Feasibility Study for Potassium Iodide (KI) Distribution in New York City

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Acronyms and Abbreviations

ATA	American Thyroid Association
CDC	Centers for Disease Control
Ci	curie
DOHMH	Department of Health and Mental Hygiene
EPA	Environmental Protection Agency
EPZ	emergency protective zone
FDA	Food and Drug Administration
FEMA	Federal Emergency Management Agency
KI	Potassium iodide
MHRA	Medical and Health Research Association
NRC	U.S. Nuclear Regulatory Commission
ORH	Office of Radiological Health
PAG	Protective Action Guidelines
RDD	radiological dispersion device

Introduction

The New York City Department of Health and Mental Hygiene (DOHMH), Bureau of Environmental Science and Engineering, Office of Radiological Health (ORH) [as the primary local technical consultant in the event of a radiological or nuclear incident within the boundaries of New York City] requested the assistance of Brookhaven National Laboratory (BNL) with the development of a Feasibility Study for Potassium Iodide (KI) distribution in the unlikely event of a significant release of radioactive iodine in or near New York City. Brookhaven National Laboratory had previously provided support for New York City with the development of the radiological/nuclear portions of its All Hazards Emergency Response Plans. The work is funded by Medical and Health Research Association (MHRA) of New York City, Inc., under a work grant by the Federal Centers for Disease Control (CDC) for Public Health Preparedness and Response for Bioterrorism. This report is part of the result of that effort.

Summary of Potassium Iodide

Potassium iodide is a chemical compound that can be used to protect the thyroid gland from possible radiation injury caused by exposure to radioactive iodine (radioiodine). Some radiological emergencies may release large amounts of radioiodine to the environment. Since iodine concentrates in the thyroid gland, inhalation of radioiodine or ingestion of food contaminated with radioiodine can lead to radiation injury to the thyroid, including increased risk of thyroid cancer and other thyroid diseases. Taking KI saturates the thyroid gland with stable (nonradioactive) iodine. This prevents or reduces the amount of radioiodine that will be taken up by the thyroid. It is most effective when taken before or shortly after exposure to radioiodine begins. KI does not protect against radiation doses received from external sources of radiation or from radionuclides, other than radioactive isotopes of iodine, which may be ingested or inhaled. It also does not protect body organs or tissues other than the thyroid gland.

The risks of stable iodine administration includes sialadenitis (inflammation of the salivary gland), gastrointestinal disturbances, allergic reactions and minor rashes. In addition, persons with known iodine sensitivity should avoid KI, as should individuals with dermatitis herpetiformis, and hypocomplementemic vasculitis, extremely rare conditions associated with an increased risk of iodine hypersensitivity.

Thyroidal side effects of stable iodine include iodine-induced thyrotoxicosis, which is more common in older people and in iodine-deficient areas, but usually requires repeated doses of stable iodine. In addition, iodide goiter and hypothyroidism are potential side effects more common in iodine sufficient areas, but they require chronic high doses of stable iodine. Therefore, individuals with multinodular goiter, Graves' disease, and autoimmune thyroiditis (most likely to be adults) should be treated with caution, especially if dosing extends beyond a few days. FDA has determined that short-term administration of KI at thyroid blocking doses is safe and, in general, more so in children than adults.

Summary of Radioiodine

There are, at present, thirty-five known isotopes of Iodine with thirty-four of them being radioactive, and only one, Iodine-127, non-radioactive or stable. Twenty-six different isotopes of radioiodine are produced within the fuel or cores of nuclear reactors, as fission products. Because of relatively short half-lives of most of the radioiodine isotopes, only a few of them are of interest in terms of potential human health or environmental effects, as a result of their release. These can be found in Table 1.

Table 1. Radioiodine Isotopes of Interest

Isotope	Half-life	Decay	Use/Origin	Daughter product	Annual Limit on intake ¹	
					Inhalation	Ingestion
Iodine-123	13.13 hours	Electron capture with X-ray and gamma-ray emissions	Nuclear medicine – imaging and diagnostics	Te-123	6,000 µCi	3,000 µCi
Iodine-125	60.14 days	Electron capture with X-ray and gamma-ray emissions	Nuclear medicine – ‘seeds’ for prostate cancer therapy	Te-125	60 µCi	40 µCi
Iodine-129	1.57E7 years	Beta decay with beta- and gamma-ray emissions	Very small quantities created as fission product	Xe-129	9 µCi	5 µCi
Iodine-131	8.04 days	Beta decay with beta- and gamma-ray emissions	Nuclear medicine – thyroid therapy / fission product	Xe-131	50 µCi	30 µCi
Iodine-133	20.8 hour	Beta decay with beta- and gamma-ray emissions	Fission product	Xe-133	300 µCi	100 µCi

¹ Annual limits on intake as taken from Federal Guidance Report No. 11, “Limiting Values of Radionuclide Intake and Air Concentration and Dose Conversion Factors for Inhalation, Submersion, and Ingestion,” EPA-520-1-88-020, Oak Ridge National Laboratory, 1988. ^[1]

The largest potential sources of radioiodines are the cores of commercial nuclear power reactors, where they are created within the individual fuel elements, as a consequence and end product of the fission process. There are typically millions of curies of radioiodines contained within a full core at power. In the unlikely event of a severe power reactor accident or incident, sufficient damage may occur to the various redundant protection systems in place such that significant quantities of gaseous fission

products (including radioiodines) could be released and require immediate protective actions be taken by members of the public living within the 10-mile plume exposure pathway. Immediate protective actions to be taken may include: evacuation outside the 10-mile emergency protective zone (EPZ), sheltering in place for up to 24 hours, and/or the ingestion of KI (for protection against the uptake of radioiodine inhaled from the passing plume). For residents within the 50-mile ingestion exposure pathway, protective actions would be directed to preclude the consumption of potentially contaminated food, especially the dairy food chain.

Historically, radioactive iodine has been linked with thyroid cancers in children who were exposed to fallout from the Chernobyl nuclear power plant disaster in 1987. The Chernobyl cancer data (in regions that did not distribute KI nor implement ingestion pathway controls) to date reveals:

- >2000 cases of thyroid carcinoma in an exposed population of 4 million
- Approximately 250 new cases per year
- Total cases projected to be 4,000-6,000 cases
- Total numbers of deaths are less than 5, due to complications of surgery, not the cancer
- Expect 10,000 to 20,000 extra thyroidectomies in the region
- Only children younger than 18 or *in utero* (between 3 to 9 months) at time of exposure have had cancer—no adults
- No other significant increases in any other types of cancer

However, that was based on a release of over 7 million curies of Iodine-131, with children who lived in the contaminated areas of Belarus and the Ukraine receiving average thyroid doses of 200–500 rem, and 1 percent of the children having thyroid doses above 1,000 rem accumulated chronically over several days. These dose estimates are subject to considerable error and could underestimate the true dose because of the uncertainty about the contribution of the short-lived isotopes of radioiodine to this dose. The dominant route of entry for the Iodine-131 was milk ingestion with direct inhalation accounting for less than 10 percent of the total dose to the thyroid. There were no prophylactic measures taken to reduce iodine uptake via contaminated food for most of the exposed populations around Chernobyl.^[2]

The Chernobyl Reactor experiment gone awry was one of a kind and should not be seen as the reference accident for future emergency planning purposes; certainly not in the United States, or countries that operate light-water power reactors built to western safety standards. The purpose of the experiment was to determine, in the event of a loss of station power, whether adequate core cooling water would be supplied by a slowing turbine before the diesel emergency power supply was available. The test was carried out without a proper exchange of information and coordination between the team in charge of the test and the personnel in charge of the operation and safety of the nuclear reactor. Consequently, inadequate safety precautions were included in the test

program and operating personnel were not alerted to the nuclear safety implications of the electrical test and its potential danger. The event occurred due to a combination of operator error and design flaws of the reactor, more so the latter than the former.^[3]

By way of comparison, the worst commercial power reactor accident in the history of this country was the event at Three Mile Island, Unit 2. Radioiodine releases were conservatively estimated at 15–30 curies of Iodine-131 and 3-4 curies of Iodine-133. A maximum thyroid dose of less than 20 millirem (0.020 rem) for any one individual was calculated. None of the 762 people of the Three Mile Island who volunteered for *in-vivo* bioassay had Iodine-131 levels above 2.00E-09 curies equivalent to a dose of less than 12 millirem (0.012 rem).^[4]

The Hanford Nuclear Site in southeastern Washington State was established in 1943 to produce plutonium for atomic weapons. In 1986, it was revealed that during the initial years of plutonium production at Hanford, large amounts of gaseous and vaporized radionuclides were released into the atmosphere. It was subsequently estimated that about 740,000 Ci of Iodine-131 were released. This disclosure prompted concerns among people living near the Hanford site that such releases may have increased their risk of developing thyroid disease. Studies of persons exposed to diagnostic or therapeutic doses of iodine provide no convincing evidence that such exposure increases the risk of thyroid disease. The Hanford Thyroid Disease Study was mandated by Congress in 1988 to determine if incidence of thyroid disease was increased among persons exposed as children to atmospheric releases of Iodine-131 from Hanford. The results, as reported in the final report released in June 2002, indicated no evidence of a relationship between Hanford radiation dose and the cumulative incidence of thyroid cancer, benign thyroid nodules, autoimmune thyroiditis, and hypothyroidism. Exposures reviewed had occurred during infancy and childhood at median dose levels of 97 mGy (9.7 Rad) and mean dose level of 174 mGy (17.4 Rad).^[5,6]

Despite its availability in limited quantities at most hospitals with Nuclear Medicine departments, radioiodines, in general, are not considered feasible for use in a radiological dispersion device (RDD); primarily due to their relatively brief half-lives and distribution in small quantities for use in medicine and industry. The only sizeable quantities of radioiodine are found in a commercial reactor core.^[7,8]

Current Status of KI in the United States

The federal government has offered KI for states with commercial nuclear reactors, and is to be distributed within a 10-mile emergency protective zone (EPZ) around each nuclear reactor. Of the 34 states that are eligible for this, only 18 have chosen to participate. There is no plan within the U.S. Nuclear Regulatory Commission (NRC) to extend the size of the plume exposure pathway around commercially licensed nuclear power plants from 10 to 20 miles (or any other distance.) Recent speculation about increasing the KI distribution zone around nuclear power plants came out of a Congressional committee that was intended to resolve the differences between the Senate and House version of the *Public Health Security and Bioterrorism Preparedness*

and Response Act of 2002. While neither the Senate nor the House versions of the bill had a proviso calling for an increase in planning distance, one of the committee members introduced this resolution of a non-discrepancy. Ultimately, it appeared in the *Federal Register* as something that States were being asked to comment on (whether or not they wished to increase this KI distribution zone around nuclear power plants from 10 to 20 miles). The Federal Emergency Management Agency (FEMA) was to conduct a review during observed and graded ingestion pathway exercises conducted at the various nuclear power plants at least once every six years.^[9]

There is no technical basis to increase the plume exposure pathway from 10 to 20 miles, because there would not be sufficient environmental transport of radioiodine out to those distances to warrant taking KI. The children of Belarus and the Ukraine, who developed thyroid cancer as a delayed result of their exposures to radioiodine during and after the release at Chernobyl, had all received hundreds of rem of exposure to their thyroid glands. The dose was accumulated predominantly as a result of inadequate ingestion exposure pathway protective actions (not due to the inadequate plume exposure pathway protective actions). Prior to the accident, the children were already iodine deficient due to dietary factors, and so took up all the radioiodine that was added to their diet by consuming the contaminated foodstuffs. Within New York City, due to proactive steps such as iodination of salt, and wide availability of fresh seafood, diets are iodine sufficient.

KI and the Public Perception

Potassium iodide has received media attention, much of which is erroneous. Many media and public officials have wrongly identified KI as an “anti-radiation” pill, and much of the advertisement for commercial KI also gives the impression that KI is what one takes for any radiation exposure. The presumed educated public is aware that KI or some pill exists that could be taken in the event of a radiological or nuclear terrorist event. The mixture of fear and misunderstanding surrounding radiation and KI reveals a need for public education, but more importantly, education about the risks of radiation and how to respond in emergencies in general.

KI Recommendations from Experts

The NRC does not recommend distribution beyond the 10-mile EPZ based on the pathways of intake of KI. Their basis for the 10-mile emergency protective zone is that this is the area that radioactive iodine would have the highest concentration in the air, and the risk of inhalation of significant amount of radioactive iodine is the greatest. Outside of this EPZ, the concentration in the air would be much less, but fallout on the ground could accumulate on foodstuffs and grass. The main pathway of radioactive iodine intake outside of the 10-mile EPZ would be through the ingestion pathway by eating leafy vegetables exposed to I-131 or drinking milk by cows that fed on contaminated fodder or pasture. Embargoing vulnerable foods and feeding cows with stored feed can mitigate this pathway.^[10-12]

The Food and Drug Administration (FDA) and Environmental Protection Agency (EPA) have approved the following daily dose schedule for KI tablets, which are available at many pharmacies and over the Internet for homebound individuals:

Table 2. Threshold thyroid radioiodine exposures and recommended doses of KI for different risk groups

	Predicted thyroid exposure [rem]	KI dose [mg]	Number of 130-mg tablets	Number of 65-mg tablets
Adults over 40 years	> 500	130	1	2
Adults 18–40 years	> 10	130	1	2
Pregnant or lactating women	> 5	130	1	2
Adolescents 12–18 years*	> 5	65	1/2	1
Children 3–12 years	> 5	65	1/2	1
1 month – 3 years	> 5	32	1/4	1/2
Birth – 1 month	> 5	16	1/8	1/4

*Adolescents approaching adult size (> 70 kg) should receive the full adult dose (130 mg).

Risk Assessment for New York City

The FDA guidelines for the administration of KI state that it should be administered if the expected doses to the thyroid are to be greater than 5 rem. The potential for these doses would come from a disaster at a nuclear power plant or a nuclear bomb. If a nuclear device were detonated in or near New York City, radioiodine uptake and concentration by thyroid gland is not the primary public concern, nor would the pattern of the exposed population be predictable compared to an EPZ for a power plant.

Although it is possible that a terrorist could use radioiodine within a “dirty bomb” or other RDD, this is considered inconsequential from a public health standpoint. It is not a significant threat because of the impossibility of accumulating a kilocurie size quantity necessary to pose a risk of reaching the minimum projected threshold dose for implementation of protective action guidelines.

There are no commercial nuclear power plants or nuclear reactors of any type that have New York City within their 10-mile plume exposure pathway/EPZ.

There is not a credible accident or malevolent scenario that could involve risk of massive numbers of New Yorkers needing to take KI as a result of being inside the plume exposure pathway of a radioiodine release with sufficient inventory to trigger protective action guidelines.

New York City isn't Chernobyl

Since most of the recommendations for KI are derived from the experience after the Chernobyl disaster, it is important to note some of the significant differences between these two regions and why New York City is not as vulnerable as the regions surrounding Chernobyl.

1. Evacuation/sheltering in place

The unfortunate decision to not alert the public about the disaster at Chernobyl was made to avert widespread panic. Neither protective action was utilized which would have avoided much of the exposure to vulnerable populations. In New York, unless there was a complete breakdown in communication infrastructure, these protective actions would be utilized.

2. Protracted fire at Chernobyl

The moderator of the Chernobyl reactor core was made of over 1,300 tons of graphite, which was the major contributor to the fire burning for ten days, sending out repeated plumes of radioactive isotopes. There was no containment building as compared to the design of U.S. commercial reactors. The Indian Point facility is not vulnerable to an incident like that which occurred at Chernobyl.

3. Unprotected food sources

In the immediate aftermath of Chernobyl, foods were not embargoed and cattle were not taken off of exposed pastures. These measures would be immediately instituted if an event occurred here. The major pathway for intake of radioactive iodine was by the ingestion pathway, causing over 80 percent of the thyroid dose. By eliminating this source, New York City would make a significant decrease of thyroid doses without any other measure.

4. Iodine deficiency

In the regions surrounding Chernobyl, there is a high prevalence of iodine deficiency, up to 60 percent of the population. These individuals are much more susceptible to radioactive iodine because their thyroids take up any iodine much more readily. In the U.S., due to proactive steps such as the iodination of salt, our diets are iodine sufficient. One estimate of the protective benefit of an iodine sufficient diet is that it would decrease the uptake of radioactive iodine by 50 percent. New York City, specifically, is not an area of dietary iodine deficiency.

Usage of KI

Though not particularly expensive, KI is problematic to stockpile because of its relatively limited shelf life and the difficulties of broad distribution if needed immediately during an emergency. But active distribution by a local government is not an inexpensive proposal. If the American Thyroid Association (ATA) recommendations were followed, with both home distribution and stockpiles throughout the city for post-event distribution, several major steps would be required. These recommendations would require significant resources to develop the formal plan, secure and distribute the KI, and maintain the program. As new children are born, and young children age, more KI would be needed. As people relocate, inventory previously distributed is lost. Furthermore, when KI was offered for distribution within the 10-mile EPZ around Indian Point, less than 20 percent of the people took advantage of the offer. For concerned individuals residing beyond the 10-mile plume exposure pathways surrounding nuclear power plants, the pills are available without prescription and over the counter at pharmacies and through direct order over the Internet.

While KI is most effective when taken slightly before exposure to a plume containing radioiodine, if one expects to traverse an area within the footprint of a plume containing radioiodine, a better mitigation would be a respirator with appropriate filters for radioiodine (and particulates). Given the primary route of exposure for radioiodine is inhalation, this would apply for emergency responders who may have to enter regions with airborne activity and remain there for some time as part of their emergency response assignment, and not just for evacuation (as would be the case for the public). There is always a risk giving KI to an individual who may be sensitive or allergic to iodine. Many people who are allergic or sensitive to shellfish are, in fact, sensitive to the iodine in the shellfish. This can be pre-determined for first responders and emergency responders at leisure, but not always when dealing with the public during an emergency.^[13]

Before KI became so readily available (in the late 1980s), some studies were done on the efficacy of topical application of tincture of iodine and/or povidone-iodine solution (Betadine) to the skin as a means of providing a loading of stable iodine to saturate the thyroid and prevent or reduce the potential uptake of the radioiodine. There is an established scientific basis for the success of that method for protection of the thyroid gland. As the method relies solely on the topical application of first-aid treatments typically found in most homes and having no particular shelf-life problems, it may provide the public with an alternative to worrying about when and where to get and take KI in an actual emergency.

Preliminary human studies have shown that 4 mL of 2 percent tincture of iodine applied to a single forearm produced an average serum iodine level of 138 pg mm^{-3} ($13.8 \text{ } \mu\text{g dL}^{-1}$) at 2 hours post-application. Previous studies have indicated that serum levels greater than 100 pg mm^{-3} ($10 \text{ } \mu\text{g dL}^{-1}$) provides nearly 100 percent blockage of radioiodine uptake by the thyroid gland. In the absence of KI tablets or solution for ingestion, for thyroid protection from airborne radioiodine uptake, topical application of 8 mL (equivalent to 120 drops, or 1.5 teaspoons, or $\frac{1}{2}$ tablespoon, or $\frac{1}{4}$ ounce) of 2 percent tincture of iodine or Betadine (Povidone-Iodine solution) to the skin of the abdomen over

an area of approximately 4" by 8" would produce serum Iodine levels greater than 200 pg mm^{-3} ($20 \mu\text{g dL}^{-1}$) persisting over 26 hours with an effectiveness comparable to oral KI in blocking uptake of radioiodine. **CAUTION: TOPICAL application only.** Ingestion of tincture of iodine or Betadine can cause poisoning. (There is anecdotal information regarding such occurrences in Eastern Europe when another Russian Reactor was believed to be having an accident.) A significant public information and education effort must accompany any such recommendation to the public.^[14,15]

Considerations for New York City

First, it should be understood that any option regarding distribution of KI to the public in New York City require significant public and provider education. Even without any distribution, this is a mandatory public health step: to educate the public about the risks of radiation exposure from terrorism and about the benefits and limitations of potassium iodide. This can be both a tool to reassure the public by better preparing them, lowering the public anxiety of radiation, and offering them concrete actions to take, including the use of KI, or, if not available, alternative topical applications, in even the incredible event of a radioiodine plume within New York City with sufficient concentration or inventory to reach an EPA protective action guidelines (PAG) prompting thyroid protection from airborne radioiodine. Potential Ingestion pathway exposure should always be addressed by proper implementation of controls against contaminated foodstuffs. In New York City, exposure to radioiodine via the ingestion pathway would not be a concern, due to contaminated foodstuffs interdiction combined with the lack of locally raised dairy animals and limited farming of fresh fruits and vegetables.

Recommending KI after an incident has occurred, and utilizing points of distribution such as fire houses, schools, and police stations, is considered hazardous and not feasible for an urban environment. If a plume of radioactive iodine were approaching from outside New York City with sufficient radioiodine activity to cause projected doses of 5 rem to the thyroid gland, then there would be multiple complicating factors. Traffic would become impossible as people fleeing from the origin of the plume approach New York City, while city residents try to leave the city, and others (within the city) try to get to KI distribution points, making matters worse. At these levels of radiation, it would be safer to shelter-in-place than to evacuate. Sending people to obtain KI would expose them to much higher levels than they would if they stayed in place. In addition, ideally, KI must be administered within 3 hours after exposure, and to try to distribute 8 million doses within three hours in a chaotic environment without a guarantee that there would even be a workforce to distribute the KI is considered nearly impossible.

As for the problems with pre-distribution, besides logistical problems, is that it is an ineffective method for dispensing KI. Studies have shown that most people lose their tablets, or do not carry it with them. Any plan using pre-distribution should include frequent reminders and redistribution of KI on a regular basis, otherwise the program is nothing more than a limited attempt at appeasing the public's anxiety rather than an appropriate public health step. This would also require redistribution every 3 to 5 years since that is the recommended shelf life of KI at this date.

Recommendations

1. Extensive public education should be provided about radiation terrorism and the limited use of KI. Encourage the public to obtain KI for their families if they want to take a proactive step, but also underline the low probability of a significant radiological event ever happening. Also advise them about the value of topical applications in lieu of KI, if none is available. This step could be consistent with encouraging parents of newborns to use car seats, and to have certain first aid medications in their homes.
2. Work with pharmacies, both local and at the national level, to increase the availability of KI in New York City. Use the “clout” of New York City to encourage a fair and reasonable price for members of the public wishing to obtain KI. Provide educational materials to pharmacies that could be given out to their customers.
3. Educate health providers about the limits of the use of KI and provide them with information that they could share with their patients.
4. Despite the lack of any immediately identifiable credible scenario prompting distribution of KI in response to a localized event, KI should be available for distribution to a limited number of emergency responders and evacuees from an area where a 5 rem dose of radioactive iodine is possible. A suitable stockpile might be 10,000 doses (130 mg tablets) for emergency workers and 1,000 doses (130 mg tablets) for locally affected members of the public, split up and stored at the primary, secondary, and tertiary EOC/EOFs for New York City.

Conclusions

1. There is no credible radiological scenario that would prompt the need for large segments of the general population of New York City to take KI as a result of a projected plume exposure to radioiodine reaching even the lowest threshold of 5 rem to the thyroid.
2. KI should be stockpiled in amounts and locations sufficient for use by first responders / emergency responders in response to any localized release of radioiodine.

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