medical Exposure) Regulations (Northern Ireland) 2018'.

There are clearly a large number of alternative wordings that might be suggested, so the reasons for this particular proposal are expanded on below:

i) 'Under UK Law,…' This emphasizes that the statement following is enforceable by law and that punishment can ensue if it is not complied with. It also implies broad coverage greater than just the National Health Service.
ii) 'medical procedures…' The statement covers only medical exposures.
iii) 'x-rays or radioactivity…' This should be clearer to the public than the technical term 'ionising radiation', although that appears in the footnote citing the regulations. This description may not strictly cover some medical procedures such as particle therapy, although such procedures would require explicit informed consent at which point justification can be clarified.
iv) 'after confirmation that…' The regulations mandate that the process of justification must occur before a medical exposure can take place, but the decision to proceed is a determination made by the IR(ME)R Practitioner.
v) 'health benefits…' Health benefits are plural to encompass benefits to society from clinical trials and health screening as well as the benefit specific to the individual.
vi) 'associated risk…' This is only the risk from the medical exposure, so workplace and natural radiation are purposely excluded. Risk is technically a probability rather than a detriment, but is the term used in Schedule 2 of IR(ME)R and a more easily understood word in this context.
vii) 'radiation.' This is the word that invokes the most anxiety in the general public and it comes at the end of the statement so that the reassurance is given first.

The vocabulary and wording of the statement is aimed at providing a concise and simple summary of a complex subject. Although the statement might appear simplistic to the technical expert, consideration should be given to the estimated 7.1 million of the UK population who read at or below the level of an average 9 year old, and the more than 40% of adults who struggle to understand health content written for the public [19].

The possibility of failed examinations and of successful examinations with negative radiological findings needs to be considered alongside any general statement on justification. It is assumed that the IR(ME)R practitioner holds a positive attitude to the outcome at the point of making the decision to proceed with a medical diagnostic procedure or treatment. The working assumption is that there will be an outcome beneficially affecting the clinical management of the patient, and that this individual patient will not be the one where the diagnosis or subsequent treatment fails. Successful examinations with negative radiological findings also have a value for beneficial clinical management of the patient from the standpoint of differential diagnosis. The justification of radiology-based health screening programmes (where negative findings predominate) is covered by societal benefit.

Conclusions

The proposed statement ‘under UK law, medical procedures that use x-rays or radioactivity can proceed only after confirmation that the resulting health benefits will be greater than any associated risk from radiation’ is a simple declaration of a legal requirement that fits in with the traditions of medical ethics and does not require detailed qualification. Although IR(ME)R 2017 also states that benefits and risks are to be explained to patients prior to exposure, this is related to informed consent and is independent of the prior process of justification, as covered by this statement. It seems reasonable, therefore, to make patients and the public more aware of the protection that UK law already provides for them before consent is sought.

REFERENCES

1. Statutory Instrument 2017. The Ionising Radiation (Medical Exposure) Regulations www.legislation.gov.uk/uksi/2017/1322/contents/made

2. Ebdon-Jackson S and Frija G 2021. Improving justification of medical exposures using ionising radiation: considerations and approaches from the European Society of Radiology *Insights Imaging* 12-2 https://doi.org/10.1186/s13244-020-00940-0

3. World Medical Association 2018. https://wma.net/policies-post/wma-declaration-of-geneva

4. International Commission on Radiological Protection 2007. ICRP Publication 105 radiological protection in medicine *Ann ICRP* **37** 6 ISBN 978-0-7020-3102-1

5. Royal College of Radiologists 2017. iRefer referral guidelines: eighth edition https://www.rcr.ac.uk/sites/default/files/documents/irefer_introductoryiaea.pdf

6. International Commission on Radiological Protection 2018. ICRP Publication 138 Ethical foundations of the system of radiological protection *Ann ICRP* **47** 1 ISBN 9781526450142

7. Malone J and Zölzer F 2016. Pragmatic ethical basis for radiation protection in diagnostic radiology *Brit J Radiol* **89** 1059 https://doi.org/10.1259/bjr.20150713

8. Royal College of Radiologists 2012. Standards for patient consent particular to radiology, second edition ISBN: 978-4-905034-57-4 https://www.rcr.ac.uk/sites/default/files/publication/BFCR(12)8_consent.pdf

9. Elwyn G *et al* 2012. Shared Decision Making: A model for Clinical Practice *J Gen Intern Med* **27** 10 1361-1367 doi: 10.1007/s11606-012-2077-6

10. Clinical Imaging Board 2020. https://www.sor.org/news/import/patient-information-posters-available-to-download

11. The Society and College of Radiographers 2019. Communicating radiation benefit and risk information to individuals under the ionising radiation (medical exposure) regulations ISBN 978-1-909802-36-0 https://www.sor.org/getmedia/8f42784b-9786-4bc7-adf5-ad5c6f836e98/irmer_benefits_and_risks_1.pdf_2

12. World Health Organization 2016. Communicating radiation risks in paediatric imaging ISBN 978924151034 https://www.who.int/publications/i/item/978924151034

13. Zanzonico P and Stabin MG 2014. Quantitative benefit-risk analysis of medical radiation exposures. *Semin. Nucl. Med*. **44** 210-214

14. Zanzonico P B 2016. The neglected side of the coin: quantitative benefit-risk analyses in medical imaging. *Health Phys.* **110** 301-304

15. Kotre C J 2023. Comparing benefit and detriment from medical diagnostic radiation exposure using disability-adjusted life years: towards quantitative justification. *J. Radiol. Prot.* https://doi.org/10.1088/1361-6498/ad1159

16. Statutory Instrument 2004. Medicines for Human Use (Clinical Trials) Regulations https://www.legislation.gov.uk/uksi/2004/1031/contents/made

17. Davies E *et al* 2022. Survey of the publics' preferences for communication of medical radiation risk *J. Radiol. Prot*. **42** 021506

18. International Atomic Energy Agency and World Health Organization 2012. Bonn call for action: 10 actions to improve radiation protection in medicine in the next decade https://www.iaea.org/sites/default/files/17/12/bonn-call-for-action.pdf

19. NIHR Evidence: Health information: are you getting your message across? 2022. doi: 10.3310/nihrevidence_51109 https://evidence.nihr.ac.uk/collection/health-information-are-you-getting-your-message-across