KI Use in Radiation Emergencies: FDA Treatment Recommendations

After careful review of the data from Chernobyl relating estimated thyroid radiation dose and cancer risk in exposed children, FDA is revising its recommendation for administration of KI based on age, predicted thyroid exposure, and pregnancy and lactation status (see Table).

Threshold Thyroid Radioactive Exposures and Recommended Doses of KI for Different Risk Groups

	Predicted Thyroid exposure(cGy)	KI dose (mg)	# of 130 mg tablets	# of 65 mg tablets
Adults over 40 yrs	≥500	130	1	2
Adults over 18 through 40 yrs	≥10			
Pregnant or lactating women	≥ 5			
Adoles. over 12 through 18 yrs*		65	1/2	1
Children over 3 through 12 yrs				
Over 1 month through 3 years		32	1/4	1/2
Birth through 1 month		16	1/8	1/4

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

The protective effect of KI lasts approximately 24 hours. For optimal prophylaxis, KI should therefore be dosed daily, until a risk of significant exposure to radioiodines by either inhalation or ingestion no longer exists. Individuals intolerant of KI at protective doses, and neonates, pregnant and lactating women (in whom repeat administration of KI raises particular safety issues, see below) should be given priority with regard to other protective measures (i.e., sheltering, evacuation, and control of the food supply).

Note that adults over 40 need take KI only in the case of a projected large internal radiation dose to the thyroid (>500 cGy) to prevent hypothyroidism.

These recommendations are meant to provide states and local authorities as well as other agencies with the best current guidance on safe and effective use of KI to reduce thyroidal radioiodine exposure and thus the risk of thyroid cancer. FDA recognizes that, in the event of an emergency, some or all of the specific dosing recommendations may be very difficult to carry out given their complexity and the logistics of implementation of a program of KI distribution. The recommendations should therefore be interpreted with flexibility as necessary to allow optimally effective and safe dosing given the exigencies of any particular emergency situation. In this context, we offer the following critical general guidance: ***across populations at risk for radioiodine exposure, the overall benefits of KI far exceed the risks of overdosing, especially in children, though we continue to emphasize particular attention to dose in infants***.

These FDA recommendations differ from those put forward in the World Health Organization (WHO) 1999 guidelines for iodine prophylaxis in two ways. WHO recommends a 130-mg dose of KI for adults and adolescents (over 12 years). For the sake of logistical simplicity in the dispensing and administration of KI to children, FDA recommends a 65-mg dose as standard for all school-age children while allowing for the adult dose (130 mg, 2 X 65 mg tablets) in adolescents approaching adult size. The other difference lies in the threshold for predicted exposure of those up to 18 years of age and of pregnant or lactating women that should trigger KI prophylaxis. WHO recommends a threshold of 1 cGy for these two groups. As stated earlier, FDA has concluded from the Chernobyl data that the most reliable evidence supports a significant increase in the risk of childhood thyroid cancer at exposures of 5 cGy or greater.

The downward KI dose adjustment by age group, based on body size considerations, adheres to the principle of minimum effective dose. The recommended standard dose of KI for all school-age children is the same (65 mg). However, adolescents approaching adult size (i.e., >70 kg) should receive the full adult dose (130 mg) for maximal block of thyroid radioiodine uptake. Neonates ideally should receive the lowest dose (16 mg) of KI. Repeat dosing of KI should be avoided in the neonate to minimize the risk of hypothyroidism during that critical phase of brain development (Bongers-Schokking 2000; Calaciura et al., 1995). KI from tablets (either whole or fractions) or as fresh saturated KI solution may be diluted in milk, formula, or water and the appropriate volume administered to babies. As stated above, we recommend that neonates (within the first month of life) treated with KI be monitored for the potential development of hypothyroidism by measurement of TSH (and FT4, if indicated) and that thyroid hormone therapy be instituted in cases in which hypothyroidism develops (Bongers-Schokking 2000; Fisher 2000; Calaciura et al., 1995).

Pregnant women should be given KI for their own protection and for that of the fetus, as iodine (whether stable or radioactive) readily crosses the placenta. However, because of the risk of blocking fetal thyroid function with excess stable iodine, repeat dosing with KI of pregnant women should be avoided. Lactating females should be administered KI for their own protection, as for other young adults, and potentially to reduce the radioiodine content of the breast milk, but not as a means to deliver KI to infants, who should get their KI directly. As for direct administration of KI, stable iodine as a component of breast milk may also pose a risk of hypothyroidism in nursing neonates. Therefore, repeat dosing with KI should be avoided in the lactating mother, except during continuing severe contamination. If repeat dosing of the mother is necessary, the nursing neonate should be monitored as recommended above.