



Inova Children's Hospital

Pediatric and Radiology Service Line Response to FDA Drug Safety Communication on Iodine-Containing Contrast for Pediatric Patients Released March 2022:

FDA Drug Safety Communication: [FDA recommends thyroid monitoring in babies and young children who receive injections of iodine-containing contrast media for medical imaging](#)

Key Takeaways:

- [A March 2022 FDA recommendation indicates thyroid monitoring is recommended within 3 weeks of an iodine-containing contrast administration for infants and children 0-3 years old](#)
- [Ambulatory physicians ordering these studies are responsible for coordinating thyroid testing and family education on testing](#)
- [If the patient has a study completed while admitted and remains admitted, the inpatient care team will order and follow results](#)
- [Necessary testing will be communicated to the ambulatory physician via the discharge summary, After Visit Summary, and the Radiology Report.](#)

What are the concerning contrast studies?

Any study that involves administration of intravenous contrast containing iodine is included; this includes CT scans such as head CT, abdominal and chest CTs, and cardiac catheterizations. Some interventional radiology vascular access procedures will use IV contrast.

What about other contrast studies that are not IV administration?

The warning is for *Intravenous* iodine contrast administration, so other forms of contrast material do not have the same effect because of either quick elimination or poor absorption, for example, VCUG and UGI studies do not place patients at high risk. MRI studies do not use iodine containing contrast.

Which patients are at highest risk?

Children from newborns thru 3 year olds who have not yet reached their 4th birthday are those at risk. The highest risk are those newborns that are born prematurely or have a low birthweight or less than 3 months of age, and those children that have underlying conditions such as congenital heart disease and any that require treatment in the Neonatal ICU or Pediatric ICU.

How do we know if one of these contrast studies was done?

Any ambulatory provider (primary care or specialist) ordering a contrast study should ensure information is provided to the patient's care givers and testing and follow up is completed. If the contrast study was done at an Inova facility either as a patient in the emergency department or an during a hospital stay, the treating provider will notify the primary care pediatrician via the discharge summary and the parental After Visit Summary (AVS) and give guidance to the child's care givers. The radiologists have added a statement into their report referencing the FDA alert as a reminder to providers. If the thyroid testing was completed during the hospital stay, this will be included in the discharge summary.



When should the thyroid studies be done?

The FDA recommends within 3 weeks of the study. The Pediatric Endocrine Society (PES) recommends testing between 2-3 weeks after the study has been completed. If the child is still in the hospital at the time the thyroid tests are recommended, the care team will order and follow up those results and will include those in the discharge summary. The Cardiology team has committed to following up on these studies for those patients exposed during a cardiac catheterization procedure. The Oncology team will follow up on studies they have ordered for their patient population.

What tests should be ordered?

Pediatric Endocrinology Society recommends initially testing TSH.

What should be done if the thyroid studies are abnormal?

Per the Pediatric Endocrine Society recommendations: The majority of patients with iodine-induced hypothyroidism will have TSH levels well above the normal range for age. While there are no data to provide a reliable TSH-cut off for when to initiate thyroid hormone replacement therapy, premature infants and acutely ill children typically have an inappropriately low or normal TSH level when assessed within the context of a low free T4.

1. If the TSH is greater than 10mU/L; this is considered abnormal and warrants confirmatory testing of TSH and Free T4.
2. If the confirmatory testing TSH is > 20 mU/L or TSH is high and Free T4 is low, levothyroxine should be initiated. Please refer to Pediatric Endocrinology.
3. If confirmatory testing TSH is between 10-20 mU/L with normal Free T4, then repeat testing should be completed.

The on call Pediatric Specialists of Virginia Pediatric Endocrinologist is available to answer questions and provide guidance to providers. They can be reached thru the Inova One-Call system **1-877-900-9543 (1-877-900-9KID)** or the Pediatric Specialists of Virginia office provider line: **703-778-1234**.

Why is this important?

Normal thyroid function is critical for normal neurocognitive development and skeletal maturation. Consequences of hypothyroidism during early life may include irreversible impairments in motor, hearing, and cognitive development, especially in the first 36–40 months of life during which myelination is still incomplete. The impact of subclinical hypothyroidism on neurological development remains poorly understood, especially in children less than 3 years old.

Why does this happen?

The physiologic basis for decreased thyroid dysfunction after excess iodine exposure is known as the acute Wolff-Chaikoff effect, in which the thyroid gland responds to excess iodine by a temporary reduction of thyroid hormone production, perhaps through the formation of inhibitory substances. In most individuals, suppression is transient if the iodine exposure does not continue with thyroid hormone production typically returning to normal after 1-2 weeks.



References:

<https://www.fda.gov/safety/medical-product-safety-information/iodine-containing-contrast-media-drug-safety-communication-fda-recommends-thyroid-monitoring-babies>

<https://pedsendo.org/news-announcements/pes-statement-on-thyroid-monitoring-in-infants-and-young-children-receiving-iodine-containing-contrast-media/>

Barr ML, Chiu HK, Li N, et al. Thyroid Dysfunction in Children Exposed to Iodinated Contrast Media. *J Clin Endocrinol Metab.* 2016;101(6):2366-2370. doi:10.1210/jc.2016-1330

Parazzini C, Baldoli C, Scotti G, Triulzi F. Terminal zones of myelination: MR evaluation of children aged 20–40 months. *AJNR Am J Neuroradiol.* 2002;23:1669–1673. [PMCID: PMC8185844] [PubMed: 12427621]

Rovet JF. The role of thyroid hormones for brain development and cognitive function. *Endocr Dev.* 2014;26:26–43. [PubMed: 25231442]

Zoeller RT, Rovet J. Timing of thyroid hormone action in the developing brain: clinical observations and experimental findings. *J Neuroendocrinol.* 2004;16:809–818. [PubMed: 15500540]