

Medical imaging may detect unrelated diseases in research participants

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In about 40 percent of research participants undergoing medical imaging, radiologists may detect a tumor or infection unrelated to the study but that may be meaningful to the individual's health, according to a report in the September 27 issue of *Archives of Internal Medicine*.

"An incidental finding in human subjects research is defined in a major consensus project as an observation 'concerning an individual research participant that has potential clinical importance and is discovered in the course of conducting research, but is beyond the aims of the study,'" the authors write as background information in the article. "Numerous reports have detailed how the detection of an incidental finding can result in the early beneficial diagnosis of an unsuspected malignant neoplasm or [aneurysm](#). However, others describe harm and excessive cost resulting from treatment of radiographically suspicious incidental findings. Moreover, clinical experience dictates that many incidental findings are of indeterminate clinical significance and generate uncertainty among both research participants and their physicians."

Nicholas M. Orme, M.D., of Mayo Clinic, Rochester, Minn., and colleagues evaluated the medical records of 1,426 research participants who underwent an imaging procedure related to a study conducted in 2004. Each image was interpreted by a radiologist the day it was performed, and an expert panel reviewed all incidental findings that resulted in a clinical action during a three-year follow-up period.

Of the 1,426 research imaging examinations, an incidental finding

occurred in 567 (39.8 percent). The risk of an incidental finding increased with age. More incidental findings were generated in patients undergoing computed tomography (CT) scans of the abdomen and pelvic area than in any other imaging procedure, followed by CT of the chest and [magnetic resonance imaging](#) (MRI) of the head.

Clinical action was taken for 35 (6.2 percent) of the individuals with an incidental finding; in most cases (26 of 567, or 4.6 percent) the medical benefit or burden of these actions was unclear. However, action resulted in clear medical benefit for six of the 567 patients (1.1 percent) and clear medical burden in three patients (0.5 percent).

"This study demonstrates that research imaging incidental findings are common in certain types of imaging examinations, potentially offering an early opportunity to diagnose asymptomatic life-threatening disease, as well as a potential invitation to invasive, costly and ultimately unnecessary interventions for benign processes," the authors write. "The majority of incidental findings seem to be of unclear significance. These instances represent a dilemma for researchers."

The findings should help researchers identify imaging studies at high risk for generating incidental findings and develop a plan for managing them, the authors conclude. "Timely, routine evaluation of research images by radiologists can result in identification of incidental findings in a substantial number of cases that can result in significant medical benefit to a small number of patients," they write.

More information: Arch Intern Med. 2010;170[17]:1525-1532.

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