Bioethics Commission on incidental findings: Anticipate and communicate

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Researchers conduct a memory study, scan a participant's brain, and find more than they bargain for: a tumor. What do the researchers owe the participant? What does the participant want to know? This is an increasingly common scenario for practitioners across contexts and for recipients of unexpected results that can be discovered through a variety of procedures and tests. Today the Presidential Commission for the Study of Bioethical Issues (Bioethics Commission) offered analysis and guidance on this issue and released its report Anticipate and Communicate: Ethical Management of Incidental and Secondary Findings in the Clinical, Research, and Direct-to-Consumer Contexts.

"How clinicians, researchers and direct-to-consumer companies manage incidental and secondary findings will likely touch all of us who seek medical care, participate in research, or send a cheek swab to a company for a peek at our own genetic make-up," said Amy Gutmann, Ph.D., Commission Chair. "The reality is that we might find out more than we bargained for. Yet practitioners are getting conflicting advice about how to manage such findings across contexts and modalities such as genetics, imaging, and biological specimen testing. We all need to know how to better manage health information we did not expect."

Incidental findings – whether or not we can anticipate them – give rise to a wide range of practical and ethical challenges for recipients and practitioners. Emerging medical technologies, changing cost structures, and evolving medical practice have increased remarkably the likelihood of discovering incidental findings in the clinic, research, and commercial

direct-to-consumer contexts. Such findings can be lifesaving, but also can lead to uncertainty and distress if they are unexpected or identify conditions for which no effective treatment is available.

"For every setting and type of test or procedure, when it comes to incidental findings, the Bioethics Commission recommends anticipating and communicating," Gutmann said. "All practitioners should anticipate and plan for incidental findings so that patients, research participants, and consumers are informed ahead of time about what to expect and so that incidental findings are aptly communicated if they are found. The best way forward is shared decision-making between practitioners and potential recipients."

Incidental findings typically include findings that lie outside the aim of a test or procedure. However, sensitive and unexpected results in the direct-to-consumer context merit many of the same ethical considerations. Secondary findings raise related issues: these discoveries are also not the primary target of the testing but, unlike incidental findings, they are actively sought.

Currently, there are no consistent guidelines for how we best manage these discoveries. Recent reports show how unsettled the issue of incidental findings is: for example, one report recommended scans for early cancer screening; another report, released the next month, suggested early scans can cause more harm than good by detecting too many problems, thus leading to overtreatment.

"More information is not always better. Incidental findings might, but do not always, have important, actionable implications for our health and emotional as well as physical wellbeing. 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," Gutmann said.

Recommendations:

The Bioethics Commission offered specific recommendations for handling incidental and secondary findings in clinical, research and direct-to-consumer settings. There are, however, some ethical principles and duties that span all three contexts for which the Bioethics Commission made five broad recommendations.

- Practitioners should inform potential recipients, in any setting, about the possibility of incidental or secondary findings, and if and how those findings will be disclosed, before the start of a test or procedure. Informed consent and open communication between providers and potential recipients is essential.
- Professional representative groups should develop guidelines that categorize findings likely to arise from each diagnostic modality, and develop best practices for managing them.
- Federal agencies and other interested parties should fund research to keep abreast of the rapidly evolving types and frequency of findings; potential costs, benefits, and harms; and recipient and practitioner preferences about incidental and secondary findings.
- Public and private entities should prepare materials and enhance education of all stakeholders, including practitioners, institutional review boards, and potential recipients about the ethical, practical, and legal considerations raised by incidental and secondary findings.
- There is a need – based on justice and fairness – not just for a privileged few but for all individuals to have access to 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. Affordable access to care and quality information about incidental and secondary findings, before and after testing, can be potentially

lifesaving.

Anticipate and Communicate is the Bioethics Commission's sixth major report. The Bioethics Commission seeks to identify and promote policies and practices that ensure that scientific research, health care delivery, and technological innovation are conducted by the U.S. in a socially and ethically responsible manner. The Bioethics Commission is an independent, deliberative panel of thoughtful experts that advises the President and the Administration, and, in so doing, educates the nation on bioethical issues. To date the Bioethics Commission has:

- Advised the White House on the benefits and risks of synthetic biology;
- Completed an independent historical overview and ethical analysis of the U.S. Public Health Service STD experiments in Guatemala in the 1940s;
- Assessed the rules that currently protect human participants in research;
- Examined the pressing privacy concerns raised by the emergence and increasing use of whole genome sequencing;
- And conducted a thorough review of the ethical considerations of conducting clinical trials of medical countermeasures with children, including the ethical considerations involved in conducting a pre-and post-event study of anthrax vaccine adsorbed for post-exposure prophylaxis with children.

More information: bioethics.gov/node/3183

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