Issues affecting adoption of personalized medicine

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ABSTRACT

Personalized medicine offers a new paradigm for the development of drugs and the practice of medicine. While the potential benefits of personalized medicine include development of drugs that are safer and more effective for specific disease populations, such benefits cannot be realized until certain obstacles to adoption are removed. Obstacles in public policy include uncertain regulatory requirements, insufficient insurance reimbursement for diagnostic tests linked to pre-emptive care, incomplete legal protections to prevent genetic discrimination, the lack of a comprehensive healthcare information technology system, and a medical education system that has not taught physicians how to incorporate personalized medicine diagnostics or pharmacogenomics into their practices. A supportive public policy environment would address each of these issues, and provide incentives to reinforce emerging business models that accelerate the co-development of drugs and diagnostic tests. Understanding all of these key factors – from obstacles to incentives – is a necessary step in determining how to apply resources to influence the direction of personalized medicine and its progress. In the absence of uniform federal regulations around genetics privacy and discrimination, many states have established their own regulations, resulting in an uneven landscape of protection, which works against the adoption of personalized medicine. Physicians and other healthcare providers will have to administer or advise on the application of a growing number of molecular and genetic tests and pharmacogenomic drugs, make treatment decisions based on more predictive evidence and estimations of risk, utilize information systems for managing patient care, and deal with new ethical and legal issues that arise from molecular and genetic testing. Medical education curricula have generally not incorporated personalized medicine concepts. Only a few comprehensive genomic education programs exist worldwide. Despite all pioneering efforts, the current availability of genetics training for physicians does not meet the anticipated need and the current educational infrastructure would have to be updated in order to facilitate adoption of personalized medicine. Nonphysician specialists, including nurses, pharmacists, and genetic counselors may also require updated educational and certification programs in genetics and personalized medicine.

Key words: genetic discrimination, personalized medicine, privacy & regulations.