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Until There Is a Resolution of the Pro-LNT/ Anti-LNT Debate, We Should Head Toward a More Sensible Graded Approach for Protection From Low-Dose Ionizing Radiation

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Abstract

Current regulation of ionizing radiation is based on the linear no-threshold (LNT) model where any radiation dose increases cancer risk and is independent of dose rate, resulting in large amounts of time and money being spent protecting from extremely small radiation exposures and hence extremely small risk. There are animal studies which demonstrate that LNT is incorrect at low doses, supporting a threshold or hormesis model and thus indicating that there is no need to protect from very low doses. This has led to a sometimes bitter debate between pro-LNT and anti-LNT camps, and the debate has been at a stalemate for some time. This commentary is not aimed at taking either side of the debate. It is likely that the public, workers, and the environment are adequately protected under current regulation, which is the most important outcome. Until those on one side of the debate can convince the other, it would be sensible to move forward toward a graded (risk-based) approach to regulation, where the stringency of control is commensurate with the risk, resulting hopefully in more sensible practical thresholds. This approach is gradually being put forward by international radiation protection advisory bodies.

Keywords

LNT, radiation, risk assessment, regulation

Commentary

The main role of government environmental regulators is to protect human populations from damaging doses of chemicals and radiation. There is no absolute known cutoff between damaging and nondamaging doses for any of these agents. Therefore, regulators take a precautionary approach and try to ensure that even the most sensitive people in a population are adequately protected.[1,2] The precautionary approach involves using toxicology data indicating doses that cause harm and then applying somewhat arbitrary large modifying and uncertainty factor numbers to arrive with lower acceptable doses which should be safe, in an attempt to make sure that everyone is protected. It is not possible physically or economically, however, to protect from every interaction between agents in the environment that may be harmful and so regulators use the concept of as low as reasonably achievable (ALARA).[3] ALARA weighs up the cost of protection versus the theoretical harm. For noncarcinogens in the environment, threshold doses have been applied below which there should be no harm. For carcinogens such as ionizing radiation, maximum radiation limits have been applied, below which there should be minimal harm. Measurements may be recorded to ensure that the thresholds/radiation limits are not exceeded.

Identifying safe thresholds/limits for agents in the environment is not an exact science because of the many unknowns and complexities of exposure routes and interactions with other agents in the body. Unfortunately, applying numbers to any

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regulation implies that it is an exact science and this can lead to a fixation on the numbers. The thresholds/limits are determined in the absence of all or most of the other agents in the environment that the population is simultaneously exposed to and the true threshold/limit will be different for every person depending on their genetics, age, and lifestyle. The most important goal of regulation is that populations are protected. For most agents in the environment, the precautionary approach will ensure that populations are overprotected. Sometimes populations might be unintentionally underprotected. Of all agents in the environment, ionizing radiation perhaps causes the most emotive responses from the public. The history of radiation exposure has been associated with medicine, industry, nuclear threat and war, and nuclear accidents. It is the latter that many people focus on and radiation has become widely feared. Of all agents in the environment, the biological effects of radiation have been studied most intensively and yet determination of appropriate safe limits is still in dispute. The reasons for the dispute are not only based on science but also on historical and political factors.[4-7]

From the mid-1960s, regulation of ionizing radiation in the environment has been based, in part, on the foundations of the linear no-threshold (LNT) model.[8] The fundamental aspects of the model are that no matter how small the radiation exposure, there will be an increase in cancer risk and that damage leading to cancer is independent of dose rate. Currently, there is no consistent evidence to support increased cancer risk in humans at doses below an acute 100 mGy dose and even higher doses at low dose rate.[9] There is also evidence in vivo in animals demonstrating that acute doses of radiation below 100 mSv and quite high doses administered chronically at low dose rate can be protective from cancer.[10,11] Hence, the concept of LNT at low doses in animal studies is not strictly correct.

There is an ongoing debate about the lack of evidence for LNT at low doses, with quite polar stances leading to pro-LNT and anti-LNT camps.[12-15] Pro-LNT camps try to defend LNT against anti-LNT criticism, even when LNT is based on sketchy data from a very early time in the understanding of radiobiological mechanisms. Data obtained for different research end points at relatively high radiation doses, including mutation data in lower organisms and cancer epidemiology data, have been extrapolated to lower doses using a straight line going through the origin to indicate increased cancer risk at any dose. It is now widely accepted that it is unlikely that current epidemiology methodology will be able to provide definitive support for LNT given the uncertainties associated with interpreting epidemiological data at low doses.[16] Anti-LNT camps refute LNT using largely more recent biological data to purport that a threshold or hormesis model is more appropriate than LNT. For the same reasons as stated above for the pro-LNT argument, epidemiology is unlikely to provide definitive data for a threshold or hormesis model either. Data supporting anti-LNT come largely from experiments using different test systems, different doses/dose rates, and different end points at different time points. Subsequently, there is a tendency to compare in vitro studies with animal studies and then further extrapolate to conclusions regarding health outcomes in humans, ironically not so unlike drawing a straight line through to an origin. Epidemiology or experimental animal systems with long-term health end points using relevant doses/dose rates are the only studies of even some relevance to a regulator. At present, neither the pro-LNT nor the anti-LNT camps can categorically prove their positions. Hence, in the mean time, we are left with the status quo,[17] which currently comprises various radiation limits which from the perspective of harm are effectively very conservative thresholds.

There have been many calls for regulators to drop LNT for an alternative model. But how relevant is LNT to the current model of radiation regulation? Do regulators use LNT in its strictest sense? Regulators do not prevent the public from receiving any man-made radiation because LNT states that any radiation dose will increase cancer risk. The bottom line is that even though regulators tend to default to the idea that every photon is increasing cancer risk and hence harm, they know they cannot protect from every photon in the environment. Regulators allow a certain amount of harm based on acceptable risk. The current acceptable risk from man-made radiation is below 1 mSv/y for the public and below 20 mSv/y for a worker, although regulators spend much time and effort protecting from doses much lower than these. Natural background radiation is considered an acceptable risk and is exempt from regulation, even though it can vary by several times more than the public dose limit. Actual doses received by the public are theoretical estimates and the vast majority of radiation workers receive only a tiny fraction of the yearly limit. Meanwhile, many members of the public and workers will receive substantial medical exposures that will dwarf their exposure from other sources.[18] If medical exposure was included in the dose limits, then the limits would have to be substantially increased for modern health care to function. Regulators do not regulate all aspects of medical radiation exposure to patients because the risk is considered acceptable relative to potential benefit where justification is made by medical practitioners. The results from the tragic events of Chernobyl and Fukushima have forced regulators to apply higher limits for the public in emergency situations, to ensure that greater good than harm results in such extenuating circumstances.[19,20] Therefore, regulators do not regulate some areas of radiation exposure, and other areas already use various conservative thresholds for convenience sake to enable society to function in a world that is dependent on the many benefits of radiation. LNT is easy to understand in that it can provide a basis to arrive at some theoretical numbers to apply in a regulatory sense. LNT has been used to help justify current dose limits, not by itself, but in association with a precautionary approach and ALARA, albeit that different jurisdictions may currently interpret and/or apply these principles to differing degrees.

Pro-LNT and anti-LNT camps are all on the same side when it comes to protecting the public and workers. It would be accepted by most that protecting the public and workers has been achieved by regulators to the extent that radiation exposure cannot be reduced to zero using ALARA. It would just not be reasonable to remove all radiation from our environment and considering that life on earth has evolved in the presence of natural radiation would likely be detrimental.[21] Enormous advances have been made in understanding low-dose radiobiology with the potential to be harnessed in different areas of science, particularly medicine.[22] Most regulators accept low-dose radiobiology concepts, including adaptive responses, bystander effects, and hormesis, as being a part of the radiobiological response, but what evidence have scientists really provided to the regulator that would help them to implement higher thresholds/limits or hormesis in a regulatory sense? From a purely practical point of view, only a threshold model is relevant for implementation by a regulator. The threshold for the public will be based on the most sensitive people in the population. Hormesis, a proven fundamental phenomenon at particular doses and for definitive time periods for agents in the environment,[23] will be occurring within the threshold concept and is therefore already incorporated.

So, why are we having this pro-LNT/anti-LNT debate? It is because the precautionary approach and ALARA have resulted in regulators, in many instances, regulating μSv doses which are at least 10 000 times lower than where evidence of harm has been convincingly proven. This is done using LNT in its strictest sense and because it is achievable. However, often the resources spent to achieve such regulation is not commensurate with the acceptable risk.[24] The anti-LNT argument would suggest that the vast amount of money spent on protecting from such low doses would be better spent protecting from known real harms, whether that be in the radiation industries or in other areas of society. Most regulatory agencies understand this argument and the more sensible graded approach, where the stringency of control is commensurate with the risk, should result in more time and money protecting from known or potential higher radiation exposures compared to lower radiation doses. The graded approach is starting to make ground internationally. A movement toward a graded approach in radiation regulation was a recurring theme at the recent 5th International Symposium of the System of Radiological Protection (ICRP 2019). The ICRP has also recently published ICRP 142 recommending an integrated and graded approach in the management of NORM (Naturally Occurring Radioactive Material) for the protection of workers, the public, and the environment.[25] The International Atomic Energy Agency is also moving in a similar direction. Until an alternative model for LNT is accepted by government agencies, current radiation limits do not need to change but the amount of time and money spent measuring and regulating those limits needs to be reduced and/or reallocated in a more common sense fashion. These changes are occurring, albeit very slowly. *However, in order to sensibly apply the graded approach, regulators do need to adopt acceptable risk as, exactly that, acceptable. There is no point in regulating acceptable risks where there is no feasible way that dose limits could be exceeded.*

The pro-LNT/anti-LNT debate has led to much unnecessary division between scientists and regulators. The important question is "Are the public and radiation workers protected using our current radiation limits"? It is very likely that the answer is "Yes." Can the public/workers be protected in a more efficient and sensible manner? The answer is "Yes." The latter question is gradually being addressed based on the graded approach to regulation of radiation. Basically, the current dose limits will not change until it is demonstrated that the regulations are no longer protective of public health and the environment. In the short term, if LNT is left out of the argument, and replaced with suggestions for sensible approaches to improve the ways to reduce financial and administrative burden based on acceptable risk using a graded approach within the current regulatory system, then there will be a clearer path forward toward more sensible regulation of ionizing radiation.

Authors' Note

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