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Potassium Iodide Prophylaxis: What Have We Learned and Questions Raised by the Accident at the Fukushima Daiichi Nuclear Power Plant

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There is no doubt that when potassium iodide (KI) is administered in a timely fashion, much of the potential exposure to radioactive iodine isotopes from an atmospheric release can be safely averted (1–3). The United States of America Food and Drug Administration (FDA) and the World Health Organization (WHO), among others, have established guidelines for the use of KI in these settings (4,5). Legislation in the United States requires all areas within a 20-mile (32-km) radius of a nuclear power plant (NPP) to have KI-related policies and has made it possible for affected states to obtain KI from federal sources. Executive action during the recent Bush administration reduced the radius to 10 miles (16 km). Nevertheless, the current status is a vast improvement over what it was before the American Thyroid Association (ATA) and its members began advocating for change (6).

The ATA has continued concerns about the KI distribution policy of the United States, especially in two areas, as expressed in the March 30, 2011, letter from the ATA to Dr. John P. Holdren, Director of Office of Science and Technology Policy (7). One concern is that the decision of whether to store KI at sites where it is intended to be distributed (known as "predistribution") is left to the individual states. The position of the ATA, which it has vigorously advocated in the United States, is that there should by universal predistribution of KI to households and other key locations in the vicinity of NPPs. Second, the ATA advocates that the area of predistribution should be extended from the current 10-mile radius around NPPs to a radius of 50 miles (80 km) around NPPs.

Given the events in Fukushima 1 year ago, it is appropriate to evaluate the ATA's position and ask if it should be altered, enhanced, and/or affirmed with renewed vigor.

March 2011 Events at the Fukushima Daiichi Nuclear Power Plant

Sufficient time has passed since the catastrophe at Fukushima that, in addition to extensive news coverage, authoritative accounts of the events and their magnitude are available. Specifically, presentations at the Nippon Foundation–sponsored "International Expert Symposium in Fukushima: Radiation and Health Risks," The Institute for Nuclear Power Operation's detailed report, and other reports have been published (8–12).

Damage to the plant by the earthquake and the subsequent tsunami preceded by hours the spike in radioactive release caused by the loss of cooling water and the subsequent hydrogen explosion in unit 1. The delay allowed time for evacuation of the population closest to the Fukushima Daiichi Nuclear Power Plant (FDNPP). Spikes continued for days as two other explosions, at units 3 and 4, occurred and the radius of evacuation expanded. The seriousness of the accident was enormously reinforced and complicated by the fact that thousands of people died or were injured as a result of the earthquake and tsunami. Moreover, communications and other services were severely affected.

Despite the dire circumstances, no radiation-related deaths occurred at the FDNPP. The position of the FDNPP on the sea coast meant that some of the releases went over the ocean rather than reaching the Japanese population. Thus, the spread of radioactivity was uneven. A low level of I-131 was detected in the drinking water for a short time as far away as Tokyo (about 150 miles [241 km] from Fukushima). The amount of radioactive iodine released is currently estimated to be 1.6×10^{17} becquerel, about 10% of the amount released in the Chernobyl accident (10).

At the time of the earthquake, KI had not been predistributed to household in Japan. Days after the crisis began, a recommendation from the federal government to give KI at evacuation sites was issued, but with a few local exceptions, KI was not administered to the general population (10). Some emergency workers at the FDNPP, American military personnel, and American civilians were given KI. Control of the food chain and water apparently was effective, perhaps facilitated by the fact that milk is not a large part of the typical Japanese diet. Also, since it was winter, cows were not in the fields where they would be more likely to be exposed to atmospheric fallout. In Tokyo the transient appearance of small amounts of I-131 in the water caused concern, especially for pregnant and nursing women, and a shortage of bottled water was reported. Thousands of miles away, in the United States, a shortage of commercially available KI tablets occurred.

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Despite the magnitude of the damage to the FDNPP, the initial thyroid measurements in children were reported to be low, apparently much lower than either the WHO or U.S. thresholds for triggering the administration KI (12).

Questions Raised by the FDNPP Accident

The first question raised by the FDNPP accident is whether this experience indicates that, in some situations, a major release of radioactive iodine can be managed without recourse to KI. In the FDNPP accident, at least, this was the case. Evacuation, control of the food chain, and other factors averted high dose exposures to the population near the FDNPP. Consequently, the dose-threshold for administering KI was not reached. However, rather than complacency and an argument against predistribution, this experience should highlight the probability that every radiation emergency will have unique and unforeseen features. In other scenarios, depending on a host of factors, evacuation and/or access to uncontaminated food and water may not be available options. Even in the case of the FDNPP accident, there were difficulties in evacuating the hospitals in the Fukushima area (13). Although the radiation was not catastrophic for the population as a whole, a few workers at the plant inhaled sufficient I-131 to result in thyroid doses above those designated for the use of KI. Fortunately, this was a rare occurrence, but it highlights the fact that the inhalation pathway cannot be ignored in all cases.

Further, the events following the radiation from the FDNPP reveal a gap in determining what advice should be given to the public to ensure minimal radiation exposure in settings in which environmental releases of I-131 are extremely high but the thyroid dose is unlikely to exceed the thresholds for initiating KI prophylaxis. This is a complex issue because of the multiplicity of possible scenarios. These include variations relating to short-term and long-term exposure, evacuation and nonevacuation, and available and unavailable sources of uncontaminated water and milk. Perhaps a clearer statement about this would have ameliorated the reported "runs" on bottled water in Japan and on KI that occurred in areas remote from Japan.

Two other questions are "What does the FDNPP accident show about value of predistribution of KI?" and "How large an area should be included in predistribution planning?" Perhaps one of the lessons from the accident is that predistribution to households is likely superior to distribution at evacuation centers after a radiation release when the situation is very likely to be chaotic. Even in a society such as Japan where social order is notable, KI was not given even after federal recommendations to use it at evacuation sites (12). Conversely, in the United States where there was no reason to take KI, commercial supplies reportedly did not meet the demand, a situation that might not have occurred if the availability of KI was adequate and the public was informed about the appropriate circumstances and timing for taking KI prophylaxis.

With regard to the areas that should be included in predistribution planning, it is notable that after the FDNPP accident some populations, particularly in Iitate Village 25 miles (40 km) from the FDNPP, were beyond the initial evacuation radius of 19 miles (31 km), but were within the plume of fallout. It was not until March 30, 19 days after the Tohoku earthquake and tsunami, that evacuation was ordered. While the distribution of the thyroid cancers following the Chernobyl accident provides the most cogent argument for a larger radius, the pattern of spread of radioactivity after Fukushima also supports this view (8).

Are the current action thresholds for administering KI contained in the U.S. and WHO guidelines realistic? Even though they are not in complete accord about what threshold to use (e.g., 50 mGy vs. 10 mGy up to age 18), the U.S. and WHO guidelines rely on the best available data. The events at Fukushima reveal two disturbing facts. First, the general public is not in a position to fully understand the rationale for the thresholds and how exposure of the thyroid is projected. It seems likely that, in the event of a nuclear accident, there would be a clamor for KI regardless of guideline or regulatory thresholds. Second, although it is not clear whether political factors played a role in Japan relating to the FDNPP accident, they are likely to come into play in reactor emergencies. Public officials responsible for making recommendations in these circumstances, sometimes with fragmentary information, may lack an understanding of quantitative aspects of radiation that underlie the rationale for the thresholds. Yet they must be very sensitive to the public's reaction and response. The fact that KI was not administered even after a governmental decision to do so raises this question. However, interestingly, that decision in Japan contrasts with the experience thousands of miles away in the United States, where KI consumption increased.

Looking past the immediate response to radiation release disasters, what should public health authorities advise if the release of I-131 is prolonged and it is not possible to evacuate people far enough to prevent ongoing exposure, especially to pregnant and nursing women? The FDA (14) and WHO (5) both caution pregnant and lactating women not to take repeated doses of KI because of the potential adverse effects on the fetal and breastfeeding infant thyroids. Should evacuation not be possible, what should be done? Even if evacuation is possible, should pregnant and nursing women be relocated to more distant sites? The events at Fukushima raise these questions without resolving them.

The ATA's "For Immediate Release March 29, 2011: ATA Advisory supports public health recommendations by Japanese government" includes advice to pregnant and lactating women. In view of the subsequent downturn in the levels of I-131 in Tokyo drinking water, the reassurances in the statement about extent of exposure were warranted. The Advisory says: "Because iodine is concentrated in breast milk, and because breastfeeding women drink more water daily than other adults, women who are lactating are best advised to limit ingestion of water contaminated with I-131." It continues: "However, if exposure to this level of I-131 in drinking water cannot be avoided, it is still reasonable to continue breastfeeding." In our view, the statement leaves some unresolved questions and concerns about interrupting breastfeeding. These become evident when the ATA advice is compared with the advice of the FDA (4) and the Centers for Disease Control and Prevention (15) about how to manage breastfeeding. The ATA Advisory states: "Average intakes of drinking water by infants fed powder-based formulas are about 0.8 liters daily. Assuming a one-time contamination of drinking water at the I-131 levels detected in Tokyo, an infant's thyroid gland could be exposed to approximately 9 mGy radioactive iodine." The assumptions applied in making such calculations are not stated explicitly. We would suggest that such calculations depend on parameters that are often highly uncertain for infants because of limited data on, for example, the iodine pharmacokinetics and the magnitude of the radiation dose to risk conversion. In practice, other complicating factors also exist, such as how long the contaminated water will be consumed or whether bottled water with little or no contamination might be available to prepare formula. For thyroid exposures, we would expect infants and neonates only a few days or weeks old to be among the most sensitive individuals in the population. For infants under age 1 who are breastfeeding, the risk for thyroid cancer is high, perhaps even higher than the overall estimates in the "pooled analysis" (16). We think that mothers should be cautious about breastfeeding during such an incident. It would seem that advising mothers to refrain from breastfeeding for a brief time may be the best advice.

We have seen firsthand the incredible damage and ongoing recovery at Fukushima Daiichi 6 months after the accident (ABS) and in the nearby city of Sendai 9 months afterward (JMS). One cannot but be in awe of the courageous response of Japan to the emergency and the resulting needs of its people. Since 1986 there have been many publications with titles that are a variation of "The lessons of Chernobyl." Without question, those lessons have been very important to the people of Japan. Perhaps that may give some solace to those who suffered the consequences of the Chernobyl accident. Now, as the residents of Fukushima and the surrounding areas recover, we are responsible to them to learn the lessons they can teach us.

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