

United States Nuclear Regulatory Commission

Protecting People and the Environment

Potassium Iodide and Thyroid Cancer What We've Learned & EPA PAGS 2017

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KI & Thyroid Cancer

- We've learned that...
 - Radiation induced thyroid cancers appear to have distinct genetic fingerprints
 - Ingestion was the important route of exposure at Chernobyl
 - Iodine sufficiency status of thyroid gland is significant in development of thyroid disease
 - Thyroid cancer incidence appears to be increasing world wide



Reactor Accidents

- Windscale 1957
- TMI Unit 2 1979
- Chernobyl 1986

• Fuksuhima 2011









Windscale 1957

- Nuclear reactor fire at Sellafield, UK
 - October 1957
 - 20,000 Ci of ¹³¹I released
 - Impacted counties in northwest England (Cumbria, Lancashire)
- Prompt ban of milk originating in an area of about 200 square miles for over a month
 - Reduced risk to population of thyroid cancer
- Predicted ~260 excess thyroid cancers, no significant increase has been observed
 - excess cases were predicted to occur at ~6.5 per year
 - expected natural incidence in UK > 600 per year



Three Mile Island Unit 2

- March 1979 reactor was operating at 97% power
- Noble gases released ~10 million curies
- Iodine releases very limited
 - estimated to be about 15 curies
 - Only trace amounts of iodine found in environment
- Maximum dose to member of public closest to site ~85 mrem



Chernobyl

- Reactor accident April 1986
- ~46 million curies of I-131 released from Chernobyl
- Limited protective measures were taken for population
 - Towns closest to reactor were evacuated
 - No protective actions implemented for milk, food in the days following the accident for wide areas impacted by fall-out from the accident



Chernobyl

- Unexpected rise in thyroid cancers occurred about 5 years after the accident
 - Expected latency period ~30 years
 - Challenged the understanding of radioactive iodine and thyroid cancer
- ~6,000 cases of thyroid cancers in people who were under the age of 18 at the time of the accident
 - ~15 fatal thyroid cancers (2016)



Chernobyl

- Thyroid cancers attributed to ingestion of contaminated milk for days/weeks after the accident and iodine insufficiency of the pediatric population
 - World Health Organization
 - "Since radioactive iodine is short lived, if people had stopped giving locally supplied contaminated milk to children for a few months following the accident, it is likely that most of the increase in radiation-induced thyroid cancer would not have resulted"



World Health Organization

- Updated iodine prophylaxis guidelines in 1999 to reflect the state of knowledge to date regarding thyroid cancer and radioactive iodine based on Chernobyl
 - 10 mGy (1 rad) (over 10 days) avertable thyroid dose up to 18 years old, pregnant & lactating women
 - 100 mGy (10 rad) avertable thyroid dose under 40 years of age
 - 5 Gy (500 rad) projected thyroid dose over 40



Food and Drug Administration

- Issued updated iodine prophylaxis guidelines in 2001
 - 5 rad projected thyroid dose (over 4 days) up to 18 years old, pregnant and lactating women
 - 10 rad projected thyroid dose 18- 40 years old
 - 500 rad projected thyroid dose over 40



NRC KI Program

- Rule change in Jan 2001 based on Chernobyl data
- Over 48 million tablets distributed to requesting states to date



Chernobyl 20+ years later

- Ongoing studies point to serious iodine deficiency and failure of protective actions to prevent ingestion as the cause of the increased thyroid cancers in children
- Genomic changes in DNA identified in tumors of 26
 children with thyroid cancer from Chernobyl
 - "What's really remarkable is that in every single one of these cases, we were able to find the driver mutation the actual genetic change that caused the cancer,"

Dr. James Fagin, Memorial Sloan Kettering Cancer Center



Fukushima







Fukushima

- Reactor accident March 2011
- -~4.5 million curies of I-131 released
- Protective measures were promptly implemented for population
 - Populations were evacuated and sheltered in place based on risk
 - Environmental sampling and subsequent food restrictions implemented in the days following the accident



Lessons from Fukushima KI Use

- Use of KI was not implemented uniformly
- Most, if not all, areas populations were already evacuated when KI decisions were made
 - Very little KI was administered to the populationanecdotal use of KI
- Prompt interdiction of food/milk/water prevented uptakes
- Population considered iodine sufficient due to diet



Lessons from Fukushima

- Thyroid doses very low amongst the pediatric population
 - <0.1 rad- ~10 rad upper bound</p>
 - No increases in thyroid nodules or other evidence of thyroid disease
 - Extensive testing has revealed a higher rate of thyroid nodules in the pediatric population of Japan than expected
 - Control prefectures have similar rates as exposed prefectures



Claims of thyroid cancer after Fukushima

- Some researchers claim increases in thyroid cancer in children exposed to Fukushima radiation
- Comparisons with control populations show that the Fukushima child thyroid cancer frequencies are consistent
 - 41.2% Fukushima children with detectible nodules/cysts; the combined percentage found in the three control prefectures was 56.6%.
 - 0.6% Fukushima children with the anomalies met additional testing criteria, other prefectures had a rate of over 1%.



Claims of thyroid cancer after Fukushima

- Important study findings:
 - Child thyroid anomalies first detected in Fukushima Prefecture have been occurring quite normally across the entire country, but had gone largely unnoticed before the national screenings of 2012-13.
 - Tumor biopsies have found no indication of radiogenic origins and most have indications of adult thyroid tumors



Are Thyroid Cancer Rates Increasing World-Wide?

- In the last decades thyroid cancer incidence has continuously and sharply increased all over the world
 - Some experts attribute increased incidence of thyroid cancer to the increased detection of small cancers in the preclinical stage
 - Some experts believe the data suggests a true increase above the increased detection
 - Some experts attribute increase to nuclear power
 - Mostly likely due to a combination of more sensitive diagnostic procedures and of a true increase due to increased exposure to medical radiation, increase in stable iodine uptake and other environmental factors



Other environmental factors?

Chernobyl childhood thyroid cancers and nitrates in ground wateris there a link?

Oblast	Mean ¹³¹ l thyroid dose ^a (mGy)	Nitrate in groundwater (mg/L)	Number of pediatric thyroid cancers	Incidence rate ^b (per 100,000 PY)
Minsk ^c	26	130	114	1.20
Gomel	320	112	552	11.0
Mogilev	65	40	56	1.50
Brest	51	185	245	5.51
Grodno	11	53	58	1.74
Vitebsk	3.5	77	19	0.48
Belarus	78	-	1,044	3.48

^a Adapted from [27].

^b Crude incidence rates for 1986–2004 period.

^c Including the city of Minsk.

doi:10.1371/journal.pone.0137226.t001

Major Factors Affecting Incidence of Childhood Thyroid Cancer in Belarus after the Chernobyl Accident: Do Nitrates in Drinking Water Play a Role? Valentina M. Drozd, Vladimir A. Saenko, et.al. PLoS ONE 10(9): e0137226 https://doi.org/10.1371/journal.pone.0137226



Fukushima Health Effects

- Fukushima Medical University "Health Management Survey" long-term study of population around Fukushima
 - -~449,000 respondents
 - ~ 99.8% whole body doses <500mr-2.5rem</p>
 - average effective dose received annually in Japan from natural background radiation is about 200 millirem
 - Long term monitoring for impact on child thyroid



Fukushima Impacts on Health

- "The most important health effect is on mental and social well-being, related to the enormous impact of the earthquake, tsunami and nuclear accident, and the fear and stigma related to the perceived risk of exposure to ionizing radiation"
 - UNSCEAR 2013



Fukushima Impacts on Health

- Stochastic effects from radiation dose
 - Whole body doses very low; likely no increases in cancer amongst the population
 - Thyroid doses in children are low; increases in thyroid disease unlikely
- Deaths from evacuation
 - Approximately 1600 people have died from effects of evacuation
 - 90% of evacuation related deaths were for persons above 66 years of age.



Impacts of Evacuation and Relocation

- Any traumatic incident can cause stress symptoms, depression, anxiety, and medically unexplained physical symptoms
- Stress and depression follow any disaster where people are uprooted, lives may have been lost, and the social fabric of lives and communities are destroyed
 - Hurricane Katrina
 - Super Storm Sandy
- Response to a radiation event is thought to be very stressful due to the fear of radiation and its perceived impact on health, however low the dose
- Risks of low dose radiation is not well communicated to the public
- Public believes any radiation dose as "harmful to health"



Lessons Learned: Chernobyl

- World Health Organization et al Chernobyl Forum report on Health,(2005) noted that "the mental health impact of Chernobyl is the largest public health problem unleashed by the accident to date"
- Psychological distress arising from the accident and its aftermath has had a profound impact on individual and community behavior



Chernobyl Forum Report

- Populations in the affected areas exhibit strongly negative attitudes in self-assessments of health and wellbeing
- Strong sense of lack of control over their own lives
- Exaggerated sense of the dangers to health of exposure to radiation
- Affected populations believe that exposed people are condemned to a shorter life
- Anxiety over the effects of radiation on health shows no sign of diminishing
- Overriding sense of victimization and dependency
- Loss of self-initiative to build their own life



Lessons Learned: Fukushima

- Fukushima Medical University undertaking long term studies of impacted populations
- Dr. Koichi Tanigawa, of Fukushima Medical University, "although the radiation dose to the public from Fukushima was relatively low, and no discernible physical health effects are expected, psychological and social problems, largely stemming from the differences in risk perceptions, have had a **devastating** impact on people's lives
- The **most important health effect** is on mental and social wellbeing, related to the enormous impact of the earthquake, tsunami and nuclear accident, and the **fear and stigma** related to the perceived risk of exposure to ionizing radiation, UNSCEAR 2013



Lessons Learned: Fukushima

- Approximately 1600 people have died from effects of evacuation within first 3+ months
- Deaths were attributed to physical and emotional effects as a result of evacuation and loss of all possessions
- 99.8% whole body doses <500mr-2.5rem
- average effective dose received annually in Japan from natural background radiation is about 200 millirem



What can we do?

- Need to do more to help the public understand relative risks of low dose radiation
 - What are the risks?
- Need to ensure that we learn from Chernobyl and Fukushima
 - Do not create a victim class based on radiation stigma
- Behavioral health support should be part of an all hazards approach to any disaster



EPA PAG MANUAL





What is a Protective Action Guide (PAG)?

- A dose guideline that triggers an action
 - Based on dose avoidance
 - Examples include evacuation, sheltering-in-place, food interdiction, water interdiction/alternative supplies, relocation, use of medicines designed to reduce dose, (KI, DTPA, etc)
- Non-regulatory guidance developed by federal interagency radiation emergency experts



When are PAGS used in a Rad Emergency?

 PAGS apply only to incidents involving significant releases of radionuclides resulting in doses offsite to the general public generally in excess of the PAG guidelines



What events are considered for PAGS?

- Nuclear Power Plant Incidents
- Terrorism
 - Radiological Dispersal Device (RDD), "dirty bomb"
 - Improvised Nuclear Device (IND) "nuclear bomb"
- Release from a contaminated site
 - Waste management
 - Nuclear weapon



2017 PAG Manual

- Applicability to a wider range of scenarios
- Updated guidance on radioactive contamination in food
- Clarified guidance for administration of potassium iodide (KI)
- Provides guidance on reentry, late phase cleanup and waste disposal consideration
- Includes drinking water PAGs
- Includes language on using Federal Radiological Monitoring and Assessment Center (FRMAC) derived value tables



PAGS for Stages of Response

- Early Phase
- Intermediate Phase
- Late Phase



Early Phase Changes

- Evacuation/shelter 1-5 rem
- Administration of KI 5 rem child thyroid dose
 - No longer tied to evacuation
- Emergency worker exposure limits:
 5, 10, 25+ rem per year –scenario dependent



Potassium Iodide

- Updated manual includes the 2002 FDA guidance
- Recommends use at the lowest intervention threshold
 - 1 year old age group dose is expected to be limiting
 - Administration of KI at 5 rem
 - No longer tied to evacuation
- 1992 PAG manual recommended KI at 25 rem adult thyroid dose



Intermediate Phase PAGs

- Relocate population at projected doses in excess of 2 rem in the first years; 0.5 rem in subsequent years
- Food interdiction: most limiting of 0.5 rem whole body or 5 rem to most exposed organ/tissue, derived intervention levels provided
- Drinking water: two tiered approach 100 mrem projected dose to sensitive populations (children, pregnant women); 500 mrem to general population



The Late Phase Clean up Process

- Begins when the focus sifts to reducing longer term exposure and improving living conditions
- Months to years
- Based on societal objectives for expected land use
- No numeric PAG
- PAG manual provides high level guidance



The Late Phase Waste Management

- Waste will likely overwhelm existing capacity in the US
- Primary responsibility for waste management decisions falls to state and local officials

