INVITED EDITORIAL

Uncertainty evaluation and expression in dose and risk assessment

To cite this article: Penelope Allisy-Roberts and Philip Day 2008 J. Radiol. Prot. 28 265

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Uncertainty evaluation and expression in dose and risk assessment

Background

Papers submitted to the Journal of Radiological Protection often cover a wide range of measurements and dose assessments. Sometimes the conclusions, including recommendations, are based on these assessments but without consideration of the uncertainties involved. As knowledge of the uncertainties is an important factor in determining the reliability and applicability of any quantitative estimate, the Journal is seeking to develop guidelines for authors in this area. In relation to internal emitters, the issues were considered in some detail by the Committee Examining Radiation Risk from Internal Emitters (CERRIE) [1], and discussed in a paper recently published in the Journal [2].

It is also evident that there is a tendency to confuse the dosimetric quantities and their units, these sometimes being used interchangeably. Hence it was thought to be of assistance to authors to indicate the main points that should be considered in any submission to the Journal, and these are included in the following summary.

1. Quantities and units. All the dosimetric quantities are defined in terms of the SI units of energy release, or energy absorption per mass, J kg\(^{-1}\). For air kerma and absorbed dose (and with radiotherapy in mind), the special name gray (Gy) was adopted. For all the operational quantities expressed in terms of dose equivalent, the special name sievert (Sv) has been adopted since 1979 to differentiate these quantities as being in the domain of radiation protection rather than radiotherapy [3]. Note that the SI unit for both the gray and sievert is J kg\(^{-1}\). As the Sv is also ascribed to the specific ICRP protection quantities, equivalent dose and effective dose, when a radiation dose is expressed in Sv particular care must be taken to indicate clearly the actual dosimetric quantity under consideration, as discussed below and previously [4].

2. Types of uncertainty. Uncertainty, in relation to dose and indeed risk assessment, encompasses far more than the measurement uncertainty of the physical quantities. Whilst some uncertainties are readily quantifiable, others are less so but may be of equal or even greater importance in affecting the overall conclusions. The most common categories of uncertainty which will need to be considered in a scientific paper are listed below.

- Measurements of radionuclide activity, absorbed dose, personal, ambient or other dose equivalent will have associated uncertainties, which will be quantifiable, including the calibration of the instruments used to make the measurements.
- Sampling uncertainties will be associated with the limited amount of material sampled in an analytical survey (environmental variability), or in the selected locations of ambient dose measurements. Additionally the sampling distribution itself may well not be representative.
- Modelling uncertainties arise through the inevitable use of numerical or mathematical models to represent physical, biological and environmental processes. The models
themselves may be incomplete representations, or the parameters used in the models may be estimates or judgements.

- Conceptual uncertainties arise if the overall scheme of, say, a dose assessment is inadequate, for example where some significant pathway or mechanism has been overlooked.

3. **Intakes.** Estimates of intake/uptake (e.g. by humans) will depend on food-chain models and habit surveys, and will certainly be subject to physiological variability. If uptake by a reference individual is being estimated, the uncertainty in using the outcome to estimate the uptake in others should be discussed.

4. **Biological distribution.** Biokinetic pathways and organ dosimetry necessarily depend on models. These are themselves generalisations subject to physiological variability and are often based on sparse and in some cases inappropriate data, for example animal data used to determine the parameters for human models. Note also that using model distributions and conversion coefficients for healthy humans [5] may not reflect the uptake in a particular disease state.

5. **Radiation weighting.** There are uncertainties associated with the conversion of the absorbed dose (Gy) to the equivalent (biologically effective) dose (Sv) within the specified organ or tissues. The conversion involves the use of a ‘relative biological effectiveness’ (RBE) factor for different types of radiation, RBE being defined as the ratio between two absorbed doses delivered with two radiation qualities, one of which is the reference radiation, that result in the same effect in a given biological system, under identical conditions. Although basically experimental, RBE values are referenced to many different end-points, often determined in animal experiments of rather doubtful applicability to cancer initiation in humans and hence not at all precise. Additionally, there seems to be no generally accepted reference radiation energy for RBE measurements relating to radiation protection, both x-ray and gamma radiation being used, whereas $^{60}$Co is the recommended reference radiation for radiotherapy RBE values [6]. For regulatory radiation protection purposes, the ICRP has identified a simple set of generic ‘radiation weighting factors’ ($w_R$) as quantities ‘having no associated uncertainty’ on the grounds that they have been defined as part of the set of rules for regulatory dose assessment [7].

6. **Effective dose.** Conversion of equivalent (organ) doses to the whole-body quantity effective dose—a radiation protection risk-based quantity (also expressed in sievert)—involves the use of subjective risk factors embodied in the ‘tissue weighting factors’ ($w_T$). These factors, although constant for the period of validity, tend to be updated every 10 years or so as they depend in part on the subjective assessment of ‘detriment’ and more importantly on new epidemiological evidence [8] and improvements in cancer treatment. The values for the tissue weighting factors are decided by the ICRP, and although it is obvious that the values cannot be precise as they are risk-based, again for regulatory purposes a simple set of age-averaged and sex-averaged values has been identified [7], and the ICRP has judged that for regulatory risk-assessment it is not appropriate to attribute an uncertainty to them. Guidelines associated with the use of effective dose in scientific papers are considered in more detail below as authors need to be aware of the uncertainties surrounding the scientific values on which judgments are based.
7. The role of ICRP Recommendations. When considering uncertainties, it is necessary to distinguish between ‘regulatory’ and ‘scientific’ dose and risk assessment. For the former, the ICRP has defined equivalent dose and effective dose as quantities intended for use in radiological protection, i.e. principally for regulatory purposes, for constraints and dose limits. The methodology of dose evaluation, and the models and parameters recommended, are generic, and the radiation and tissue weighting factors, $w_R$ and $w_T$, although informed by science, are defined by committee decision as constants without uncertainty for this purpose. Thus, the manner in which equivalent dose and particularly effective dose are used can be inappropriate, and should be approached with great caution. To quote ICRP [7]: ‘The main uses of effective dose are the prospective dose assessment for planning and optimisation in radiological protection, and demonstration of compliance with dose limits for regulatory purposes. Effective dose is not recommended for epidemiological evaluations, nor should it be used for detailed specific retrospective investigations of individual exposure and risk.’ Indeed, the ICRP recommends that retrospective assessments for known individuals or groups should use more appropriate parameters than the generic sets defined for regulatory radiation protection [7].

Consequently, for scientific rather than regulatory purposes, dose assessment should always be as precise and accurate as possible, implying the use of specific information, models, parameters, RBE values, and age- and sex-related and organ-specific risk coefficients appropriate to the individual situation under investigation. In these situations, a full discussion of assumptions, estimation and, where appropriate, numerical evaluation of uncertainties, should be made along the lines indicated below. In scientific work, ‘equivalent dose’ should not be used in individual cases where explicit RBE values have been used in place of the generic $w_R$ values; instead the term ‘radiation weighted dose’ is preferred. Similarly, the use of ‘effective dose’ is not appropriate, and using the weighted doses for organ-specific, age- and sex-related risk assessment for the specific organs irradiated (see chapter 12 in [8]) would be more relevant and enable an individualized risk assessment, following an accidental exposure for example.

However, as effective dose is a measure of detriment, there may be circumstances where it could be used for risk comparison purposes, for example in comparing alternative imaging techniques prior to selecting a diagnostic technique on specific individuals. This is useful for control (regulatory) purposes or for providing information for public consumption and understanding.

Guidelines

The way in which uncertainties are dealt with in any particular paper will necessarily depend on the context. It is clearly important that uncertainties are addressed and discussed in a paper, but guidelines must be flexible enough to encourage discussion and allow for new approaches to this important topic. Consequently, for scientific work in which radiation dose and/or risk evaluation plays a part, a broad set of guidelines which addresses the whole spectrum of ‘uncertainties’ is recommended.

(i) The quantities under consideration should be clearly identified and the units used correctly so that there can be no confusion.

(ii) Measurement uncertainties should be evaluated, promulgated, combined and expressed in appropriate statistical terms based on standard textual references on measurement statistics, for example the Guide to the Expression of Uncertainty in Measurement (GUM)
The combined standard uncertainty of a measurement result, $u_c$, is taken to represent the estimated standard deviation of the result. It is obtained by combining the individual standard uncertainties $u_i$ (and covariances as appropriate) of the inputs to the measurement model, whether arising from a statistical or non-statistical evaluation, using the law of uncertainty propagation for combining standard deviations. When these uncertainties are symmetrical, a gaussian distribution is assumed with a coverage probability of about 68%. The indicator ± should not be used for standard uncertainties but may be used for expanded uncertainties, see (iv)).

(iii) When combined standard uncertainties are used with a coverage factor $k = 1$, they should be contained within parenthesis between the value and its unit and refer to the final digit(s), for example 36.7(4) MBq. The standard uncertainty should include statistical (e.g. counting) and experimental (measurement) components as well as any estimates due to the sampling or other aspects [9]. If the uncertainty expressed contains only some of these components, this limitation should be stated clearly.

(iv) More usually, 95% confidence levels are preferred and so expanded uncertainties are given with a coverage factor $k$, the value of which is taken from Student’s $t$-distribution, and for more than 30 degrees of freedom $k \approx 2$. As in the case of standard uncertainties this presumes a symmetrical distribution, and for expanded uncertainties the indicator ± is often used but there should be a clear statement about the confidence level, normally taken as 95% but sometimes 99% at $k \approx 3$ may be required.

(v) If the distribution is not symmetrical, the situation should be fully described. In particular, if the range of values includes zero or negative values which may have no physical meaning, the distribution is clearly non-symmetrical and the actual minimum and maximum values should be given, or preferably, statistical measures characterizing the non-symmetrical nature of the distribution should be provided. Particular examples can be found in survival analysis, life-tables and relative risk assessments, most of which show exponential features and may require double-log transformations to determine appropriate confidence limits. The results can then be presented with a confidence interval (CI) as for example 0.03 Gy$^{-1}$ to 1.88 Gy$^{-1}$ in: ‘The relative risk for all solid cancers in this population is 0.87 (95% CI 0.03, 1.88) Gy$^{-1}$’ [8].

(vi) In cases where measurement distributions are not known, or are limited by the paucity of measurements/samples, exact statistical analysis is often not appropriate and may well lead to a false sense of precision. Examples would be where uncertainties in measurement refer to statistical counting uncertainties only, and take no account of the limitations of sampling, although the latter will usually make a far larger contribution to the overall uncertainty. In such cases where measurement distributions may not be well defined, the evaluation and combination of uncertainties must be treated with great caution. If Monte Carlo methods are used rather than classical statistical analysis [10], sufficient detail of the methodology must be given so that this is transparent to the reader.

(vii) In all other situations, particularly where biological models are involved, and a conversion to effective dose in sievert is required, it may not be appropriate to make a quantitative statistical analysis of uncertainty, as any such process would itself be imprecise and any quantitative (numerical) outcome probably misleading. However, a full discussion of uncertainties, their sources, variability, asymmetry and bias, and possibly orders of magnitude should form part of any discussion of results.

(viii) When considering risks to individuals, e.g. retrospective risk assessments, the type of exposure (external and internal, whole body or specific organ), the type of radiation and the individual’s age and sex should all be taken into account.
(ix) Numerical values cited in papers should never be given to more significant figures than the total uncertainty warrants. For example, effective dose will rarely be more precise than 10% and a calculated/estimated value for an effective dose with its expanded uncertainty of \(27.23 \pm 2\) mSv should be cited as \((27 \pm 2)\) mSv at the 95% confidence level, although for transparency and to help the reader trace the calculations or estimations, one additional figure could be used in data tables.

Conclusion

A realistic estimate of statistical uncertainty, in the mathematical sense, as recommended in the guidelines can only be achieved for the measurement processes included under paragraph 2 above, and even then, not necessarily with the precision envisaged by the GUM. Other uncertainty sources, as discussed in paragraphs 2 to 6, can be estimated but such estimates will probably be semi-quantitative at best, and may not be capable of expression in a meaningful numerical sense at all. In any event, it is generally acknowledged that the likely range of uncertainty in dose and risk estimates is itself very uncertain, and it is important that this fact be acknowledged.

References

[5] ICRP 2002 CD1 Database of Dose Coefficients: Workers and members of the public (Amsterdam: Elsevier) 72

Some other relevant references:

- www.npl.co.uk/upload/pdf/up_a_gum_tree.pdf
- physics.nist.gov/cuu/Uncertainty/index.html
- www.bipm.org/en/publications/guides/

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