Duty of Candour and Clinically Significant Accidental or Unintended Exposures: revisiting the definition of moderate harm for patient safety incidents involving ionising radiation

ABSTRACT

Objective:
To explore a quantitative interpretation of the term 'moderate harm' as applied to the triggering of the Duty of Candour associated with Clinically Significant Accidental and Unintended Exposures of ionising radiation.

Methods:
Current definitions of 'moderate harm' were matched to the lay descriptions of disease and injury states used in the calculation of detriment as disability-adjusted life years (DALY) by the World Health Organisation, to obtain a value of detriment associated with 'moderate harm'. Published conversion factors between effective dose and DALY were used to calculate the effective dose associated with the same detriment.

Results:
The DALY loss associated with a moderate harm incident is estimated as 0.0216 years. This corresponds to the detriment resulting from an exposure to ionising radiation of 21 mSv. An effective dose of 21 mSv relates to a probability of induced cancer of 0.0012.

Conclusion:
The results obtained closely match existing guidance although the method used is completely different. It is concluded that there is no evidence to change the existing guidance on the triggering of DoC in radiation incidents.

Advances in knowledge:
An alternative approach to linking 'moderate harm' and radiation detriment has reinforced existing guidance.

Introduction

On 6 February 2013 the Francis Report[1] into failings at the Mid-Staffordshire NHS Foundation Trust was published. As a result of a recommendation in this report, the Duty of Candour (DoC) was introduced as a requirement for all NHS and non-NHS providers of services to NHS patients on 1 April 2013. In December 2013 a preliminary commentary was published[2] which pointed out that the definition of 'moderate harm' given in the National Patient Safety Agency document 'Seven steps to patient safety' (no longer current) would be difficult to interpret for radiation overexposures in diagnostic radiology. A suggestion was made that for stochastic radiation effects, a 0.001 probability of inducing a fatal cancer might be a suitable trigger for DoC in medical radiation incidents. A number of developments since 2013 point to this initial suggestion being in need of re-examination.

DoC became part of the Health and Social Care Act 2008 (Regulated Activities) Regulations 2014[3], with radiation incidents triggering DoC defined as Clinically Significant Accidental or Unintended Exposures (CSAUE) in the updated Ionising Radiation (Medical Exposure) Regulations of 2017 (IR(ME)R 2017)[4]. Although the triggering of DoC for incidents resulting in moderate harm or greater has not been intentionally changed, the guidance on the interpretation of moderate harm is now that from the Care Quality Commission (CQC)[5], and that associated with the Learn From Patient Safety Events service (LFPSE)[6]. This service is currently replacing the National Reporting and Learning system in England, Wales and Northern Ireland. For CSAUE, the guidance is given in the document 'IR(ME)R: Implications for clinical practice in diagnostic imaging, interventional radiology and diagnostic nuclear medicine'[7]. The proposal of a trigger at a 0.001 or greater lifetime probability of radiation-induced cancer is adopted, although this is subtly different from the 0.001 probability of radiation-induced fatal cancer suggested from the admittedly speculative cost-benefit approach used in reference 2. This subtle change in definition has the result of slightly lowering the value of adult effective dose associated with the 0.001 risk from 20 mSv to 18 mSv, but it should be emphasized that the trigger level is the risk not the effective dose, so that paediatric conversion factors can be applied where needed. In this paper an alternative approach to linking moderate harm and radiation exposure is offered as a cross-check on the current recommendation. The established link between radiation exposure and health detriment in terms of disability-adjusted life years[8,9] will be used to explore a quantitative interpretation of the term 'moderate harm'.

Disability-adjusted Life Years (DALY)

The disability-adjusted life year (DALY) is a measure of overall disease burden which has been adopted as a public health measure by the World Health Organisation (WHO)[10]. It quantifies the impact of a disease on a population by combining mortality and morbidity into a single metric. The DALY is defined as:

$$DALY = YLL + YLD = N_m.LE + N_i.DW.YD$$

where :

DALY	Disability-adjusted life year
YLL	Years of life lost due to premature mortality (year)
YLD	Years lived with a disability (year)
N_m	Number of deaths (person)
LE	Standard life expectancy at age of death (year/person)
N_i	Number of incident cases (person)
DW	Disability Weight (DALY/year)
YD	Mean years of disability (year/person)

The result of this calculation is an estimate of the number of years of healthy life lost to premature death and disability by disease in a population. The DALY value is a sum of YLL, related to premature deaths, and YLD, related to the length of time lived with a disability, and it is this latter term which can be related to definitions of moderate harm for the individual, via the disability weight (DW) and length of time the disability is suffered (YD). The DW represents a rate of health loss as the fractional number of healthy years lost per year of disability. The

values of DW range from 0 (perfect health: no loss) to 1 (dead) and have been established using large-scale international surveys to elicit judgements on the health losses associated with causes of disease and injury. More than 30,000 such standardised surveys have been conducted to build up the DW data[10]. Strong evidence for consistent results across samples from different cultures has been reported[11].

Matching disability weights to definitions of moderate harm

The overarching definition of moderate harm as a moderate increase in treatment: 'an unplanned 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 treatment area (such as intensive care)'[5] will adequately cover the majority of incidents where the history of the incident can be demonstrated to fit this description of events. For radiation overexposure incidents, however, where the stochastic detriment will be delayed, it is necessary to match the anticipated radiation detriment to the few additional definitions of moderate harm where a degree of disability and its duration are given.

The currently available additional definitions[5,6] of moderate harm related to DoC plus a WHO category of 'adverse effects of medical treatment'[12] are summarised in table 1 in terms of the description of disability and its duration. The large number of established DW values and associated lay descriptions published by WHO[10] were used to match DW to the descriptions of moderate harm in table 1. This process has an unavoidable subjective element, and the various judgements and assumptions made in the matching of each definition are detailed below.

Moderate psychological harm

This definition is based around psychological conditions which limit the independence of the patient for a period less than six months. The minimum time duration 'more than a few days' was interpreted as 28 days in line with other definitions in table 1. The conditions included were ones where the description included such phrases as 'great difficulty with daily activities', 'depends on others', 'requires help', but very long term conditions that could not be reasonably expected to resolve in six months were excluded. Six conditions remained: major depressive disorder moderate episode, major depressive disorder severe episode, bipolar disorder manic episode, headache migrane, anxiety disorder moderate and anxiety disorder severe. The mean value of DW was 0.441.

Moderate physical harm

This definition is based around physical conditions which limit the independence of the patient for a period less than six months. The minimum time duration (not given) was again interpreted as 28 days in line with other definitions in table 1. Phrases indicating dependence on others were again used, and conditions likely to fall below the severity required for a reportable incident were eliminated. Where different grades of condition were indicated, the 'moderate', 'severe' or 'very severe' categories were included. Even though some conditions would be unlikely to arise from a medical incident they were included to improve the estimation of overall DW for moderate physical harm. The final list consisted of 25 conditions with an evenly distributed range of DW values. The mean value of DW was 0.297.

Prolonged psychological harm

This definition is based on the patient suffering moderate psychological harm for a period exceeding 28 days with no upper limit. Psychological conditions classed as 'moderate' or 'severe' were included and long term conditions were included. This gave a list of 21 conditions with an evenly distributed range of DW values. The mean value of DW was 0.372.

Sensory, motor or intellectual impairment
This definition covers a person experiencing a sensory, motor or intellectual impairment lasting at least 28 days but with no upper limit. The conditions selected included various grades of hearing and sight loss, and various grades of motor impairment and intellectual disability. This gave a list of 20 conditions with an evenly distributed range of DW values. The mean value of DW was 0.284.

Prolonged pain
This is described as pain that a service user suffers for a period of at least 28 days with no upper limit. Physical conditions where pain is mentioned in the lay description were included. Short-term conditions were excluded. This gave a list of 61 conditions with a long tail of higher DW values. The median DW value of 0.166 was thought the most appropriate average value in this case (mean 0.211).

Adverse effect of medical treatment
Figures for YLD (1235 years), incidence (121374 new cases per year), deaths (1266 per year) and prevalence (9271 per year) for the condition 'adverse effect of medical treatment' for the UK in 2019 were obtained from the extensive WHO Global Burden of Disease data resource[12]. Noting that the incidence for YLD (not including deaths) is 120108 cases per year, and that for a low frequency of disease, prevalence can be taken as the product of incidence and disease duration, then the duration of the condition reported can be estimated as 9271 / 120208 years or 28.2 days. This is in line with other definitions in table 1, so the duration aspect is in agreement with the definitions of moderate harm. YLD is calculated as the product of prevalence and DW[10], so the WHO value for DW must therefore be 1235 / 9271 or 0.133. This figure applies to all UK cases of adverse effect of medical treatment in the WHO data including cases which might fall below the threshold for reportable incidents, possibly reducing the resulting average value of DW. Despite this possible problem, this source of information has the advantage that it requires no subjective judgement to calculate, and it is therefore included as a cross-check on the rest of the results.

Results

The DW results derived above are summarized in table 2. The mean DW for the six categories of moderate harm is 0.282 DALY per year. A patient suffering this rate of DALY loss for a period of 28 days (from table 1) as a result of a reportable incident would therefore lose 0.0216 years of DALY, and this can be interpreted as representing the threshold for DoC.

Although no definitive calculation quantifying the DALY loss as the result of exposure to ionising radiation has yet been agreed, at least two papers have offered such calculations. Shimada and Kai[8] give a lifetime loss of DALY per person of 0.84 per Sv for Japanese males, and 1.34 DALY loss per Sv for Japanese females, a male-female average of 1.09 DALY loss per Sv. Vaillant et al[9] calculate a detriment of 0.99 DALY loss per Sv based on DALY per incidence

weighting factors applied to the nomimal risk coefficients for ages 0-85 (male and female combined) from ICRP Report 103[13].

If the present best estimate of the radiation detriment in terms of DALY loss per person is taken as the mean of these two calculations, then a value of 1.04 years of DALY loss per Sv can be used to link effective dose to moderate harm via the DALY loss of 0.0216 years at the moderate harm threshold. This gives an effective dose of 21 mSv, which is very much in line with the previous attempt to make this connection[2]. If the currently recommended[13] lethality-adjusted risk coefficient for cancer of 0.055 per Sv is applied to this 21 mSv effective dose, then the resulting risk is 0.0012, again very much in line with the 0.001 cancer risk currently recommended[7] as the trigger for DoC in the case of stochastic effects arising from CSAUE.

Conclusions

The link between radiation exposure and health detriment in terms of disability-adjusted life years has been used to explore a quantitative interpretation of the term 'moderate harm' as applied to the triggering of Duty of Care and Clinically Significant Accidental or Unintended Exposures. The large number of established DW values and their associated lay descriptions were used to match DW to the descriptions of moderate harm in current guidance documents, giving an average DW value of 0.282 DALY lost per year. The minimum period most frequently associated with moderate harm incidents in the guidance is 28 days. From these the DALY loss associated with a moderate harm incident can be estimated as 0.0216 years. From published coefficients relating effective dose to lifetime loss of DALY, this corresponds to the detriment resulting from an exposure to ionising radiation of 21 mSv. An effective dose of 21 mSv relates to a probability of induced cancer of 0.0012. Although the approach suffers from an element of subjectivity in the matching of DW to descriptions of moderate harm, the results are entirely consistent with the previous estimates of the accidental or unintended effective dose and cancer risk corresponding to 'moderate harm', which were calculated using a completely different approach. It is concluded that there is no evidence to change the existing guidance of a 0.001 cancer risk from stochastic radiation effects for the triggering of DoC in radiation incidents.

NHS/ non-NHS	Criterion for Moderate Harm	Time for Moderate	Time for Severe
NHS[5]	Moderate psychological harm: distress that did or is likely to affect the patient's normal activities for more than a few days but is unlikely to affect the patient's ability to live independently for more than six months	'More than a few days'	6 months
NHS[5]	Moderate physical harm: has limited or is likely to limit the patient's independence, but for less than 6 months	Not stated	6 months
NHS & non-NHS[5,6]	Prolonged psychological harm: psychological harm which a service user has experienced, or is likely to experience, for a continuous period of at least 28 days	28 days	
Non-NHS[6]	The person experiencing a sensory, motor or intellectual impairment that has lasted, or is likely to last for at least 28 days	28 days	
Non-NHS[6]	Prolonged pain: pain which a service user experiences, or is likely to experience, for a continuous period of at least 28 days	28 days	
NHS & non-NHS[11]	Adverse effects of medical treatment	28.2 days (derived)	

Table 1

Summary of definitions of moderate harm used in matching to disability weight.

Criterion for Moderate Harm	Average Disability Weight	Individual-DALY loss 28 days	Corresponding Effective Dose (mSv)
Moderate psychological harm: distress that did or is likely to affect the patient's normal activities for more than a few days but is unlikely to affect the patient's ability to live independently for more than six months	0.441	0.0338	32.5
Moderate physical harm: has limited or is likely to limit the patient's independence, but for less than 6 months	0.297	0.0228	21.9
Prolonged psychological harm: psychological harm which a service user has experienced, or is likely to experience, for a continuous period of at least 28 days	0.372	0.0285	27.4
The person experiencing a sensory, motor or intellectual impairment that has lasted, or is likely to last for at least 28 days	0.284	0.0218	21.0
Prolonged pain: pain which a service user experiences, or is likely to experience, for a continuous period of at least 28 days	0.166	0.0127	12.2
Adverse effects of medical treatment	0.133	0.0102	9.8
Averages:	0.282	0.0216	20.8

Table 2

Results of matching the criteria for moderate harm to other disease and injury conditions with known disability weights. The average disability weights are means except for prolonged pain where the distribution was skewed and the median value is given.

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