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COMMENTARY

Duty of candour and the definition of moderate harm for radiation overexposure and exposures much greater than intended in diagnostic radiology

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On 1 April 2013, a new standard National Health Service (NHS) contract came into use for all organizations commissioning NHS healthcare services, with the exception of services commissioned under primary care contracts. The contract requires all NHS and non-NHS providers of services to NHS patients to comply with a duty of candour. This requirement arose from a recommendation of the Francis Report into the failings at Mid-Staffordshire NHS Foundation Trust.¹ Under this duty of candour, if a reportable patient safety incident occurs or is suspected to have occurred, the healthcare provider must give information on the affected patient(s) about the incident and conduct an investigation within 10 days. Only incidents resulting in moderate or severe harm or death are covered by this contractual duty. Harm is defined using the definitions provided in the National Patient Safety Agency (NPSA) document “Seven steps to patient safety”.² The question arises as to how exposures much greater than intended reported to the Care Quality Commission under the Ionising Radiation (Medical Exposure) Regulations 2000 (IRMER)³ or patient overexposures reported to the Health and Safety Executive under the Ionising Radiations Regulations 1999 (IRR)⁴ should be interpreted within this definition of harm, so that the duty of candour can be complied with appropriately.

This article makes some pragmatic proposals for numerical patient dose thresholds that could be taken as broadly corresponding to the definition of moderate harm required to trigger the duty of candour. It is accepted that the concept of a firm link between the numerical values of radiation exposure and the actual harm is questionable, as explored by the International Commission on Radiological Protection (ICRP) when originally developing the concept of an index of harm.⁵

The broader question regarding the range of possibilities for causing harm by radiological misdiagnosis is not covered in this discussion, and it should be emphasized that justified high patient doses are by definition not incidents

and would, therefore, never trigger the duty of candour as defined above.

HARM FROM RADIATION OVEREXPOSURE INCIDENTS

The NPSA² has defined the levels of harm caused by an incident that require action under the duty of candour to be:

- moderate—any patient safety incident that resulted in a moderate increase in treatment and which caused significant but not permanent harm
- severe—any patient safety incident that appears to have resulted in permanent harm
- death—any patient safety incident that directly resulted in death.

Harm is defined as injury, suffering, disability or death and, importantly, in the context of radiation late effects, the different levels of harm do not include time limits. Clearly, the most important definition to match with radiation incident severity is that of moderate harm, at which level the duty of candour is triggered. The NPSA clarify the meaning of “moderate increase in treatment” as a return to surgery, an unplanned re-admission, a prolonged episode of care, extra time in hospital or as an outpatient, cancelling of treatment or transfer to another area such as intensive care as a result of the incident. An example given of a radiology-related moderate harm incident is that of a broken foot not detected on X-ray, resulting in the patient being sent for extensive physiotherapy with a consequence of further pain and damage.² This example would cover the situation where a radiation incident such as imaging the wrong side then directly resulted in the incorrect or repeated treatment of the patient, which caused moderate or greater harm. This would trigger the duty of candour owing to the demonstrable outcome of moderate harm. It should be noted that such a moderate harm “wrong side” incident might not actually trigger conventional reporting under IRMER, as the total

effective dose to the patient may only be doubled and therefore not exceed the reporting thresholds given in Health and Safety Executive (HSE) Guidance Note PM77⁶ except for CT, although interpretation on this point varies.

Stochastic effects

The main health detriment of exposure to ionising radiation in diagnostic radiology is radiation-induced cancer, a condition that would certainly be in the moderate harm category or greater. Clearly, as a stochastic effect, it is the likelihood of cancer rather than its severity that is quantifiable from a radiation dose estimate; therefore, it becomes challenging to define severity of harm by using a measure related only to its probability of occurrence. The NPSA definitions of severity of harm given above are intended to be linked with five levels of consequence scores and five levels of likelihood scores with the objective of scoring overall risk, where the risk score is the consequence score multiplied by the likelihood score.⁷ This approach of defining risk as the product of severity of harm and probability of harm is used below, but an attempt is made to use numerical estimates of severity and probability with the objective of suggesting a value of radiation dose that could be used to trigger the duty of candour. In the remainder of this document, the word risk refers to this product of severity and probability, except where it is referred to as a probability categorization in other documents where it appears in quotes, e.g. “moderate risk”.

Risk has been defined as “the chance that someone or something that is valued will be adversely affected in a stipulated way by the hazard”.⁸ The calculation of risk, R (the chance of an identified consequence occurring per annum) can be given as the product of S (the severity of harm) and P (the probability per annum of the occurrence of that harm). If we accept that it is valid to use the same approach to lifetime risks, such as the lifetime risk of a radiation-induced fatal cancer, then this can be used as an approach to quantify the likelihood associated with the threshold for a moderate harm incident. It is first necessary to introduce a quantitative measure of the severity of harm.

For the purposes of cost–benefit analysis in major project planning, and industrial, transport and road safety, the monetary value of the cost to society of a fatality, and hence the amount worth spending to prevent a fatality, is required to be defined. However, as well as the obvious ethical problem with the concept, the actual value used will depend on the context and considerations of how much various national populations or organizations would be prepared to pay to prevent a fatality. The HSE have previously taken a benchmark monetary value for preventing a fatality of £1 000 000,⁸ whilst more recently quoting £1 112 000 for the human cost plus a further £212 000 for the associated financial cost.⁹ Estimates across the rest of Europe vary.¹⁰

For the purposes of making an approximate estimate, a value of £1 000 000 is taken here as the value of one life lost. With this as a starting value, we can then consider a progressive scaling of severity in terms of financial consequence. If we take a threshold cost of a “moderate increase in treatment” to be £1000, then we have a nominal severity of 0.001, compared with a severity of 1.0 for a death.¹¹ The choice of £1000 as the cost of a “moderate

increase in treatment” is somewhat arbitrary, but the choice is supported by a frequency analysis of the spreadsheet of 2013–14 payment by results tariffs for admitted patient care and out-patient procedures,¹² which shows a strong peak in the range £501–£1500.

If we assume that a given patient is very unlikely to be the victim of more than one serious radiation incident in a lifetime, then a known incident ($p = 1$) resulting in the nominal financial severity of $S = 0.001$ associated with moderate harm, will result in a lifetime risk $R = 0.001$. If we take the view that this overall risk value should stay constant at $R = 0.001$ for an incident with a probability of causing a radiation-induced cancer with severity $S = 1$ (fatal), then the corresponding probability of this fatal incident is $p = 0.001$. ICRP Report 60¹³ gives a coefficient for lifetime likelihood of fatal cancer induction of 5% per sievert. The later ICRP Report 107¹⁴ recommends that this approximated fatal cancer probability coefficient, on which current international radiation safety standards are based, continues to be appropriate for the purposes of radiological protection. Using this factor, an effective dose of 20 mSv would result in a probability of fatal cancer induction of $p = 0.001$. It is therefore suggested that an additional effective dose of 20 mSv arising from an incident would be an appropriate value to trigger the duty of candour as a moderate harm incident for the majority of patients.

This level of probability is also in-line with the Chief Medical Officer’s report of 1995, which recommended a lifetime probability of death of adverse response of one in 1000 as the start of a “moderate risk” category.^{15,16} This categorization is also used by the Health Protection Agency (HPA) in describing the lifetime probabilities of cancer induction associated with justified diagnostic radiology examinations.¹⁷ The HPA do point out that the patient’s age and sex can lead to the probabilities associated with effective dose being increased, and this should be borne in mind when deciding whether to class an exposure as “moderate risk” or “low risk”. Nevertheless, for the majority of patients, a 20-mSv trigger level would be appropriate for a once in a life event.

Deterministic tissue injuries

A third type of a moderate harm diagnostic radiology radiation incident involves deterministic tissue injury caused by an accidental exposure. Since tissue injuries take time to develop, this situation may be different from one where the harmful consequence is easily demonstrable. It is important to note that a skin reaction or epilation resulting from a justified high-dose procedure would not fall into this category as this would not be an incident.

Skin effects such as erythema or epilation progress from temporary to permanent as the absorbed dose increases. Using the logic that permanent changes would correspond to the severe, *i.e.* permanent harm class of incident above, then the definition of moderate harm is probably best matched to the onset of temporary erythema and temporary epilation with a threshold absorbed dose in the context of intervention radiology of 2 and 3 Gy, respectively,¹⁸ values in-line with other recommendations.^{19,20}

The dose threshold for long-term effects on the lens of the eye has been the subject of much recent discussion, including the

question of whether it may have elements of a stochastic process, but the presently accepted value of a threshold absorbed dose is 0.5 Gy.¹⁴

CONCLUSION

In summary, it is suggested that the duty of candour in the standard NHS contract can be reasonably triggered for reportable diagnostic radiology incidents of overexposure of patients (IRR⁴), or exposures much greater than intended (IRMER³), when:

1. a reportable radiation safety incident has resulted in demonstrable moderate clinical harm or greater to the patient(s) affected
2. a reportable radiation safety incident has resulted in an additional effective dose to the patient(s) affected of 20 mSv or more
3. a reportable radiation safety incident has resulted in an additional skin absorbed dose ≥ 2 Gy or an eye lens absorbed dose ≥ 0.5 Gy.

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