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Managing Incidental Findings: Lessons From Neuroimaging

Emily Borgelt , James A. Anderson & Judy Illes

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distribute the burdens of positive ethical duties (including the discovery and disclosure of beneficial genetic information) in a way that is just and effective.

The positive ethical duty to provide "high benefit" for today's research participants must be weighed against comparable ethical duties to non-research participants and (via the swifter attainment of generalizable knowledge) to future people who may not receive it because of "mission creep" in the institution of research. We can only balance these competing obligations well if we choose an ethical lens that allows us to see them in the first place. ■

REFERENCE

Gliwa, C., and B. E. Berkman. 2013. Do researchers have an obligation to actively look for genetic incidental findings? *American Journal of Bioethics* 13(2): 32–42.

Managing Incidental Findings: Lessons From Neuroimaging

Emily Borgelt, University of British Columbia and Stanford Center for Biomedical Ethics
James A. Anderson, University of British Columbia
Judy Illes, University of British Columbia

Gliwa and Berkman (2013) undertake a comprehensive analysis of the literature in genomics to assess the obligations of researchers to manage unexpected findings. Their focus on the genomics literature exclusively, however, overlooks a valuable source of guidance—the formidable body of work dedicated to neuroimaging research over the past decade. This is a lost opportunity: empirical research and working groups have promoted awareness and consensus, and have yielded institutional procedures for the handling of incidental findings in neuroimaging studies. While there is still room for improvement—from cost mitigation and streamlining to consideration of vulnerable populations—the field and literature have come a long way from the first major meeting on the issue in 2005 (National Institute of Neurological Disorders and Stroke [NINDS] 2005). No doubt, there are differences between genomics and neuroimaging research, but leveraging multidisciplinary expertise and insight enriches the conversation and facilitates the pursuit of best practices.

Neuroimaging research arguably has already met—or is at least much closer to meeting—the three criteria proposed by the authors to signify an obligation to review data for findings unrelated to the purpose of the study: (1) identification of an anomaly may provide serendipitous benefits to participants (Hilgenberg 2006); (2) for some, participantion in research may be the only means of access to a brain scan; and (3) the burden of reviewing scans in terms of both time and resource costs has come down using innovative, systematized approaches (Cramer et al. 2011; Shoemaker et al. 2012). We propose that there is value in a brief review of lessons learned from neuroimaging, therefore, that may inform the question about obligations now emerging in genomics research. We integrate into this three-part discussion our observations from a scan of the landscape of handling incidental findings specifically in the area of brain imaging research in mental health.

Prescribe, codify, standardize, disseminate. In the earliest debates on incidental findings, the focus was largely on the question of *whether* brain scans should be screened for anomalies and, if so, what the duty would be to return information to participants. Consensus at the time was that transparency about the possibility of an incidental finding was key but disclosure was not. This position was purposely flexible, giving researchers room to handle incidental findings in a way that was best suited to their program of research and institutional requirements, and avoiding unnecessary barriers to scientific progress.

Today, however, neuroimagers express concern about the lack of prescription, codification, standardization, and dissemination of guidance. While guidance exists from three of the neuro-related institutes at the National Institutes of Health (NIH), many researchers are not aware of their existence or location for reference. This is a prime opportunity for improvement, and genomics research faces a similar opportunity to engage in the development of standardized and accessible guidlines before an obligation to look for abnormalities actualizes.

Researchers need resources. Researchers should not be asked to review data for abnormalities unarmed or underresourced. In our discussions with neuroimagers, they called for more training and support materials related to identifying and handling incidental findings, and to communicating about findings both during the consent process and disclosure of a discovery. They underscored the

Address correspondence to Emily Borgelt, University of British Columbia, National Core for Neuroethics, UBC Hospital, Koerner Pavillion, 2211 Wesbrook Mall, Vancouver, British Columbia, V6T 2B5, Canada. E-mail: emily.borgelt@gmail.com

importance of the availability of financial resources through grant support for screening and interpretation as needed.

One size may not fit all. Different research populations and different findings may necessitate different considerations of risk, benefit, and the meaning of "incidental." This seems obvious but, to date, work on incidental findings in neuroimaging has focused nearly exclusively on healthy adult volunteers. Recent work has only begun to identify the variable needs of study populations, such as children and adolescents providing assent (Downie and Marshall 2007; Kumra et al. 2007), and indigenous populations providing community consent (Brief, Mackie, and Illes 2012). In mental health research, disclosure of an incidental finding might exacerbate the condition of study, such as an anxiety disorder. The first economic analysis of incidental findings suggested that, at least in the case of intracranial aneurysms, participant screening by age and gender is essential (Sadatsafavi et al. 2012). Taken together, these findings highlight the importance of nuanced consideration of incidental findings at all stages of the research design, implementation, and follow-up.

Consent communication is paramount. Return of information about an incidental finding in brain imaging research is an expectation found to be shared widely by participants irrespective of clinical actionability (Kirschen, Jaworska, and Illes 2006). While more research is needed to understand this phenomenon fully, the consent process is clearly a key mechanism for achieving this goal. However, in our own analyses and others' (Palmour et al. 2011), consent documents often lack key details about how incidental findings would be identified and returned. Furthermore, in consent documents we examined, mean Flesch–Kincaid reading scores typically registered just over a 12th-grade reading level. For these challenges, there are easy, inexpensive solutions: increasing the level of detail about disclosure procedures and providing supplementary communication resources such as FAQs (frequently asked questions) handouts or glossaries, alongside easier-to-read consent documents.

Gliwa and Berkman (2013) note that genomics research may not yet be at the point where researchers are obligated to look for incidental findings. It is possible that they may never be. However, at this early stage, there is a golden opportunity for the genomics field to take advantage of the lessons learned from neuroimaging and to apply them proactively. Continued challenges in both arenas underscore the need for ongoing refinement of the practice and ethics of handling incidental findings through all mechanisms. ■

REFERENCES

Brief, E., J. Mackie, and J. Illes. 2012. Incidental findings in genetic research: A vexing challenge for community consent. *Minnesota Journal of Law, Science and Technology* 13(2): 435–736.

Cramer, S. C., J. Wu, J. A. Hanson, et al. 2011. A system for addressing incidental findings in neuroimaging research. *Neuroimage* 55: 1020–1023.

Downie, J., and J. Marshall. 2007. Pediatric neuroimaging ethics. *Cambridge Quarterly of Healthcare Ethics* 16(2): 147–160.

Gliwa, C., and B. E. Berkman. 2013. Do researchers have an obligation to actively look for genetic incidental findings? *American Journal of Bioethics* 13(2): 32–42.

Hilgenberg, S. 2006. Transformation from medical student to patient. *Annals of Internal Medicine* 144(10): 779–780.

Kirschen, M. P., A. Jaworska, and J. Illes. 2006. Subjects' expectations in neuroimaging research. *Journal of Magnetic Resonance Imaging* 23: 205–209.

Kumra, S., M. Ashtari, B. Anderson, K. L. Cervellione, and L. Kan. 2007. Ethical and practical considerations in the management of incidental findings in pediatric MRI studies. *Journal of the American Academy of Child and Adolescent Psychiatry* 45(8): 1000–1006.

National Institute of Neurological Disorders and Stroke. 2005. Detection and disclosure of incidental findings in neurological research. Available at: http://www.ninds.nih.gov/news_and_events/proceedings/ifexecsummary.htm

Palmour, N., W. Affleck, E. Bell, et al. 2011. Informed consent for MRI and fMRI research: Analysis of a sample of Canadian consent documents. *BMC Medical Ethics* 12: 1. doi:10.1186/1472-6939-12-1

Sadatsafavi, M., C. Marra, D. Li, and J. Illes. 2010. An ounce of prevention is worth a pound of cure: A cost-effectiveness analysis of incidentally detected aneurysms in functional MRI research. *Value in Health* 13(6): 761–769.

Shoemaker, J. M., M. T. Holdsworth, C. Aine, et al. 2012. A practical approach to incidental findings in neuroimaging research. *Neurology* 79: 1298–1299.