Medical Xpress

Returning genetic incidental findings without patient consent violates basic rights, experts say

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Informed consent is the backbone of patient care. Genetic testing has long required patient consent and patients have had a "right not to know" the results. However, as 21st century medicine now begins to use the tools of genome sequencing, an enormous debate has erupted over whether patients' rights will continue in an era of medical genomics.

Recent recommendations from the American College of Medical Genetics and Genomics (ACMG) suggest no. On March 22, the ACMG released recommendations stating that when clinical sequencing is undertaken for any medical reason, laboratories must examine 57 other specific genes to look for incidental findings. These findings must then be reported to the clinician and the patient. In an April 25 "clarification," ACMG said that failure to report these findings would be considered "unethical." The patient has no opportunity to opt-out of the testing of the 57 genes, except to decline all sequencing. The recommendations also apply to children.

In a paper to be published in *Science* May 16 online ahead of print, authors Susan M. Wolf, J.D. (University of Minnesota), George J. Annas, J.D., M.P.H. (Boston University), and Sherman Elias, M.D. (Northwestern University) push back against these recommendations, and offer compelling reasons why patient autonomy must remain firmly in place as science advances. Their article on Patient Autonomy and Incidental Findings in Clinical Genomics urges ACMG to reconsider

their recommendations. This article is published with a reply by Amy McGuire, J.D., Ph.D. (Baylor College of Medicine) and colleagues.

Wolf, Annas, and Elias argue that, "The ACMG's 'minimum list [of 57 genes]' includes mutations in genes that patients have long been able to refuse testing for, including cancer risk mutations (such as BRCA1) and cardiovascular risk mutations." They point out that "There are many circumstances in which a patient may decline such testing and information, even if the results could open avenues for intervention. The patient may already be battling another disease, such as advanced cancer, or be late in life and see more burden than benefit in added genetic information. The patient may also fear that 'extra' results in their medical record will invite risk of discrimination."

ACMG says that applying these recommendations to children may help adult family members understand their own health risks. However, Wolf et al. point out that "this is exactly what past recommendations have rightly rejected, in limiting genetic testing and disclosure of genetic information to what is medically necessary during childhood." The authors cite long-standing policy discouraging childhood testing for adult-onset conditions. "Delaying testing and return of genetic information not medically useful in childhood allows the child to reach adulthood and then make a choice based on his or her own values."

The ACMG indicates that their list of genes to test without consent will grow. Their report says that laboratories may look for variants in other genes, "as deemed appropriate," and that ACMG will review the roster of 57 genes annually. Wolf et al. voice concern that "As the list expands, so will the scope of testing without consent…." The authors urge the importance of patients' rights, especially in an era of genome sequencing when extensive genetic information can be generated on any patient.

More information: "Patient Autonomy and Incidental Findings in

Clinical Genomics," by S.M. Wolf, *Science*, 2013.