

## ETHICS

# The Bioethics Commission on Incidental Findings

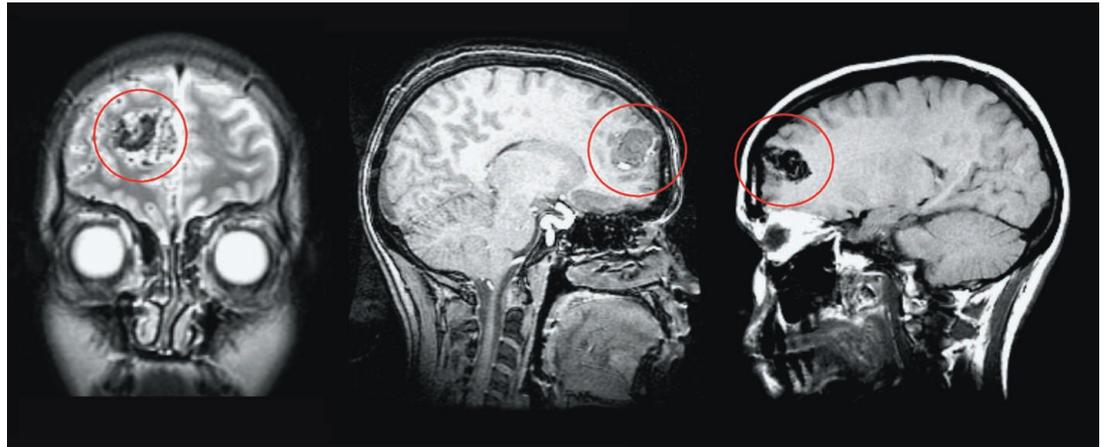
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Dr. Sarah Hilgenberg believes that participating in a research study saved her life, although she had no reason to believe this when she enrolled. While examining functional magnetic resonance images collected during a memory study, researchers found an arteriovenous malformation, an abnormal connection between arteries and veins in her brain (see the image). Sarah had the mass surgically removed, and she recovered (1). Consider also a hypothetical case in which a routine computerized

tomography angiogram turns up no clinically significant stroke warning signs but shows an unrelated nodule in the lung. During biopsy, the lung collapses, which leads to cardiac arrest and permanent anoxic brain injury. The nodule pathology report reveals benign inflammation.

Such discoveries—when physicians or researchers are looking for one thing and find something else—are known as incidental findings. Secondary findings raise related issues: They are not the primary target of testing, but (unlike incidental findings) they are actively sought. Improved technologies are making incidental and secondary findings increasingly common. They are becoming a growing certainty in clinical practice as well as in the distinct contexts of research and direct-to-consumer (DTC) testing.

A new report (2) by the U.S. Presidential Commission for the Study of Bioethical Issues offers specific recommendations across all three contexts and across a wide range of testing techniques (including large-scale genetic sequencing, testing of biological specimens, and imaging). These will help ensure that incidental and secondary findings are appropriately anticipated—so that



Functional magnetic resonance images showing an arteriovenous malformation in the brain of Sarah Hilgenberg (Reprinted by permission of S. Hilgenberg).

patients, research participants, and consumers are informed ahead of time about what to expect (including the unexpected)—and aptly communicated after they are found. When dealing with incidental findings, the commission's advice is to anticipate and communicate.

## Unsettled Issues, Conflicting Advice

It would be rash—both ethically and practically speaking—to conclude that everything that can be sought should be sought, and reported, in all contexts. Results that are outside the original purpose for which a test or procedure is conducted might or might not possess important actionable implications for health and well-being. In some instances, incidental findings point to medical conditions for which there is currently no available treatment or might lead patients and their doctors to treat a condition that would be better left alone. Because there is no simple answer to the question of how best to manage incidental health information, there is much conflicting advice about whether to seek, and how to manage, incidental and secondary findings.

Recent reports from other federal advisory groups show how unsettled the issue is. One report recommended early cancer screening for heavy smokers (3). Another suggested that early scans could cause more harm than good by detecting too many prob-

lems (4); their argument is that overdetection leads to overtreatment, arguably making the treatment worse than the potential disease.

Incidental findings, whether or not anticipatable, give rise to a wide range of practical and ethical challenges for recipients and practitioners. Clinicians might discover misattributed paternity when assessing a living organ donor and potential recipient who believe they are biologically related. This is anticipatable because it is known to be a possible finding associated with the procedure. An unanticipatable incidental finding could occur when a DTC genetic testing company identifies a health risk based on a newly discovered genetic association that was not knowable at the time the sample initially was submitted. The commission's report examines both kinds of situations because they call for distinct actions before and after an incidental discovery.

The context in which incidental findings occur makes a considerable difference in how they can and should be handled. Clinicians have a primary fiduciary duty to their patients to act in their interests. Research investigators have more limited duties to research participants. Obligations of DTC providers toward consumers, beyond honest dealings, are most uncertain and in flux. Even within one of these contexts, not all individuals will have the same preferences

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with respect to disclosure, and that too makes an important difference in how incidental findings should be handled.

### Communication and Shared Decisions

The presidential bioethics commission concluded that some ethical mandates span all three contexts. The commission's first recommendation is that all practitioners—clinicians, researchers, and DTC companies—should anticipate findings and describe (wherever feasible) what incidental findings are likely to arise from the tests and procedures before they are conducted. Practitioners should inform individuals about their plan for disclosing and managing incidental and secondary findings, specifying what findings will and will not be returned.

To improve the ability to anticipate findings across all contexts, another recommendation is that federal agencies and other interested parties continue to fund research that keeps abreast of the rapidly evolving nature and frequency of findings from various modalities, along with the potential costs, benefits, and harms of identifying, disclosing, and managing the full range of possible findings. A third recommendation is to enhance the education of all stakeholders, including practitioners, institutional review boards, and potential recipients on this increasingly important issue.

In addition, the commission emphasizes the need—based on justice and fairness—not just for a privileged few but for all individuals to have access to up-to-date information and the guidance needed to make informed choices about what tests to undergo, what kind of information to seek, and what to do with information once received. Equity (along with regulatory parsimony, which supports efficiency) is far better served by increasing access to health care information and guidance for everyone rather than by restricting access.

As expert practitioners look for more findings when using techniques such as large-scale genetic sequencing, and as guidelines develop with suggestions for how these findings should be managed, some anticipatable incidental findings will become secondary findings (actively sought, although not the primary reason for undertaking the technique). Rounding out recommendations that cross all three contexts, the commission recommends that professional groups develop guidelines that are tailored to each common procedure or test to inform practitioners about the anticipatable incidental findings likely to arise. The commission drew upon the work of many scholars, professional

groups, and others who addressed incidental and secondary findings in a variety of contexts, including 16 U.S. professional societies and working groups, and 16 international professional societies and working groups. For example, the American College of Medical Genetics and Genomics (ACMG) released recommendations earlier this year (5) regarding incidental and secondary findings that arise in one specific context—the clinic—and with one modality—large-scale genetic testing.

The commission and the ACMG both emphasize the importance of informed consent of patients and open communication between providers and patients. In addition, both the commission and the ACMG emphasize the need for better data regarding incidental and secondary findings, and both recognize the evolving nature of developing guidance as science and technology advance.

Notably, the ACMG recognized that genetic variants of unknown significance, or associated diseases that are not amenable to treatment, should not be reported to patients. As the commission explains, clinicians owe a duty of beneficence to their patients, which can include avoiding causing distress without any corresponding benefit. The ACMG also has embarked on what the commission recommends: contributing its professional expertise to determining which genetic variants are clinically significant and actionable and making a list of those secondary findings.

On one point, the commission offers a different path. The ACMG recommended and later clarified that “patients cannot opt out of the laboratory’s reporting of incidental findings to the ordering clinician” (6). The commission recommends that clinicians engage in shared decision-making with patients before testing about the scope of findings that will be sought and communicated and further steps to be taken. Shared decision-making is a process by which clinicians and patients engage in a dialogue to arrive at pathways forward that reflect the best interests of the patient. Clinicians, the commission recommends, should respect a patient’s preference not to actively seek or know about incidental or secondary findings to the extent consistent with their fiduciary duty to do no harm.

There are multiple points at which a clinician’s ability to communicate effectively about incidental and secondary findings is important. Before testing, clinicians should alert patients to the possibility of discovering incidental findings, as well as any sec-

ondary findings that will be actively sought, so that patients have the opportunity to express their preferences about disclosure and subsequent management. Many patients will want their practitioner to tell them about any information discovered. Others might not want to learn about incidental or secondary findings.

A patient who does not wish to learn about information related to the primary purpose of the test should not undergo the test. If a patient wishes to opt out of receiving incidental or secondary findings that are clinically significant and actionable, then clinicians should exercise their discretion regarding whether to proceed with testing. Clinicians should explain the potential benefits of receiving such information about clinically actionable findings. Clinicians should also respect the informed preferences of patients, which can vary due to life circumstances and perspectives.

Consider this hypothetical example, reflecting one among several possible ethical outcomes of shared decision-making. For years, a nonagenarian patient has undergone many rounds of treatment for multiple cancers now thought to be in remission. After close consultation with her doctors, as well as just before her doctors prescribe a body scan after an accidental fall, she tells them that she does not want to know about incidental, possibly cancerous, masses on a scan conducted for other purposes. She feels strongly that she has undergone enough biopsies and other cancer treatments. Her doctors, who would decide differently on their own, fully respect her decision.

Within certain limitations, if clinicians feel uncomfortable with patients’ decisions not to receive such findings, they may on ethical grounds decline to perform the test and elect to refer the patient elsewhere. If they understand and respect their patients’ decision, they may ethically agree to perform the test but not return incidental or secondary findings. To help ensure an ethically defensible outcome, they need to take time to proactively confer with their patients.

Once clinicians discover and disclose incidental and secondary findings, they also must communicate with patients about various options for further pursuit of the finding. Clinicians should clearly convey to patients the possible outcomes of investigating an incidental finding, the possibility of discovering additional incidental findings, and the potential benefits and risks of either pursuing or not pursuing the finding. Payment systems should not discourage clinicians from taking sufficient time to fully communicate

to each patient this necessary information.

Clinicians are ethically free to filter incidental findings that have so little clinical significance that they would not actively seek them as secondary findings. Here, too, in keeping with shared decision-making, clinicians live up to their highest calling when they discuss how they will handle incidental findings with their patients.

### References and Notes

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3. U.S. Preventive Services Task Force Screening for Lung Cancer, Draft Recommendation Statement (AHRQ Publication No. 13-05196-EF-3, USPSTF, Rockville, MD, 2013); [www.uspreventiveservicestaskforce.org/uspstf13/lungcan/lungcandraftrec.htm](http://www.uspreventiveservicestaskforce.org/uspstf13/lungcan/lungcandraftrec.htm).
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5. R. C. Green *et al.*, *Genet. Med.* **15**, 565 (2013).
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