Putting numbers on Justification – quantifying benefit and detriment from medical exposure

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Declarations

No external financial support is associated with this presentation. Zilch. Nada.

I remain, however, open to offers.

What's the problem?

The IR(ME)R 2017 Regulations are the law.

The IR(ME)R Regulations say that medical radiation exposures must be justified by the practitioner as showing significant net benefit.

The 'direct health benefits to the individual' and 'the individual detriment the exposure may cause' have to be considered.

We strive professionally to obey the law.

So are medical exposures justified in terms of benefit and detriment?

We don't really know.

What really happens

IR(ME)R stipulates that a Practitioner takes a decision on justification.

The Care Quality Commission inspect to ensure that for medical exposures the Practitioner is identified, has appropriate training and entitlement and that a system is in place to record the fact of justification.

The actual justification remains a medical decision.

That decision is based on incomplete information.

Who cares?

Patients need to give informed consent to the procedures they undergo.

IR(ME)R Schedule 2 1(i) '…..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.'

Shared Decision Making is now an element of consent. The patients need to be consulted.

Let's hope they don't find out that almost nobody actually knows how to justify the relative health benefits and detriments from medical radiation exposure. They might start withholding consent.

The R-word (1)

IR(ME)R jumps between the words detriment and risk when trying to describe the deleterious effects of radiation exposure. We all do it.

The OED defines risk as '(Exposure to) the possibility of loss, injury or other adverse or unwelcome circumstance; a chance or situation involving such a possibility.'

It's a possibility or chance. So it's really a probability.

Medical benefit is not easy to define, but whatever it is, it's certainly not a probability. The two concepts are different and not in the same units.

The R-word (2)

We commonly talk about ‘risk:benefit ratio’ when justifying medical radiation exposure.

They are in different units so there is no such thing. Although well-intentioned, it is an antinomic oxymoron of a paradox.

Similarly, weighing scales illustrating the balance between risk and benefit on patient information posters make no sense. The two sides are not in the same units.

Let’s instead choose a well-established unit from Public Health.

Disability-adjusted life years

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

$$\mathbf{DALY = YLL + YLD = [Nm \times LE] + [Ni \times DW \times YD]}$$

DALY	Disability-adjusted life year (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 a highly averaged 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:

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

DALY	Disability-adjusted life year	
DW	Disability Weight (DALY/year)	[0-1 defined for many diseases/injuries]
YD	Years of disability (years)	[The time suffered by the individual]

What IR(ME)R requires

BENEFIT – **DETRIMENT** = positive number (‘net benefit’)

BENEFIT > **DETRIMENT**

BENEFIT/DETRIMENT > 1.0

One advantage of this ratio definition is that the units cancel out and it’s just a number that has to be greater than 1. Let’s call it a justification factor.

J: the justification factor (1)

Quantify radiation detriment as DALY lost, and medical benefit as DALY gained by undergoing successful treatment:

$$J = \frac{\textbf{DALY BENEFIT}}{\textbf{DALY DETRIMENT}} > 1.0$$

The YLD part of DALY for the individual is Disability Weight x Time

$$J = \frac{(\textbf{BENEFIT}\ \text{DW}) \times (\textbf{BENEFIT}\ \text{TIME})}{(\textbf{RADIATION}\ \text{DW}) \times (\textbf{DETRIMENT}\ \text{TIME})} > 1.0$$

J: the justification factor (2)

If we say that the time from the treatment to the eventual end of the patient's life is approximately the same as the time from the radiation exposure to the eventual end of the patient's life, then the times cancel out:

$$\mathbf{J} = \frac{(\textbf{BENEFIT DW})}{(\textbf{RADIATION DW})} > 1.0$$

If the treatment is not completely successful, then the benefit DW may be the difference between that before treatment, $\mathbf{DW_B}$ and that after $\mathbf{DW_A}$. Let's call the radiation DW $\mathbf{DW_R}$:

J: the justification factor (3)

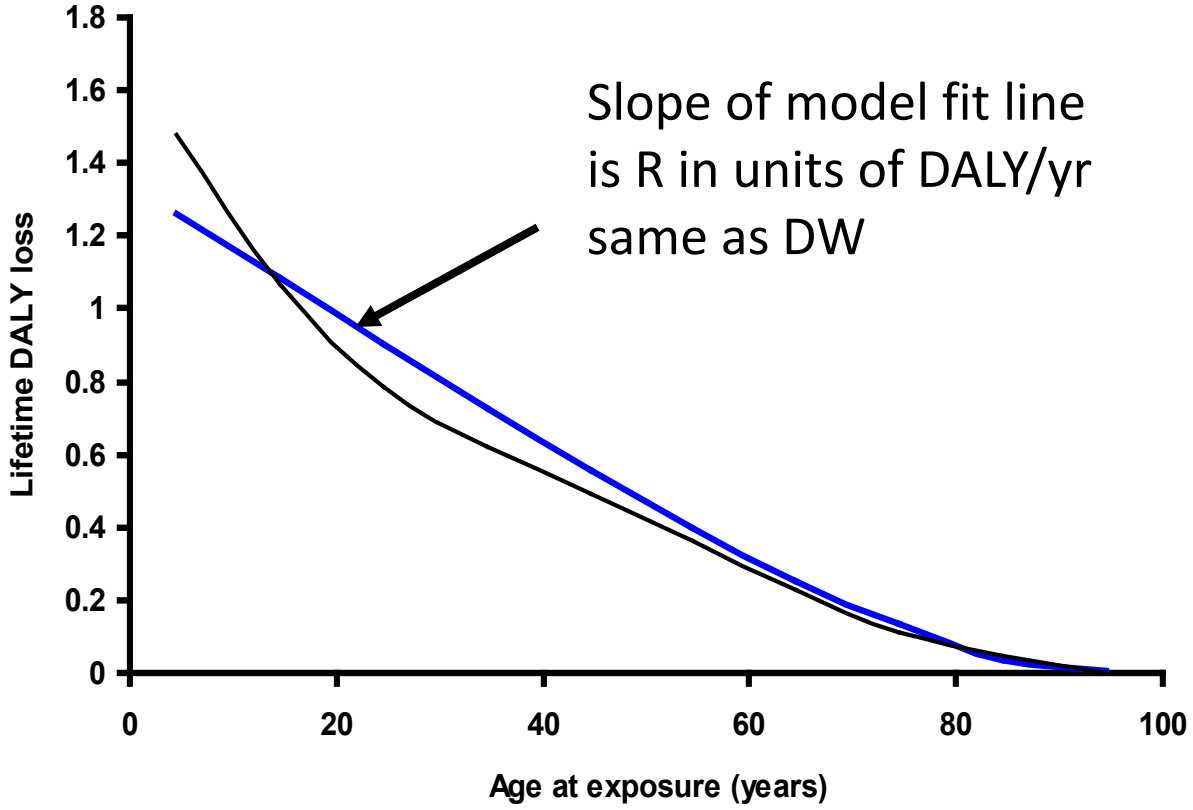
The definition of the justification factor then becomes:

$$J = \frac{(DW_B - DW_A)}{DW_R}$$

If this comes out greater than 1.0, then the exposure is justified.

Where does the radiation disability weight come from? (1)

If we calculate lifetime DALY loss as a result of an exposure to 1 Sv of radiation, plotted against the age at exposure, it can be fitted to a model which is a straight(ish) line over most of the age range. The slope of this line has the units of DALY/yr.

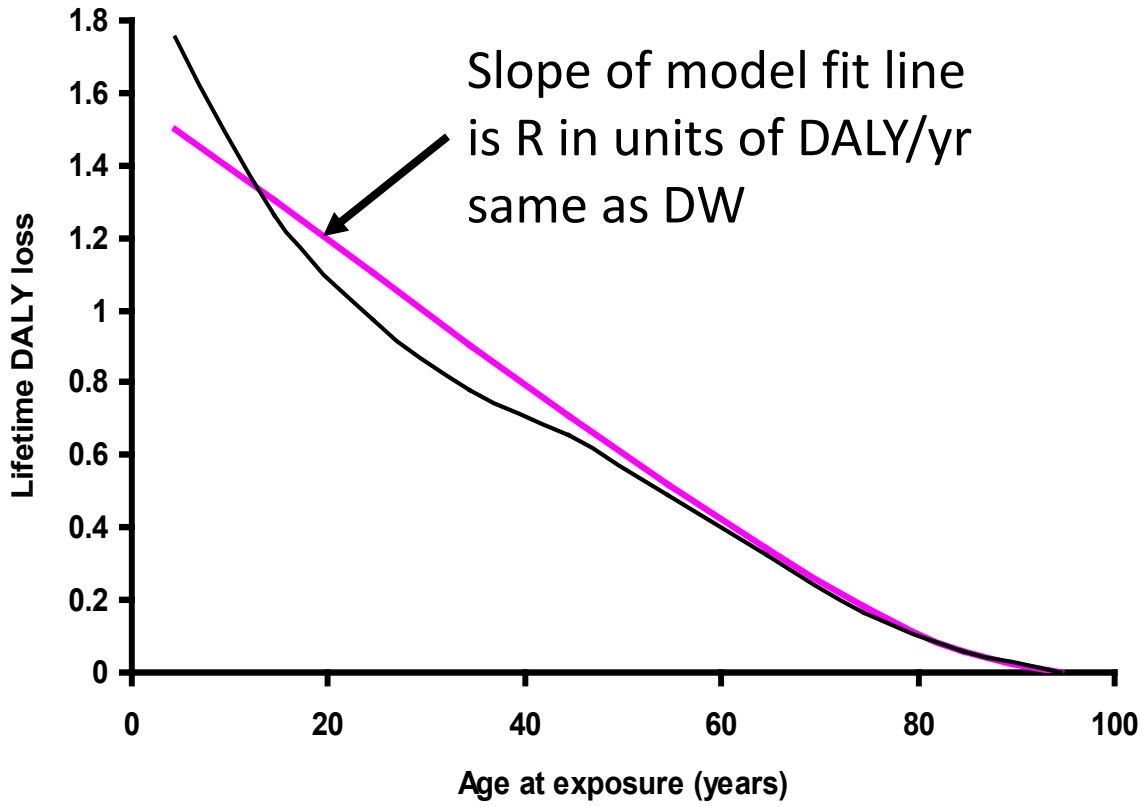


Where does the radiation disability weight come from? (2)

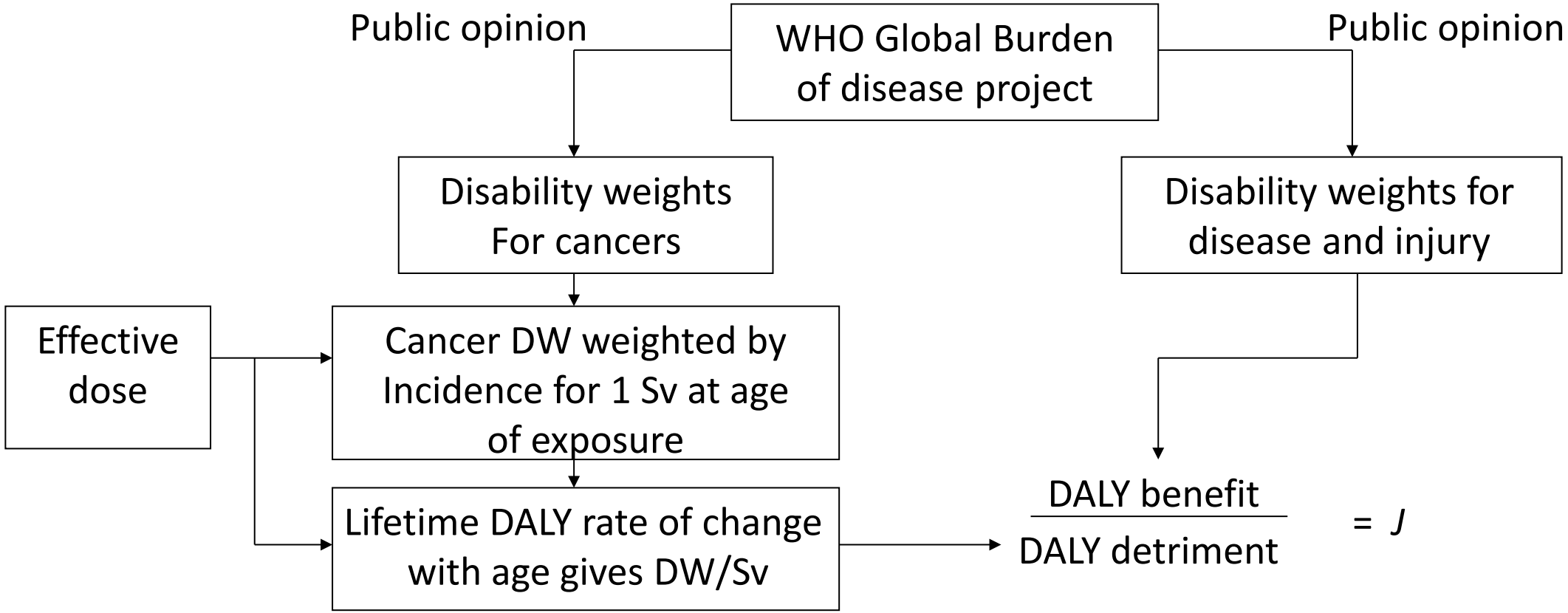
The slope, **R**, scales with dose in Sv, **E**, (linear-no-threshold assumption) and has a negative value, although DW defined by WHO as a positive number of DALY lost per year suffered. So:

$$\mathbf{DW_R} = -\mathbf{R} \times \mathbf{E}$$

R = -0.017 for males, -0.020 for females (US-European). [Updated from -0.020 and -0.022 previously reported.]

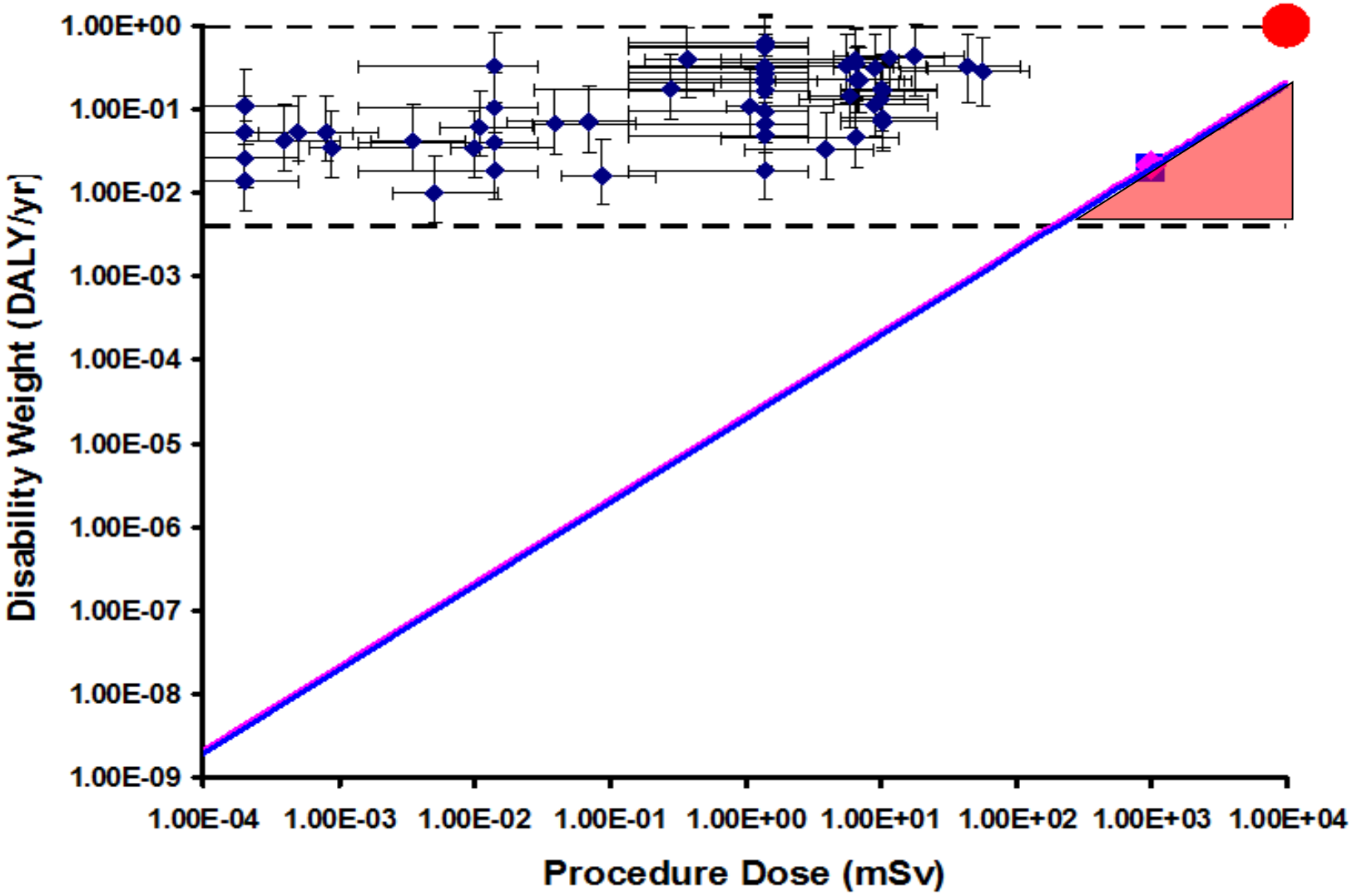


Justification Factor concept



WHO health state	Indicated examinations	Disability Weight	Typical Effective Dose (mSv)	Justification factor, J Male	Justification factor, J Female
Dental caries (symptomatic)	Intra-oral dental XR	0.01	0.005	118000	100000
Stroke: long term consequences, mild	CT head	0.019	1.4	798	679
Fractured foot	XR foot	0.026	0.0002	7650000	6500000
Fractured clavicle/scapula/humerus	XR orthogonal views	0.035	0.011	187000	159000
Dislocation of shoulder	XR orthogonal views	0.062	0.011	332000	282000
Face bone	XR facial bones	0.067	0.04	98500	83800
Stroke: long term consequences, moderate	CT head	0.070	1.4	2940	2500
Traumatic brain injury (minor)	CT head	0.094	1.4	3950	3360
Fractured sternum/ribs	CXR PA and lateral	0.103	0.039	155000	132000
Hearing loss: severe	CT head	0.167	1.4	7060	5960
Concussion	CT head	0.214	1.4	8990	7640
Cancer diagnosis and therapy	CXR and CT chest plus planning CT and 10 thorax cone-beam CT	0.288	57	297	253
Fractured neck of femur	XR pelvis and lateral hip	0.402	0.37	63900	54300
Acute MI days 1-2	CXR and Catheter coronary angiography & intervention	0.432	10	2540	2160

The Big Picture



What else could possibly go wrong? (1)

Consider a modified justification factor, **J'**:

$$J' = \frac{P.(1 - U).(1 - C).(DW_B - DW_A)}{(1 + V).\ DW_R}$$

P is the prevalence of the condition being investigated. 1 if present.

U is the real-time radiological error rate

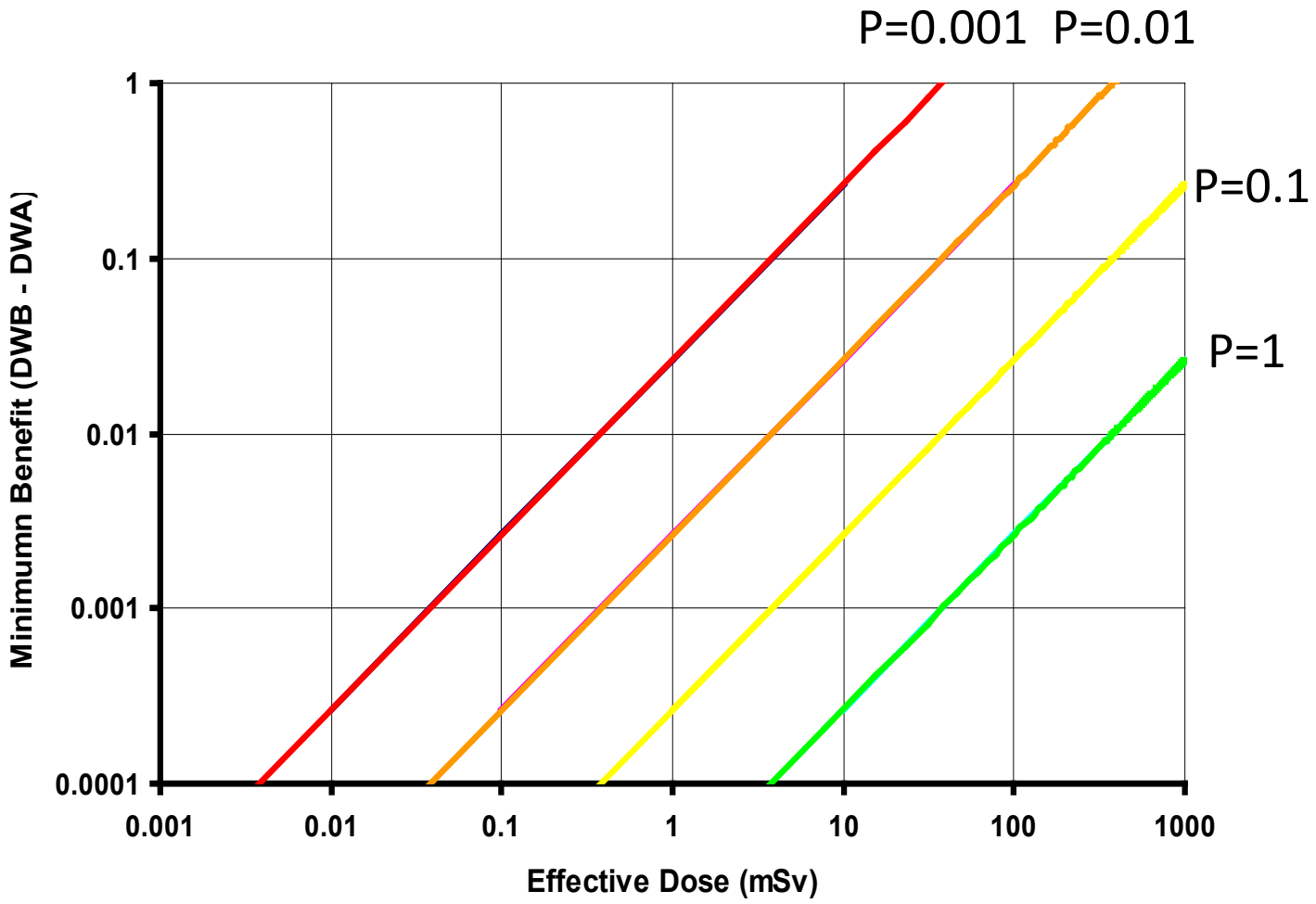
C is the complication rate of the diagnosis or treatment

V is the repeat rate for the radiation exposure

What else could possibly go wrong? (2)

Adopting realistic numbers for U,C and V, a general relationship between minimum benefit, dose and prevalence can be obtained.

The prevalence has to be low, the benefit small and the dose high before the limits of justification are approched.



Conclusions

- We assume because of our IR(ME)R procedures that all medical exposures are solidly justified. They're not. It's just an expert opinion.

- We tell the patients that they should consent to medical radiation exposure because the benefit exceeds the risk. We are talking rubbish, although we don't mean to. They're not even in the same units.

- We assume that's the best we can do. It's not. There are ways of analysing the situation based on public health and radiation epidemiology knowledge that can put justification on a quantitative basis. When we do that it looks as though the benefits really do exceed the detriments. By miles.

References

Kotre CJ 2025. Definition of a disability weight for human exposure to ionising radiation and its application to the justification of medical exposure. *BJR Open* 7 (1), tzae043 (Open access: just Google ‘kotre disability weight’ to get it. Download it now!)

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