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Translating Next-Generation Medical Tests: Ethical and Governance Challenges Raised by Medical Software

Scientists and policy makers are vigorously debating the nature of a governance framework that will enable precision medicine (also known as "personalized medicine") to become a reality. "–Omic" sciences are considered crucial to realizing the promise of precision medicine, and many commentators are considering how to promote diffusion of –omic tests into widespread clinical use. Scholars have vigorously discussed the degree of clinical validity and clinical utility new -omic tests should demonstrate before test developers or professional societies recommend their clinical use (outside of research protocols), or before insurers pay for them. But experts interested in governance have paid much less attention to questions concerning the analytical and computational components of –omic tests and other precision medicine innovations.

As scientists have gained access to greater computing power at lower prices, more data storage, more databases (including electronic health records), and much larger datasets, new analytical approaches have arisen. Analysis and reporting of –omics test results relies on suites of algorithms, reference data sets, and tens of thousands of lines of computer code. Machine learning algorithms are currently at the cutting edge of health data analysis. These algorithms generate computational models that diagnose disease, or models designed to predict a person's risk of developing future disease, her prognosis, or her likelihood of responding to particular therapies. Machine learning algorithms, rather than their human programmers, generate the diagnostic or predictive models, and such models may take account of features in the data that are not apparent to human perceptions. Sometimes, human programmers cannot ascertain which elements within a dataset a model uses to make its predictions or diagnoses.

The complexity, malleability, and sometime opacity of the analytical processes and software being incorporated into new medical tests raises numerous ethical and governance challenges. Inaccurate testing can result in failures to treat patients, or in treating them inappropriately, either of which could be debilitating or life threatening in some circumstances. In late December of 2014, one of the few FDA-approved medical devices to use next generation DNA sequencing – the Illumina MiSeqDx Cystic Fibrosis Clinical Sequencing Assay – was recalled because a problem with its software prevented the assay system from reporting certain pathological genotypes (FDA recall #Z-0850-2015, Recall Event ID #69715). This paper will identify some of the ethical and governance challenges raised by next generation medical software, will examine whether the FDA's current governance tools (medical device regulations and guidance documents) are sufficient, and will suggest possible modifications and additions to the FDA's current governance approach.