FDA issues KI recommendations

by Sophie J. Balk, M.D., FAAP, and Robert W. Miller, M.D., Dr.P.H., FAAP

In light of the events of Sept. 11, a terrorist attack on a nuclear reactor no longer is considered a remote possibility. Parents may be concerned that their children will develop thyroid cancer after exposure to radioactive iodine (RAI) released during an attack or accident.

Pediatricians may be asked to give advice about administering potassium iodide (KI), which blocks the uptake of RAI and can prevent thyroid cancer. Government recommendations offer revised guidance on KI use and stress that children are more susceptible than adults to the effects of RAI.

FDA guidance on KI use

In 1976, the U.S. Food and Drug Administration (FDA) concluded that KI was safe and effective in blocking thyroidal RAI uptake in a radiation emergency. In 1982, the FDA issued recommendations based primarily on studies of external irradiation resulting from the WWII nuclear detonations at Hiroshima and Nagasaki. At that time, the FDA concluded that at a projected dose to the thyroid gland of ≥ 25 cGy (1 centiGray = 1 rad) from ingesting or inhaling radioiodines, the benefits of taking small amounts of KI to suppress radioiodine-induced thyroid cancer outweigh the risks of short-term KI use.

In November 2001, the FDA issued new guidance on using KI, updating the dosing schedule and recommending KI at exposure thresholds of ≥ 5 rad for children and pregnant and lactating mothers. (See table, page 109.) The guidance is aimed at federal agencies and state and local governments responsible for radiation emergen-

Resources offer brothers, sisters support

Stay attuned to needs of seriously ill patients’ siblings

by Carla Kemp

Dear Mom,

Tonight Dad was telling me how hard it was when Trudy was in the hospital. He doesn’t think it was hard for me at all. I missed you. I saw her get all these presents. I saw everyone visiting her and babying her, and there was nothing I could do about it. Sometimes I feel so alone and left out and even unloved. I know I’m overreacting, and I know that some people have so much less than me, but it’s not my fault I don’t have any medical problems. I wish I did!

Love,
— Jeffrey

This letter from a 9-year-old boy illustrates many of the issues faced by siblings of children with complex medical problems. Brothers and sisters may feel rejected, depressed, guilty, scared, jealous and helpless. Pediatricians, parents and other caregivers, however, may be so focused on the ill child that they forget about the needs of the other children in the family.

Siblings — like parents of chronically ill children — need information and support. While parents can draw strength from support groups and respite services, siblings often feel isolated.

“Most of us who work in the field of pediatrics or education or developmental disabilities, if we were to meet a parent of a newly diagnosed kid, or one of our immediate reactions and first inclinations would be to introduce that parent to another parent who also has a child with a similar illness or disability,” said Donald Meyer, M.Ed., director of the Sibling Support Project of the Arc of the U.S.

“In my work, we are continually meeting sibs who are in their 40s who are only now meeting other people with brothers and sisters who have autism or spina bifida or Down syndrome,” Meyer continued. “We would never make parents wait 40 years to meet their peers, but somehow that’s OK with brothers and sisters.”

Meyer founded the Sibling Support Project (www.seattlechildrens.org/sisbups/) about 12 years ago to change that. The national program provides peer support and educational programs for brothers and sisters of people with special health and developmental needs. The group reaches out to siblings through e-mail lists, books and Sibshops, which Meyer describes as lively events with games, cooking activities and crafts.

There are about 200 Sibshops, in nearly every state.
Emergency. It is based primarily on data accumulated after the accident at the Chernobyl nuclear power plant on April 26, 1986. This disaster resulted in the massive release of 131I and other radioiodines, some with very short half-lives. The short-lived radioiodines are believed to increase the risk of thyroid cancer in children more than does 131I (Bleuer JP, et al. Environ Health Perspect. 1997;105 (suppl 6):1483-1486).

Large numbers of people, including pregnant women and children, were exposed to radioactive fallout primarily through ingesting contaminated fresh cow’s milk (resulting from cows grazing on contaminated fields), and from consuming contaminated vegetables. Significant exposure also was possible through inhaling radioiodines at the time of the fallout.

Shortly after the disaster, measurements of thyroid exposure were made of hundreds of thousands of individuals in Ukraine, Belarus and the Russian Federation where individual areas of fallout were the greatest. The Chernobyl data are considered the most comprehensive and reliable available describing the relationship of thyroid radiation and risk of thyroid cancer after an environmental release of 131I (www.fda.gov/cder/guidance/index.htm).

Children and thyroid cancer

Four years after the accident, children and adolescents in Belarus and Ukraine began to develop thyroid cancers at greatly increased rates. Hundreds of children developed thyroid cancer, with the largest numbers of cancers seen in children who were 5 years of age or younger at the time of the accident (Tronko MD, et al. Cancer. 1999;86:149-156).

In the most heavily affected areas, the incidence was up to 100 times greater than before the disaster. The majority of cases occurred in children who received less than 30 rad to the thyroid (www.fda.gov/cder/guidance/index.htm).

The high number of cancer and the short latency period may represent an interaction between radiation and host susceptibility. Iodine deficiency may have played a role (Robbins J, et al. Thyroid. 2001;11:487-491). Higher risk for thyroid cancer in children compared with adults may occur because of higher thyroid activity, the larger amount of milk ingested per unit of body weight, a higher respiratory rate, and because children are more likely to ingest or inhale contaminants closer to the ground.

KI recommendations

KI is the same chemical used, in smaller amounts, to iodize table salt. When ingested before, during, or shortly after exposure to RAI, KI “floods” the thyroid, preventing the RAI uptake. Studies of the safety of KI were conducted in Poland, where about 18 million children and adults received at least one dose after Chernobyl to protect the thyroid. Side effects, mainly GI distress or rash, generally were mild and clinically insignificant.

A few newborns receiving single doses of KI developed transient increases in TSH and decreases in FT4; no other adverse sequelae have been reported. Because of the critical role of thyroid hormone in ensuring normal development during this time, the FDA recommends that babies 1 month of age or younger treated with KI be monitored with TSH measurements (and FT4 if needed); thyroid hormone therapy should be instituted if hypothyroidism develops.

The FDA recommends that pregnant women be given KI to protect themselves and their fetuses but cautions that repeated doses should be avoided during pregnancy because of the risk of blocking fetal thyroid function with excess stable iodine. The FDA also recommends that lactating women should be given KI for their own protection, and their infants should receive KI directly. Experts consulted advised that women exposed to RAI should not breast feed unless there are no alternatives.

KI should not be given to persons with known iodine sensitivity, or to those with dermatitis herpetiformis or hypocomplementemic vasculitis (rare conditions), and should be used with caution in individuals with thyroid disease. KI protects only the thyroid gland from radioiodines, offers no protection from external radiation and does not protect the body from effects of exposure to other radioactive materials.

Since the protective effect of KI lasts about 24 hours, daily dosing provides optimum prophylaxis until a significant risk from inhalation or ingestion no longer exists. Because early action is crucial, KI optimally should be administered before exposure, upon notification of an emergency. KI may have a protective effect even if taken three to four hours after exposure.

Public health authorities’ role

Adopting and implementing these FDA recommendations is at the discretion of state and local governments responsible for emergency planning. Options include evacuation, sheltering, control of foodstuffs and administering KI. The FDA recommends that state and local health authorities who incorporate KI into emergency response plans consider predistributing KI to individuals without health contraindications.

The Nuclear Regulatory Commission is moving toward buying millions of doses of KI, with plans to offer it free to states requesting it. Thus far, Alabama, Arizona, and Tennessee have provided KI to the general public as a part of their emergency preparedness programs. Other states stockpile KI for emergency workers.

KI is safe for most people, but stockpiling KI by public health authorities for use by the general public is not widespread. Those arguing against using KI express that it may mistakenly be viewed as a cure for all radiation effects. Others argue that sheltering, evacuation and controlling the food supply are better protective strategies in the United States compared to Chernobyl, where reporting of the disaster was delayed.

While these controversies are discussed and until state and local health departments finalize their plans, individuals wishing to purchase FDA-approved KI pills can do so at some pharmacies or on the Internet at www.anbex.com and www.nukepills.com. KI tablets are available without a doctor’s prescription.

Dr. Balk is chair of the AAP Committee on Environmental Health (CCEH). Dr. Miller is former chair of CCEH and scientist emeritus at the National Institutes of Health.

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<tr>
<th>Threshold thyroid radiation exposures and recommended doses of KI for different risk groups</th>
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<tr>
<td>Predicted thyroid Exposure (rad)</td>
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<td>---------------------------------</td>
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<tr>
<td>Adults over 40 years*</td>
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<tr>
<td>Adults &gt;18 to 40 years</td>
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<td>Pregnant or lactating women</td>
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<td>Adolescents &gt;12 to 18 years**</td>
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<tr>
<td>Children &gt;3 to 12 years</td>
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<tr>
<td>Children &gt;1 month to 3 years***</td>
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<td>Birth to 1 month</td>
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| * For adults > 40 years, KI is given at higher exposure levels. Older adults are more likely to suffer side effects of potassium and less likely to profit from cancer preventive effects. 
** Adolescents approaching adult size (>70 kg) should receive the adult dose (130 mg)
*** For infants, KI from tablets or as a fresh saturated KI solution may be diluted in milk, formula or water and given in an appropriate volume.