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Medics should plan ahead for incidental findings

US bioethics commission weighs in on debate over how scientists and companies should handle inadvertent discoveries in diagnostic tests.

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Doctors, researchers and companies should expect to find information they were not looking for in genetic analyses, imaging scans and other tests, concludes a report from the US Presidential Commission for the Study of Bioethical Issues. Moreover, medics and investigators should discuss with patients and research volunteers how these potentially serious findings will be handled before the tests are carried out.

The advice given by the report echoes previous recommendations in specific fields. Still, researchers say it is a useful summary of basic overarching principles for grappling with 'incidental findings' that occur when a test ordered for one purpose uncovers information about another, unrelated health risk.

“They get to the heart of what needs to be done, and there is a need to codify this,” says James Evans, a geneticist at the University of North Carolina in Chapel Hill, of the panel's recommendations.

Although incidental findings have always occurred in medicine and research, the rise of more omniscient tests that can reveal large amounts of information about a person’s risk factors have posed urgent ethical questions about how to deal with such data.

Amy Gutmann, who leads the presidential commission, says new technology and other factors “make the likelihood of discovering incidental findings in the clinic, in research and in the commercial direct-to-consumer context a growing certainty”.

“This is an issue that affects everybody,” adds Gutmann, who is also president of the University of Pennsylvania in Philadelphia.

Looking for trouble

Guidelines issued by the American College of Medical Genetics and Genomics (ACMG) in March recommended that doctors who order genetic sequencing for their patients for any reason should also specifically look for unrelated mutations in dozens of named genes, and should tell patients about medical risks associated with these genes.

The new report endorses the idea of professional societies developing such guidance, but also says that patients should not have to learn of incidental findings if they do not want to — an important point for those bioethicists who disagreed with the ACMG’s recommendation that doctors could override patient consent in some circumstances.

“It is absolutely critical that they endorsed the notion that patients and research participants have a far-reaching right to choose not to get results,” said Ellen Wright Clayton, a paediatrician and lawyer at the Center for Biomedical Ethics and Society at Vanderbilt University in Nashville, Tennessee.

The report also says that researchers do not have a duty to seek out health-related findings in people who enrol in their research studies, because that could prove too costly and because researchers may not be adequately trained to find and interpret such results. Yet the analysis concludes that researchers should plan for how they will handle incidental findings — both those that can be anticipated and those that are unexpected — that do arise.

And it advises federal agencies to “continue to evaluate regulatory oversight” of direct-to-consumer testing companies, seemingly supporting actions such as that taken last month by the US Food and Drug Administration, which sent a warning letter to genetic-testing company 23andMe in Mountain View, California. The agency said that 23andMe has not provided information showing that its service is safe and effective.

Missed opportunity

But by attempting to provide advice for such a wide range of settings, the presidential commission may have missed an opportunity to

provide more detailed and helpful guidance, says ethicist Alex John London at Carnegie Mellon University in Pittsburgh, Pennsylvania. “Although there are many valuable recommendations in the report, it is not clear to me that such a highly general treatment will significantly advance the state of the debate,” he says.

For instance, the report says that researchers may exclude research participants who don’t want to receive incidental findings from their studies, but also that there may be circumstances in which they should override a research participant’s preference not to receive such findings.

“If there are cases where the researcher’s duty to look after the welfare of participants is so strong that it overrides the participant’s decision not to learn about incidental findings, then what we need are policies that provide some guidance about how to identify such cases and then to disclose such policies to participants before testing,” London says.

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