Duty of Candour and Clinically Significant Accidental or Unintended Exposures: revisiting the definition of moderate harm

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'Moderate Harm' – how to interpret for radiation incidents

- 2013. Argument based on cost of human life, average cost of additional treatment and risk of radiation-induced fatal cancer gave approximate trigger of 0.001 probability of fatal cancer. 5% per Sv fatal cancer risk factor implies 20 mSv effective dose trigger level. Cost argument not particularly strong, and more recent HSE discussion veering away from cost of preventing a fatality approach.

- 2020. This suggestion adopted in guidance 'IR(ME)R: Implications for clinical practice in diagnostic imaging, interventional radiology and diagnostic nuclear medicine' as 0.001 risk of radiation induced cancer, so whole population risk factor of 5.5% per Sv implying 18 mSv effective dose trigger level, or adult factor of 4.1% per Sv implying 24 mSv.

- Although it appears to work reasonably well in practice, this derivation is rather weak and could do with further work.

Disability adjusted life years

The disability-adjusted life year (DALY) is a measure of overall disease burden adopted by WHO. It quantifies the impact of a disease on a population by combining mortality and morbidity into a single metric:

DALY = YLL + YLD = (Nm x LE) + (Ni x DW x YD)

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

Disability adjusted life years

For an individual experiencing a period of non-fatal disease, the loss of years of good health in DALY is made up just of the YLD term for the individual:

$$\text{DALY}_{\text{(individual, non-fatal)}} = \text{DW} \times \text{YD}$$

DALY   Disability-adjusted life year
DW   Disability Weight (DALY/year)
YD   Years of disability (years)

Aim to estimate the values of DW and YD that correspond to 'moderate harm', then use the link between DALY detriment and effective dose to establish a trigger level.

Sources of definitions for moderate harm

Care Quality Commission 2022. Duty of candour: notifiable safety incidents.
www.cqc.org.uk/guidance-providers/all-services/duty-candour-notifiable-safety-incidents

NHS England 2023. Policy guidance on recording patient safety events and levels of harm.
www.england.nhs.uk/long-read/policy-guidance-on-recording-patient-safety-events-and-levels-of-harm/

Institute of Health Metrics and Evaluation 2020. Global burden of disease study 2019 (GBD 2019) results.
https://vizhub.healthdata.org/gbd-results/

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Institute of Health Metrics and Evaluation 2020. Global burden of disease study 2019 (GBD 2019) results.
https://vizhub.healthdata.org/gbd-results/

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

NHS/ non-NHS	Criterion for Moderate Harm	Time for Moderate	Time for Severe
NHS	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	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	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	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	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	Adverse effects of medical treatment	28.2 days (derived)	

WHO category 'adverse effects of medical treatment'

- Incidence = 121274 new cases per year (UK, 2019)

- Deaths = 1266 per year

- Prevalence = 9271 per year

- For low frequency of disease Prevalence = Incidence x Duration

  so for non-fatal cases:

    Duration = Prevalence / (Incidence – Deaths) = 28.2 days

  This is very like the 28 days in the other definitions so looks valid to include.

WHO category 'adverse effects of medical treatment'

- Value of YLD for UK in 2019 = 1235 years
- YLD = Ni x DW x YD = Prevalence x DW

so the disability weight we want is:

DW = YLD / Prevalence = 1235 / 9271 = 0.133

A problem might be that this definition is for all reported or estimated cases of 'adverse effects of medical treatment' and will include cases which fall below the level of reportable incidents, making the DW value low. Its advantage is that no subjective matching is needed.

Examples of disability weight descriptions

- Low back pain, mild - has mild back pain, which causes some difficulty dressing, standing, and lifting things (DW=0.020).

- Low back pain, moderate - has moderate back pain, which causes difficulty dressing, sitting, standing, walking, and lifting things (DW=0.054).

- Back pain, severe, with leg pain - has severe back and leg pain, which causes difficulty dressing, sitting, standing, walking, and lifting things. The person sleeps poorly and feels worried (DW=0.325).

- Neck pain, mild - has neck pain, and has difficulty turning the head and lifting things (DW=0.053)

- Back pain, most severe, with leg pain - has constant back and leg pain, which causes difficulty dressing, sitting, standing, walking, and lifting things. The person sleeps poorly, is worried, and has lost some enjoyment in life (DW=0.384).

Conversion of DALY to effective dose

Shimada and Kai (2015) :

0.84 per Sv lifetime years DALY loss Japanese males

1.34 per Sv lifetime years DALY loss Japanese females

M/F average 1.09 per Sv

Vaillant et al (2021):

0.99 per Sv lifetime years DALY loss US-Euro males/females

[Kotre (2024) unpublished:

0.88 per Sv lifetime years DALY loss US-Euro males/females]

Take average of Shimada and Kai and Vaillant = 1.04 per Sv

Matching of criteria for moderate harm to disease and injury conditions with known disability weights

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 (Mean of 6)	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 (Mean of 25)	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 (Mean of 21)	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 (Mean of 20)	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 (Median of 61)	0.0127	12.2
Adverse effects of medical treatment	0.133	0.0102	9.8
Averages:	**0.282**	**0.0216**	**20.8**

No change in guidance on DoC recommended

- The result of this calculation/estimation is a trigger for DoC for adults of about 21 mSv, similar to the level already in place but using entirely different approach.
- This corresponds to a cancer risk of 0.00085 for adults cf. 0.001 in the present guidance.
- This corresponds to a cancer risk of 0.0011 for whole population cf. 0.001 in the present guidance.

References

Kotre CJ and Walker A, 2013. Duty of candour and the definition of moderate harm for radiation overexposure and exposures much greater than intended in diagnostic radiology. *Brit. J. Radiol*., 2014;87:20130555.

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Shimada K and Kai M 2015. Calculating disability-adjusted life years (DALY) as a measure of excess cancer risk following radiation exposure. *J. Radiol. Prot*. **35** 763-775
doi: 10.1088/0952-4746/35/4/763

Vaillant L, Kai M and Hauptmann M 2021. Radiation detriment methodology: review of current non-radiation-related parameters and perspectives. ICRP Future of Radiological Protection Digital Workshop https://www.icrp.org/page.asp?id=549