Improving the scientific foundations for estimating health risks from the Fukushima incident

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Two articles in PNAS document the estimated release magnitude and distribution of cesium (Cs)-137 from the nuclear power facility incident in Fukushima (1, 2). These papers provide a step forward in developing improved characterizations of the range of environmental contamination of Cs-137 along with an improved framework for estimating exposures to environmental receptors, including forests, agriculture, wildlife, and humans. Cs-137 is the γ- and β-ray–emitting contaminant of primary concern because of the amount released and its 33-y half-life.

Since the Fukushima emergency, there has been great concern about human exposure to radionuclides, the evacuation/resettling of those whose communities were affected, how and via what basis those decisions are made, concerns with crop safety from consumption to export, the issue of remediation, the extent and nature of the areas affected (e.g., schools, playgrounds, roads, buildings, personal property), cost-effectiveness, and timeliness. These factors raise significant questions, and all are occurring within a swirl of governmental activities and multinational interactions; under the media spotlight; and within an economic, political, and social context. Given such circumstances, it is difficult to develop a scientifically based perspective to guide such acute and prolonged challenges. However, this is what is needed.

The most overriding question concerns what is a safe or acceptable exposure, given the new environmental data on Cs-137. Numerous expert advisory groups/governmental agencies have rendered guidance based on hypothetical risks of Cs-137. This guidance often converges, providing comparable risk estimates. Estimates of human risk are typically highly precise, giving the false impression of considerable accuracy. Such similarity of estimation often results from copycat thinking and little independent analysis. However, the public can become confused when informed that acceptable levels of Cs-137 in Japan are more than threefold that permitted in the Ukraine (3). Even more confusing is when the European Union raised acceptable levels of Cs-137 in food by 20-fold in response to Fukushima (4). Getting reliable information, as well as trying to understand the basis of such governmental actions, can be difficult. Also very frustrating are the questionable scientific foundations on which these various guidance decisions are based.

Cs-137 Data Gaps

What the Cs-137 risk estimates are based on should raise concerns. In their health assessment of Cs-137, the Agency for Toxic Substances and Disease Registry (ATSDR) states in the Oral Exposure section that: "No reports were located regarding health effects in humans or animals that could be exclusively associated with oral exposure to radioisotopes of cesium" (5). The ATSDR further states that: "No reports were located in which cancer in humans or animals could be associated with acute-, intermediate- or chronic-duration oral exposure to radioactive cesium" (5). The agency notes that a single high i.v. dose of $^{137}CsCl$ administered to dogs resulted in benign and malignant neoplasms in a number of organs. In a later section on the identification of data needs, the ATSDR states that: "low levels of radioactive cesium are found in the diets of individuals living in areas that have contamination with radioactive fallout; however, there is a lack of information regarding dose response following chronic-duration oral exposure. No chronic duration inhalation or oral minimum risk levels were derived for radioactive cesium" (5).

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These statements are from the US agency that assesses public health risks from contaminated sites. These data gaps have not been filled in since the 2004 publication by the ATSDR. Nonetheless, some soil and food safety/health standards for Cs-137 have been derived for public health decisions. What data/rationale are these governmental risk guidance statements based on?

In contrast to the ATSDR, the United Nations Scientific Committee on the Effects of Atomic Radiation and the Environmental Protection Agency (EPA) derived cancer risk estimates for Cs-137 intake by humans based on epidemiology, including the atomic bomb survivor data, with a refinement to Cs-137 based on other modeling activities (using potassium as a surrogate for Cs-137) to estimate the biodistribution/biokinetics of Cs in multiple organs (6). This methodology substitutes dosimetry-based estimates of risk for experimental values. Among the limitations in such an approach is the lack of validation of model predictions. Given the public health issues, it would be of value to use both approaches.

Limitations of the LNT

A problem with the EPA approach is that it depends on estimating responses at low doses and dose rates based on evidence at high doses and dose rates. Such high to low dose/rate extrapolation is problematic because of the difficulty in validating the low dose/rate responses. A report by Tanooka (7) emphasized that it is not possible to extrapolate cancer risks accurately over a very broad dose range using a linear at low dose-no-threshold (LNT) model; this limitation is at the core of disagreements with low dose/rate cancer risk assessments for ionizing radiation. Tanooka (7) reviewed the broad spectrum of ionizing radiation-cancer studies and found that the LNT consistently made erroneous predictions in the low-dose zone. This supports the ATSDR perspective that relevant data are critical to validate dosimetry model-based predictions, not to be replaced by them. This is especially the case when the public health stakes are high. The absence of animal model chronic bioassays represents an important limitation for the assessment of risk from intake of Cs-137.

Other data limitations of these governmental risk assessment activities are of concern. Limited animal and no human data exist on GI tract bioavailability of Cs-137 in humans for soil of any type (8).

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Bioavailability can be an important issue for soil-bound contaminants (e.g., Cs-137). Lack of data forces risk assessors to make assumptions rather than be guided by data, defaulting to the most conservative option.

Although this precautionary philosophy can have value, it is not without its downside. The presence of multiple highly conservative assumptions can lead to a cascading of multiplicative protective factors that can add substantial increases in remediation costs without validated assurances of accompanying benefit. When the precautionary principle is taken too far, it may adversely affect human health if it reduces exposures below those at which beneficial adaptive responses are induced (9). The "lower is always better" mantra of regulatory agencies will often counter the goal of enhancing public health (10, 11).

Similarly, the risk assessment of tightly bound soil contaminants is often markedly affected by and sometimes driven by assumptions of soil ingestion in children. When the first risk assessments for dioxin in soil (contamination at Times Beach, MO) were made by US environmental agencies in the early 1980s, they estimated that the average young child ingested 10 g of soil per day. This default assumption dominated the initial estimated costs of the soil remediation. Subsequent soil ingestion studies in children would prove this default exposure assumption represented a massive overestimation, being too high by at least 200-fold. Instead of a 10,000-mg daily soil ingestion rate for the average child, the data indicated an average ingestion of <50 mg/d (12). If these studies had not been conducted, the costs of clean-up at Times Beach alone would have been many billions of dollars more. There is still much uncertainty even with a 50-mg/d average because of a high background noise, making it difficult to detect soil ingestion below 50 mg/d. The risk assessments for Cs-137 and other soil-bound radionuclides are typically based on estimated soil ingestion rates for children in the upper 95th or 99th percentile, with values typically in the 200- to 500-mg range, depending on the data used and level of protection desired. Soil ingestion estimates, like Cs-137 GI tract bioavailability, can therefore be highly uncertain; yet, nonvalidated assumptions can markedly affect the risk assessment outcome.

In addition to the previously mentioned data limitation concerns, the most significant and overriding general issue is that cancer risk assessments are forced to follow LNT model assumption regardless of what the data from the animal bioassay may indicate. This governmental force-fed model, which has never been validated, is in conflict with a plethora of well-established adaptive mechanisms discovered after the incorporation of the LNT default model into risk assessment (9) and is inconsistent with a vast and expanding toxicological literature for chemicals and ionizing radiation (13) that disputes the accuracy of predictions based on the LNT.

The use of the LNT has a profound effect on risk assessment predictions, governmental actions, and cost of remediation, as well as determining the risk communication message (14–16). Added to this controversial use of LNT for carcinogen risk assessment by regulatory and public health agencies worldwide are recent revelations that this model became incorporated into regulatory use in the 1950s as a result of ideological motivations and manipulations of the scientific literature at the highest possible levels. Such manipulation of the risk assessment process has now become codified in most regulatory agencies (17–19). Objective attempts to resolve such contentious historical and scientific disputes are critical to issues made even more urgent by the Fukushima incident.

How is this to be accomplished? It is necessary to be guided by data as much as possible. Filling in data gaps and not relying on untested assumptions are important positive steps. The 10,000-mg assumption for soil ingestion by the average child is an example where research can test the validity of the default assumption. Obtaining chronic bioassays using a broad dose range in the standard mouse and rat models for Cs-137 would provide valuable data for risk assessors. GI tract soil bioavailability should be experimentally resolved to inform the risk assessment process better. There are likely other relevant data gaps to be addressed to provide a more reliable Cs-137 risk assessment that is relevant in situations like Fukushima. Finally, a comprehensive reappraisal of the LNT model is urgently needed, assessing its historical foundations, scientific basis, and capacity for validation.

Getting the Dose Response Right

Since Chernobyl, governments and the nuclear industry have failed to address these and other critical research questions, all of which plague the current crisis of Fukushima. It has long been known that a fission nuclear plant accident release would include major concerns with Cs-137. It is time for the responsible governmental and industrial organizations to develop a practical plan to fill important data gaps. It is also critical that the LNT model and alternative models, such as the threshold and hormesis models, be objectively assessed so that society can be guided by scientific data and validated models rather than ideological perspectives that stealthily infected the risk assessment process for ionizing radiation and carcinogenic chemicals (17, 18).

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