FDA Offers Suggestions for CT Safety

The U.S. Food and Drug Administration (FDA) announced on November 9 that it sent a letter to the Medical Imaging and Technology Alliance (MITA), a major industry organization for manufacturers of CT scanners, reporting on results of an investigation into excess radiation exposure incidents in brain perfusion imaging. The FDA found that when properly used, the CT scanners did not malfunction. Instead, it is likely that improper use of the scanners resulted in these overdoses. The FDA identified a series of "promising steps" that manufacturers could take to enhance the safety of these procedures and "reduce the likelihood of radiation overexposure in the event of improper use of the CT scanners." The letter to MITA, signed by Jeffrey Shuren, MD, JD, director of the FDA Center for Devices and Radiological Health, included the following suggestions:

(1) Brain-perfusion CT: Provide particular information and training on brain-perfusion protocols to all facilities receiving base CT equipment, whether or not the facilities purchase the related software enabling quantitative analysis of cerebral hemodynamics. Suggested information to provide includes: (a) Manufacturer-recommended parameter settings, i.e., tabulated or listed settings for each scanning-parameter set supplemented with the corresponding values expected for the dose indices $CTDI_{vol}$ and DLP. (Presumably such dose-index values would be typical of each of the associated scanning sequences comprising a complete brain perfusion protocol.) (b) A concise description for each scanning-parameter set that clearly distinguishes the particular role of its corresponding scanning sequence from the roles of the other scanning sequences comprising a complete brain perfusion study. Such descriptions may reduce the potential for inadvertently substituting technique values associated with diagnostic-quality imaging phases for the lower-dose scanning parameter settings actually needed for contrast-perfusion phases. (c) Explanation of why a relatively poorer-quality image is appropriate to reduce radiation dose in the contrast-perfusion phases in comparison to the relatively better image quality that might be needed for any diagnostic phases included in a protocol. (d) Explanation of how peak skin doses relate to CTDI (because brain perfusion studies are associated with relatively high skin doses).

(2) Automatic Exposure Control (AEC): (a) Clarify parameters affecting dose, along with clear instructions on how to appropriately set those parameters. (b) Describe how to choose AEC vs. manual modes, including examples of situations—for example, brain perfusion studies—in which AEC operation might unnecessarily complicate successful operation without additional dose savings and with no improvement in diagnostic efficacy. (c) Place emphasis on building or modifying protocols to check the need to change manufacturer-recommended or default AEC parameters to achieve optimal dose reduction, including the potential for an unintended dose increase (compared to manual mode operation) if AEC parameters are not checked. (d) Provide directions for how to modify manufacturer-recommended scanning-parameter sets; if a user were to elect an AEC mode in lieu of a recommended manual mode, the values of all dose-associated AEC-configurable parameters could default (until otherwise changed) to those that would yield a value for the sequence-maximum mAs that would match the mAs value recommended in the manual mode.

(3) Pop-Up Notification at Threshold for Deterministic Injury: Institute a pop-up notification so that prior to scanning, when the operating conditions associated with any protocol yield an expected value of $CTDI_{vol} \geq 1$ Gy, a notification would alert the operator that a high radiation dose, potentially leading to the development of clinically significant cataracts, skin injury, or hair loss, would be incurred by the patient were scanning to proceed.

(4) User-Accessible Organization of Dose-Related Information: Organize all dose-related information into 1 section of each user manual, in a dedicated dose manual, or indexed comprehensively in a concordance covering all manuals.

(5) Protocol Specifications: Provide facilities with hard copies or pdf files specifying the dose-associated parameter settings recommended for particular clinical applications, including distinct "scanning-parameter sets" for the values of each scanning sequence comprising a protocol and supplemented with the corresponding values (or, perhaps, range of values associated with AEC operation) typical for the dose indices $CTDI_{vol}$ and DLP (with phantom diameter and length identified), each set tabulated or listed.

The letter concluded by stating that the FDA was interested in follow-up meetings with manufacturers and their stakeholders to discuss these points and to continue a "constructive dialogue" on the ways in which these ideas might fit into the FDA's previously published Initiative to Reduce Unnecessary Radiation Exposure from Medical Imaging. Although these 5 suggestions are aimed at manufacturers, each has a number of potential implications for routine clinical use (including in PET/CT and SPECT/CT), and it is anticipated that both clinicians and technologists will be included in future discussions. Area analysts note that FDA "suggestions" often evolve into regulatory requirements and that imaging professionals are advised to follow these discussions closely. ✳