

# Using Metascience to Improve Dose-Response Curves in Biology: Better Policy through Better Science

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Many people argue that uncertain science—or controversial policies based on science—can be clarified primarily by greater attention to social/political values influencing the science and by greater attention to the vested interests involved. This paper argues that while such clarification is necessary, it is not a sufficient condition for achieving better science and policy; indeed its importance may be overemphasized. Using a case study involving the current, highly politicized controversy over the shape of dose-response curves for biological effects of ionizing radiation, the paper argues that the conflict could be significantly resolved through specific methodological improvements in the areas of metascience and philosophy of science. These improvements focus on taking account, respectively, of scale, data trimming, aggregation, measurability, and simplicity.

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**1. Introduction.** For the last three years, members of the International Commission on Radiological Protection (ICRP) have debated proposals to use protective action levels (PALS) to assess hypotheses about the shape of the dose-response curve for biological effects of ionizing radiation. The controversy over ICRP PALS is fueled, on the one hand, by fears of nuclear power and a repetition of the Chernobyl accident and, on the other hand, by desires to cut costs in weapons cleanup and reactor decommissioning. Academic-medical scientists tend to be aligned on one side of the conflicts, against PALS, whereas industrial-military scientists tend to be aligned on the other side, in favor of the PALS proposals.

**2. The 2001 ICRP PALS Proposals.** In its 2001 PALS proposals, the ICRP argued for radiological protection based on amended understanding of the biological dose-response curve for ionizing radiation. Designed to

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make radiation protection more consistent, complete, scientifically defensible, and simple (ICRP 2002), the PALS proposals did two things. *First*, they defined collective radiation dose as an unjustified, nonempirical “construct” and argued for defining radiation dose purely empirically, that is, purely in terms of observable effects on individuals. Collective dose is the principle, used for the past half century, whereby radiation biologists affirm that the *detriment* (caused by ionizing radiation), like cancer, is a function of the dose to the tissues. Because there is no threshold for risk from ionizing radiation (only 35 eV can scramble DNA), and because the dose-response curve is accepted to be linear with no threshold, a large dose  $X$  of ionizing radiation to a small number of people  $Y$  is taken to cause the same degree of detriment (by ionization tracks through cells) as a smaller dose  $X/z$  of ionizing radiation to a larger number of people  $Yz$ . This notion of convertible detriment is what is essential to collective dose. It enables us to calculate radiation dose, much as conservation laws enable calculations. Yet collective dose is not typically empirically (epidemiologically) confirmable because of statistical “noise” (confounders, too-small sample sizes) in the low-dose results (see Fairlie and Sumner 2000).

*Second*, proposing to simplify radiation protection, the PALS proposals divide different levels of additional, human-caused radiation exposure into different classes, based purely on quantity of exposure. Given five different quantitative dose-ranges, the PALS proposals specify five different protection actions that ought to be taken in response. At the most minimal level/class of exposures, PALS calls doses “negligible,” because they are on the order of normal background exposure (ICRP 2002; Clarke 1999). Nevertheless all background exposures themselves are risky; there is no threshold for dangerous effects of radiation on biota (ICRP 1991; NCRP 1993).

**3. Metascience.** How might one decide the plausibility of the ICRP PALS case on *metascientific* grounds? Following J. O. Wisdom (1987, vii), one can assume that ‘metascience’ has the same meaning as ‘methodology,’ and thus that a metascientific investigation is a methodological inquiry. Moreover, it is a methodological inquiry conducted with the tools of logic and science, but an inquiry that takes place *after* one has given a typical scientific explanation. For example, as Wisdom notes, one possible scientific explanation of why a man lights a cigarette is force of habit. Metascientific explanations arise when one asks, afterward, why his lighting the cigarette is a force of habit. They ask for an account of the dispositions and practices of rule-following themselves. Thus, metascientific inquiries focus on “two types of questions, namely ‘what is the explanation of the rules?’ and ‘why do people accept them?’” (Wisdom 1987,

24–25). Issues discussed under the first question include whether scientific development is discontinuous. Issues central to the second question include how to defend science as rational (Halfmann 1984, 153).

As it is often understood, metascience has at least two functions, with only one of which this paper is concerned. The *ideological* function is to defend science against external threats to its consistency and empirical procedures. The *technical* function, with which this paper is concerned, is to preserve the cognitive and empirical standards that ought to characterize good science. Focused on the technical metascientific function, this paper takes no position on conflicts such as those between logistic and structural views; between model and set theorists (see, for example, Pearce and Rontala 1983); or between eliminativists and identicists (see Maffie 1995). (Eliminativists reject epistemology in lieu of successor *sciences* such as neurosciences, whereas identicists reject any epistemology except the self-evaluative *practices* of science). This paper addresses more basic methodological questions about which model theorists, set theorists, and so on, ought to be able to agree.

In the PALS debate, there has been a tendency to ignore technical metascientific analyses that might help resolve it. In general, nuclear critics (e.g., L. Moore 2002) point to the *values* apparently driving the PALS proposals: they were made mainly by those employed by the global nuclear industry, they allow more lenient standards for radiological cleanup, they allow manipulation of doses by vested interests, and they result in avoiding costly pollution control. If the arguments in this paper are correct, one need not resort to question-begging attacks on scientists' intentions, their funders, or their vested interests. Instead one can decide the plausibility of the case on metascientific grounds alone.

What technical function might metascientific investigation of the PALS proposals serve? It might clarify how well PALS preserves the *cognitive* and *empirical* standards that characterize good science. On the empirical side, this paper argues that the PALS proposals presuppose an interpretation of the radiobiological dose-response curve that is scientifically flawed in at least two ways: (1) they propose *trimming the data* in ways that lead to inconsistent theory; (2) their *aggregation* of dose data is incomplete. On the cognitive side, the paper argues that PALS are flawed in at least three ways: (3) they ignore problems of *scale*; (4) they adopt an inconsistent position regarding *measurability* of dose; (5) they misuse the metascientific criterion of *simplicity*. Consider each difficulty in order.

*3.1. Trimming the Data.* Empirically speaking, the new ICRP proposals fall short of good science, which requires that one should not ignore any relevant information, because they presuppose what the English mathematician Charles Babbage called “trimming the data.” Ignoring exposures

arising from collective doses from various sources, as the ICRP has proposed, means that all contributions to a person's dose will not be counted. One can recognize this incompleteness by the following considerations:

1. I can determine my total individual dose of radiation only by adding all the doses I receive from each source.
2. But the new ICRP proposals tell me not to add those doses that I receive (as a member of a collective-dose population) from weapons testing, Chernobyl, and various other sources.
3. Therefore the new ICRP proposals prevent me from learning my total individual dose, because they ignore collective doses that I receive as a member of a large group

If these considerations are correct, then the ICRP proposals (to abandon collective dose) trim the dose data. They also are inconsistent in admitting the need for collective-dose calculations for workers, but denying the need for collective-dose calculations for the public (ICRP 2002, 117). Because many members of the public (those who receive X-rays or cancer treatment, for example) have radiation exposures that are greater than those of nuclear workers, it is inconsistent to calculate the collective dose for workers but not for the public. This inconsistency betrays a second inconsistency regarding the linear, no threshold (LNT) hypothesis (that risky effects of radiation are linear, with no threshold for risk at any dose). By admitting the need for collective doses in the worker case, the ICRP has admitted that even small exposures are additively or cumulatively important and ought to be monitored. Thus the ICRP proposals inconsistently reject LNT and dose additivity in the collective dose of the public, but to accept them for workers. Such an inconsistency is incompatible with good science because the ionizing radiation behaves in exactly the same way in both the worker and public cases.

Moreover, from the point of view of metascience, these inconsistencies are at odds with science as a process of theoretical unification. If Michael Friedman is right (1974, 15), then good science "increases our understanding of the world by reducing the total number of independent phenomena that we have to accept as ultimate or given." By separating worker and public exposures, and treating collective doses differently for them, ICRP PALS proposals discourage theoretical unification and thus scientific progress. If it makes sense, for example, to use the kinetic theory of gases to unify gases' obeying the Boyle-Charles Law, their obeying Graham's Law, and their having specific heat capacities, then it makes sense to use LNT and collective dose to unify understanding of worker, medical, and public doses. There is no scientific rationale for treating them differently.

As a consequence of trimming the dose data by incomplete use of

collective dose, and instead considering only doses to individuals (presumably nearby in space and time), the ICRP proposals actually may promote a “disperse and dilute” or “higher-smokestack” strategy. This strategy is to use radiological emission and effluent techniques (such as poorer radwaste canisters) that send the exposures farther away in space and time. By ignoring collective dose and sending effluents/emissions farther away, one can claim that no known individuals receive a significant dose, and therefore that such doses need not be counted. Yet if there are radiological releases, even if they are not counted as part of individual doses, obviously the radiological burden for the planet will be increased, just as it was for weapons testing. Given the cumulative and no-threshold character of the effects of radiation exposure and the long half-lives of many radionuclides, this instance of trimming the dose data could lead to increased doses.

The fact that no nation will monitor individual doses in the way required by the new ICRP proposals also suggests that actual doses are likely to increase and to be undetected. Indeed, even in the developed world, it is difficult to keep track of medical and x-ray records, which are far easier and less expensive to obtain than radiation-dose records. Such radiation records also would be more difficult to obtain/maintain (than collective-dose records based on emissions/effluents) because of individual variations among people and the need for continual individual monitoring. That is why most pollution-control regulations are written in terms of emission or effluent standards, not merely in terms of individual-dose standards, as the ICRP proposals are.

Because of the empirical difficulties with monitoring individual doses, the ICRP will have either to estimate individual doses or to use average doses. It has said it will do the latter (ICRP 2002, 122). Yet both these alternatives are undesirable. Estimation is undesirable both because it is nonempirical/nonmeasured, and because it could be manipulated or misused by those having an interest in showing alleged low doses. Using average doses is undesirable because it is dependent on the model and distribution chosen, and because using average doses fails to reflect detriment to the most sensitive population segments: average dose figures could cover up high doses to especially sensitive people, such as children.

*3.2. Ignoring Background Radiation.* By virtue of proposing a dose-response curve presupposing the acceptability of radiation releases of the same magnitude as natural background radiation (see ICRP 2002, 119–120), the ICRP defines science in terms of an ethical norm (the acceptability of background radiation levels), rather than an *empirical* one. It notes approvingly that a majority of the ICRP members agreed with the use of natural background radiation in interpreting the dose-response

curve. But both science and ethics challenge the ICRP-PALS presupposition that just because background radiation of a certain level is natural or normal, it is benign, desirable, or acceptable. From the point of view of science, the ICRP presupposition about “negligible” radiation is questionable because many experts say that even 1 mSv of background radiation is responsible for 1 in 40 fatal cancers (UNSCEAR 1994; Gonzalez 1994), and background radiation is typically several times greater than 1 mSv. If they are correct, if all exposures to ionizing radiation carry a small risk, then background radiation ought not be used as a normative criterion either for what is supposed to be purely scientific or for what is supposed to be harmless.

From the point of view of ethics, this ICRP presupposition could violate the naturalistic fallacy. G. E. Moore said anyone who identifies a moral property (e.g., good) with a natural one (e.g., what is advantageous, given natural selection) commits the naturalistic fallacy (1903). Even if Moore’s argument (that the fallacy is a genuine error) is problematic (see e.g., Darwall, Gibbard, and Railton 1997), “practical reasoning theorists,” “constructivists,” “non-cognitivists,” and “sensibility theorists” believe Moore was “on to something.” They think moral and natural properties are distinct, even if Moore’s argument for the distinction is flawed. Also, for many people, commission of this fallacy amounts to violating the is-ought distinction (the metaethical claim that one cannot deduce a moral from a nonmoral claim). Searle (1964), Flew (1970), and Darwall, Gibbard, and Railton (1997) consider the is-ought distinction and the fallacy to be *identical* (see Hume 1888 and Dodd and Stern-Gillet 1995). If these philosophers are correct, then the ICRP presupposition may fall victim to this fallacy, or to a violation of the is-ought distinction, or both. The reason is that the ICRP proposals involve not only naturalistic or scientific considerations but also normative ones, such as “how safe is fair enough” or “how much protection ought people to have?” Thus the ICRP PALS proposals may err if they presuppose that only scientific considerations substantiate conclusions that are, in part, ethical conclusions. For example, by claiming radiation releases are negligible if they are at the same level as background radiation, the ICRP may commit the fallacy by *defining* some natural/scientific property (probability of fatality) as morally acceptable, instead of *giving ethical reasons* for its acceptability.

Adopting such normative and nonempirical interpretations of the dose-response curve is not only poor science but also could lead to problematic consequences. If one wished to argue that additional radiation exposures, below background, were negligible or trivial, then one could just as easily argue, for example, that particular cases of typhus or tuberculosis were negligible or trivial, provided that they were below the normal level of either disease. Obviously, normalcy does not entail that it is always ac-

ceptable either to cause additional cases of typhus or tuberculosis or to cause additional radiation exposures. Accepting such an interpretation of the radiation dose-response curve also might deter medical and scientific progress. They could deter medical progress because one could claim all preventable biomedical risks or harms were acceptable if they were below the normal level. They could deter scientific progress because ignoring additional small doses of ionizing radiation could contaminate and bias control groups used in epidemiological studies of radiation effects. Thus, making a deliberately normative, rather than an empirical, assessment of an empirical effect could contaminate empirical results. The PALS proponents are not questionable, however, merely in terms of the way they deal with data and empirical effects, but also in terms of the way they skew the cognitive standards of good science. One cognitive standard, for example, is to consider the effects of scale.

*3.3 Ignoring the Scale of Human Exposure.* A key scientific difficulty with the presupposed dose-response curve in the ICRP proposals is that they ignore scale; they allege that the same radiation dose is no more harmful if one, as opposed to 1000, living beings is exposed to it, because the harm to any individual is no greater in one case than in the other. How do the PALS proposals justify their ignoring scale? They accept only the concept of individual dose and reject the concept of collective dose, already explained earlier. The collective-dose principle has been used for decades because radiobiologists know that the amount of damage caused by ionizing radiation is a function of amount of energy deposition in a given quantity of matter (ICRP 1991). All things being equal, the greater the dose, the greater the molecular-level disruptions of the cell being irradiated. More generally, because effects of ionizing radiation are additive, cumulative, and linear with no threshold, all radiation dose-response curves, to date, have presupposed that if one individual receives enough radiation (dose  $d$ ) to cause at least 1 cancer, then if  $x$  individuals each receive radiation dose  $d/x$ , this dose also will cause at least 1 cancer among the  $x$  people, in part because one-fourth of the  $x$  individuals will include especially sensitive individuals and in part because of the stochastic effects of radiation exposures (ICRP 1991).

Instead of assuming that biological response  $r$  to a given dose  $d$  of radiation is constant, as the collective-dose principle presupposes, so that (for example) the effects of 1 person's receiving dose  $d$  are the same as 10 persons' each receiving dose  $d/10$ , the PALS proposals reject collective dose. They argue that collective radiation dose is an unjustified, nonempirical "construct," (a) because each of these individual doses is not actually measured, (b) because effects of very small doses of radiation are negligible and often repaired by the body, and (c) because the need for

protective action is influenced by the individual dose, but not by the number of exposed individuals (ICRP 2002, 118). As a result, the ICRP proposals ignore all collective-dose contributions to cumulative individual radiation dose. Instead, they focus only on the highest doses to particular individuals and they presuppose that scale is not important (ICRP 2002, 117).

For example, suppose 1 person receives (what the ICRP calls) a “trivial” dose of radiation, 0.05 mSv (or 5 mrem), for which the ICRP (2002, 119–120) proposes that no protective action is necessary. Suppose, on the other hand, that one million people receive this same additional dose. If the ICRP is correct in ignoring the scale of exposure, then the two exposures have the same biomedical effects. But the effects arguably are not the same because, according to US National Academy of Sciences BEIR calculations, the latter exposure would result in 25 cancers in the population of one million people (Shrader-Frechette 2001). Besides, larger populations have larger numbers of sensitive individuals and people with prior high exposures from things such as X-rays, therefore higher risks. For low-dose radiation exposure, scale effects are important because the more individuals exposed to the same dose, all things being equal, the greater the probability of germline effects in subsequent generations (Dubrova et al. 1996). In other words, carcinogenic and other genetic effects increase as a function of scale. That is one reason the U.S. Public Health Service halted its practice, half a century ago, of checking for tuberculosis by doing portable (dirty) X-ray screening of thousands of rural U.S. children.

ICRP proposals fly in the face of documented scale effects in many sciences. Economists are familiar with economies of scale. And ecologists know that some effects occur only at the ecosystem level, but not at the species level. And risk assessors agree that average expected utility misrepresents loss/harm for low-probability, high-consequence events, precisely because of the effects of scale; all things being equal, large-consequence, or large-scale events do more damage than the same number of individual events’ harming the same number of people. That is why analysts typically weight some low-probability exposure to a very large group by a factor  $n$ , in order to account for the fact that even small risks to large numbers of people cause more detriment than imposing the same risk on a single person (see Fairlie and Sumner 2000, Shrader-Frechette 2001, 1991). Ignoring collective dose ignores these fundamental scalar effects.

#### *3.4. Subjective Judgments and Inconsistency Regarding Measurability.*

The new PALS proposals also are cognitively questionable because they are not consistent in their appeals for decisions regarding allowable dose levels based on “judgment” (ICRP 2002, 120). It is not consistent for the



ICRP to fault collective dose for not being measurable (ICRP 2002, 117), but then to propose subjective judgment as the alternative to collective dose (2002, 120). By calling doses “negligible” or “trivial” in PALS, the ICRP proposals also are inconsistent in using a commonsense criterion for negligibility: what seems small. From a scientific point of view, there is no negligible or trivial dose, given that all doses increase the probability of harm. As already mentioned, the new ICRP proposals likewise inconsistently reject collective dose for the public, in part because it is not measurable (ICRP 2002, 117), yet accept it for workers, although the worker case has the same measurability problems. Similarly, it is inconsistent for the ICRP to reject collective dose as not measurable but to propose using PALS that are, on its own admission, dependent on (non-measurable) judgment (ICRP 2002, 120).

By rejecting collective dose because it is not directly measurable, the ICRP (2002, 117) also is inconsistent with scientific reliance on nonmeasurable and nonobservable quantities. No one has seen quarks, for example, but virtually all high-energy physicists believe they exist. Neutrinos were believed to exist for some 25 years before they were actually observed and measured. If science used only what is directly measurable, one could never develop either hypotheses or theory. Moreover, to reject whatever cannot be directly measured is to assume that what cannot be measured is not real, and that what is not real cannot be harmful. Obviously, however, things not yet directly measurable can be harmful.

And if the arguments given earlier are correct, then although the ICRP (2002, 117–119) proposes to reject whatever is not directly measurable, it is inconsistent in proposing a system in which individual doses will not be directly measured. Instead the ICRP intends to use models, estimates, and averages to calculate individual doses. But if so, then the ICRP has an inconsistent position on measurability as a criterion for acceptable dose.

*3.5. Misunderstanding the Simplicity Criterion.* In defending its new proposals, the ICRP claims that they represent a simpler approach to radiation protection (2002, 113). It also asserts that the current model-weighting factors for determining radiation dose are more complex than can be justified (122). These and other statements, as well as the text of the new proposals, reveal that the ICRP understands simplicity in terms of expediency, facility, or ease of mathematical manipulation. This is a peculiar notion of simplicity, however, one more related to pragmatic concerns than to defensible science.

Among scientists, a new theory or approach satisfies the simplicity criterion and is able to replace an older theory only (*a*) if the newer approach has comprehensive explanatory and predictive power that is at

least equal to the old approach and (b) if the newer theory has fewer variables and is more easily manipulable (see, for example, Sober 1975). As Carl Hempel (1966, 40) put it: simplicity argues only for accepting alternative hypotheses that would account for the same phenomena. Hence, for the ICRP to make a scientifically defensible claim that its new proposals are simpler than the current system, it must show that the new proposals are at least equal to the old ones in comprehensive explanatory and predictive power. Yet because of the problems with incompleteness, ignoring important variables such as scale, and logical inconsistencies, the new proposals arguably have less comprehensive explanatory and predictive power than the current system of radiation protection. In any case, the ICRP has not argued that its new proposals have the requisite comprehensive explanatory and predictive power. One reason is that, using the PALS criterion, it acts contrary to best risk-assessment practices by reducing and comparing both voluntary and involuntary risk exposures. Assessors have repeatedly warned, in comparative risk assessment, that such reductions and comparisons are illegitimate, because dose quantity is not the only relevant variable (see Shrader-Frechette 1991).

Rather than employing the standard, scientifically defensible notion of simplicity, the ICRP has merely used the term “simpler” in a nonscientific way, in an attempt to justify a crude reduction in radiation protection. It has a pragmatically simpler approach only because it has ignored important considerations, such as collective dose, or treated them inconsistently.

**4. Other Alternatives.** Given the preceding problems with the 2001 ICRP PALS proposals, are there other alternatives to radiation protection that the ICRP reports ought to include? As the earlier arguments suggest, a more comprehensive and scientifically credible set of recommendations for radiological protection ought to focus not merely on PALS but also on

1. ALARA recommendations (to keep exposures as low as reasonably achievable), as already mandated by ICRP (1991) for human protection, or else arguments defending ICRP’s omitting ALARA in its 2002 proposals;
2. Optimization of protection (pollution-prevention) recommendations, as already mandated by ICRP (1991) for human protection, or else arguments defending ICRP’s omitting optimizing environmental protection;

The *methodological reforms* that ought to be included in the science underlying the ICRP report include recommending more empirical measures of dose, avoiding use of average doses, unifying dose measurements

through consistent uses of concepts such as collective dose, taking steps to avoid contamination of control-groups for future radiological-dose work, ensuring that their recommendations regarding worker and public doses are consistent, and encouraging dose calculations that avoid manipulation of recorded exposures. Moreover, because simplicity, consistency, transparency, and objectivity are the hallmarks of good science, ICRP scientists ought to recommend assessment of total doses and not ignoring small doses from many sources. Given new pollution-prevention technology, arguably no amounts of radiation exposure should automatically be considered “negligible,” as the ICRP (2002) report proposes, given that all such exposures are risky.

**5. Conclusion.** If the previous arguments are correct, then the ICRP PALS proposals appear to need improved scientific methods, techniques, logic, and assumptions in their use and interpretation of radiation dose-response curves. Analysis of such scientific flaws ought not be the prerogative only of physicists, engineers, or nuclear experts, but also ought to be investigated by all practitioners of metascience, including philosophers of science (see NRC 1996). Those who wish their voices to be heard on the ICRP proposals can post comments on the ICRP Web site where the draft reports have been published (<http://www.icrp.org>).

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