A Policy for Management of Incidental Findings in Imaging Research

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Introduction

The management of incidental findings in imaging research is a current source of debate in the medical community. Points of contention include: active searching for incidental findings on a research study, requirement for systematic review of imaging by a radiologist, liability of the radiologist , and appropriate management of the information in case of a finding (1,2). We recently addressed this issue in preparation for a newly funded longitudinal study designed to include imaging of 135 healthy pediatric control participants from the local community. Here we report the key elements of a policy we developed for the management of incidental findings on brain and spine MRI scans of healthy control research participants, and initial results of radiological review of research image data according to the new policy.

Methods

Policy development: Researchers, clinicians and hospital executives collaborated to develop the policy. The elements of the policy were considered within the context of our unique pediatric institution. Some issues deliberated for the policy included: requirement for a neuroradiologist to review all scans, defining categories of findings, and an opt-out choice for research participants who did not want to be informed of incidental findings. Two systems for defining categories were discussed: a clinical approach, with focus on etiology and medically specific information, versus an operational approach, which would specify outcome with nominal clinical information. The opt-out choice led to an important debate regarding the ethical dilemma of balancing the participant's right to refuse with the physician's sense of obligation to report medically significant findings, especially in a pediatric setting. A policy was drafted by the researchers and physicians involved in the study. The draft was circulated to the Institution's ethics committee, Executive legal team, and others for opinion and approval.

Initial application: To date, image data from 46 control participants have been reviewed according to the policy. This group includes 21 females and 25 males between 6 and 25 years old. Conventional imaging reviewed by the neuroradiologist included T1-weighted, T2-weighted, proton density-weighted, high-resolution T1-weighted, and FLAIR sequences acquired with a Seimens TRIO 3T scanner.

Results

Policy: The final policy requires: 1) general health screening of participant prior to enrollment, 2) neuroradiologist review of all scans, 3) neuroradiologist consensus on the characterization and categorization of a suspected incidental finding, 4) designation of a health care provider for follow-up care. The policy defines 3 categories of incidental findings: insignificant (e.g., subtle ventriculomegaly, meningeal calcifications), exclusionary (e.g., callosal abnormality, cortical dysplasia), and medically significant (e.g., neoplastic lesions, disseminated leukoencephalitis, vascular malformation). Insignificant findings require no disclosure of information to the study participant, do not impact eligibility, and do not require medical follow-up. Exclusionary findings require disclosure to the study participant, render the participant ineligible, but may not require medical follow-up. Medically significant findings require disclosure to the family, referral to the designated health care provider for follow-up, and render the participant ineligible for further participation. In lieu of an opt-out for notification of incidental findings, participants are considered ineligible to participate in the study if they refuse information about incidental findings or if they refuse to designate a health care provider for referral of medically significant finding. Similar language is required to be in all consent forms.

Application: The overall rate of incidental findings has been 44% (n=21). Insignificant findings (19 of 21) include sinusitis, pineal gland cyst, and enlarged perivascular spaces. One exclusionary finding was identified in a 7 year-old male participant who had an abnormal corpus callosum with no clinical symptoms. One medically significant finding was identified in a 10 year-old female participant who had a nonspecific T2 hyperintense left posterior medial thalamic lesion. The study participant's parents were informed and the information was well-received by the designated physician. Follow-up imaging results have not yet been reported to the research team.

Conclusion

We believe this policy effectively balances the interests of the research participants with the responsibilities and needs of the researcher in the management of incidental findings. It is our desire that sharing this experience will serve to further the discussion in the biomedical imaging community toward the ultimate goal of establishing a universal guideline.

Acknowledgments: Supported by NICHD (HD049888) and ALSAC

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