On the use of "effective dose" (*E*) in medical exposures

Effective dose (E) has been evolved by International Commission on Radiological Protection (ICRP) over the years as a principal protection quantity to meet the requirement of an appropriate quantification of radiation exposure which is to be used for regulatory purposes for implementing the basic principles of radiological protection, especially for setting and controlling dose limits for stochastic effects and for use in optimization. It equates the health detriment from an exposure of any part of the body (whether internal or external exposure) to that of a uniform whole body dose for a reference person. E is being widely used in medical exposure as is evident from reports and publications appearing in a variety of journals. For the estimation of E in diagnostic radiology, commercial computer-programs have also been in vogue and are being upgraded (e.g. PCXMC)[1] to account for the present tissue weighting factors of ICRP[2]. Medical exposures are predominantly delivered to individuals (patients) undergoing diagnostic examinations, interventional procedure, and radiation therapy. Among the three basic principles of radiological protection (justification, optimization, and dose limitation) in medical applications, dose limitation is not relevant to patients. E has some role in justification (which has the considerations of more good than harm, suitability of the procedures, and the applicability of a procedure to an individual), but it is the optimization [as low as reasonably achievable (ALARA) economic and social factors taken into account], where it is supposed to have a wide applicability.

E is linked to health-related detriments for stochastic effects and is a single risk related quantity. Many users find it a very easy and readymade device to predict cancer incidences by considering it as a reliable and accurate predictor of risk. This created a concern on the validity of such estimates and more alarmingly when low doses are integrated on large number of persons giving numbers which cannot be easily digested, as sometimes such estimates and predictions could lead to undue attention of media and other interested individuals to exploit the data in creating sensational news. Recent recommendations of ICRP[2, 3] reiterated the limitations of E and highlighted the scope of its application. Since it has already been used for risk estimation in medical practices, a serious debate on the application of E has erupted[4-9] as publications using E for estimating risk continue.[10, 11] Although experts appear to agree[4-9] with the concern raised in the recent ICRP recommendations[2] that E is not meant for risk estimation, the continuation of the use of E is due to the fact that there is no other simpler way for the estimation of risk. There has been a question that if not E then what else could be used to estimate radiation risk in medical applications. This formed a significant part of discussion in a recent ICRP symposium[9] attended by large number of experts (about 400) not only from ICRP (about 85) but also from several other leading organizations, institutions, professional bodies, etc. A task group (Task Group 79 entitled "Effective Dose") set up by ICRP is known to be examining the relevant aspects and is likely to come out with a meaningful report. In the meantime, it has become important to recognize the intricacies which inhibit the use of E in risk evaluation.

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There are two major assumptions in arriving at E: (1) At low doses, the total radiation detriment to the exposed person is taken to be the sum of radiation detriments to each of the different organs of importance, and (2) linear relationship between dose and risk without any threshold, i.e. linear non-threshold (LNT) model is applied. Based on these, it provides a single value of dose from internal emitters and external radiation field. E is the tissue-weighted sum of radiation-weighted doses of body organs and tissues [$E = \Sigma_T w_T \Sigma_R w_R D_{TR} = \Sigma_T w_T H_T$, where H_T (= $\Sigma_R w_R D_{TR}$) is the equivalent dose in tissue or organ and D_{TR} is the mean absorbed dose from radiation R in a tissue or organ T] arrived at by using tissue weighting factors (w_T) and radiation weighting factors (w_R) generated for this purpose. It is calculated [2] by averaging equivalent doses, H_T, in both the adult male (M) and adult female (F) reference phantoms for the relevant organs and tissues ($E = \Sigma_T w_T [{}^M H_T + {}^F H_T]/2$). The uncertainties involved in methodologies in arriving at w_R and w_T values and the limitations of the basic assumptions are so large that E has been termed to be no more a scientific quantity.[6] The following are the main sources of uncertainties and viabilities which indicate the inadequacy of E for risk estimation.

As $E = \Sigma_T w_T \Sigma_R w_R D_{TR}$, it may be noted that neither the absorbed dose / equivalent dose in any organ or tissue nor the effective dose can be measured directly. There are in-built errors in arriving at D_{TR}, w_R, and w_T. Heterogeneity of energy deposition within tissues causes error in arriving at D_{TR}. Also, the target cells for the induction of cancer and their locations in tissue are not well known, The uncertainty becomes considerably higher in nuclear medicine [6]. For the internal exposures, there is already considerable concern on the accuracy of the use of dosimetric and biokinetic models. There are also ambiguities in translating whole body external exposure to the internal exposures. This is further complicated by biological variability from person to person. [2] W_R values are based on radio-biological effectiveness (RBE) of the radiation and vary with the considered end point. These are frequently taken from animal and *in vitro* data and often an unavoidable extrapolation is made. A gross simplification is made by adopting only a few values for a wide range of varying radiations. Even for photons of energies from a few keV to a few MeV, variation of as much as 300% [2] is known to exist but still w_R value is taken to be 1. For w_T, summation for all ages and sexes is carried out knowing fully well that between some ages the change could differ up to six fold and for sexes of the same age it could differ up to two fold.[6] In medical exposures of patients to external radiation, low tissue weighting factors for skin, and relatively low values for a number of other body tissues, a partial body exposure can result in appreciable equivalent dose to tissue even though the corresponding effective dose may be small[2] which is concerned with only limited parts of the body. For the LNT model, the validity of assumption of linearity of dose response at low doses is recognized to remain in doubt and this status may remain so for a long time to come, although both supporting and opposing arguments are available.[2] The adoption of LNT model is considered to be the only choice for the pragmatic approach adopted by ICRP as most data of the risk are extrapolated from high doses [e.g. Japanese life span study (LSS) data as the main source]. Even the validity of the use of dose and dose rate factor (DDRF) value of 2 is also in question. [2] With respect to physiological and other parameters, the applicability of the risk estimates in different ethnic groups is also often questioned. Further, *E* is not based on data from individual persons, but to an imaginary reference person, and therefore the differences between the reference person and individuals need to be understood.

In view of such a gamut of uncertainties and variability, it is estimated that the cancer risk based on *E* for an individual could vary by one or two orders of magnitudes in some medical applications.[6] For medical X-ray procedures, another estimate[9] demonstrates that if the assessment of the risk is based on *E*, there can be an underestimation for children (0–9 years) of both sexes by a factor of 1.5–4 (reaches 4 for girls undergoing thorax examinations) and an overestimation for adults and senior patients by a factor of 2.5 and 10 (or more), respectively. Hence, due care needs to be taken for accepting any conclusion on risk based on *E*. ICRP clarified that the main and primary uses of *E* are: (1) prospectively for planning and optimization of occupational and public exposures and (2) retrospectively for demonstrating compliance with dose limits for regulatory purposes in radiological protection; not for the estimation of risk. For medical exposures, *E* is supposed to be used "for comparing the doses from different diagnostic procedures – and in a few special cases from therapeutic procedure – and for comparing the use of similar technologies and procedures in different hospitals and countries as well as using different technologies for the same medical examination."[2] The main role of *E* in medical applications is in optimization which is the term for indicating a relative aspect. For risk estimation from medical exposures, several alternate approaches are being suggested. One of them is to use *E* for risk assessment following simple adjustment to the nominal risk per unit effective dose to account for age (and sex?) difference.[9] The other[4] is to replace "*E*" by "effective risk" in which the weighting factors would be evaluated for tissue-specific lifetime cancer risks per unit equivalent dose. The "effective risk" is supposed to have the potential to be age- and gender-specific if desired to perform the role of *E*, but this is questioned.[5] The best could be to take the individual cases with all the parameters applicable to an individual as close as possible, but this seems too complicated. Till these are under discussion, evolution, and evaluation, it is important that in medical applications, use of *E* is limited to optimization and justification and the estimation of risk using *E* should be avoided. For the above use of effective dose, due care should be taken to ensure the use of relevant values of ICRP weighting factors (preferably, the most recent values should be used) as these are changed about every 15 years. It may be noted that for the same examination, the estimation of effective dose in certain cases can differ by 100% or more depending on the use of the values of the old or new ICRP recommendations.[12]

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