

REPORT 4 OF THE COUNCIL ON SCIENCE AND PUBLIC HEALTH (A-10)
Genomic-based Personalized Medicine
(Reference Committee E)

EXECUTIVE SUMMARY

Objectives. The term “personalized medicine” (PM) refers to health care that is informed by each person’s unique clinical, genetic, and environmental information. Clinical integration of PM technologies is enabling health care providers to more easily detect individual differences in susceptibility to particular diseases or in response to specific treatments, then tailor preventive and therapeutic interventions to maximize benefit and minimize harm. This report will review current status of genomic-based PM and challenges to implementing it, and will briefly summarize the activities of key federal agencies, professional organizations, coalitions, and health systems that are working to further the integration of genomic-based technologies into routine care.

Data Sources. Literature searches were conducted in the PubMed database for English-language articles published between 2005 and 2010 using the search terms “personalized medicine” and “personalized medicine AND clinic.” To capture reports that may not have been indexed on PubMed, a Google search was also conducted using the search term “personalized medicine.” Additional articles were identified by review of the literature citations in articles and identified from the PubMed and Google searches.

Results. Genetic testing has been a routine part of clinical care for a number of years in screening and diagnosis. Recently, a number of genomic-based applications have advanced beyond these screening and diagnostic techniques and are “personalizing” the delivery of care by enabling risk prediction, therapy, and prognosis that is tailored to individual patients. Yet there are challenges to the clinical implementation of PM, such as the lack of genetics knowledge among health care providers, slow generation of clinical validity and utility evidence, a fragmentary oversight and regulatory system, and lack of insurance coverage of PM technologies. A number of programs and activities at both the federal and private levels are focused on overcoming the challenges and facilitating appropriate clinical implementation of PM by conducting research, providing education and resources, and evaluating the quality of genomic applications.

Conclusions. PM promises to enable the tailoring of treatments and preventions for individual patients. In order to maximize the benefit of PM technologies for patient care, several barriers need to be addressed. Most importantly, the health care workforce must become educated about the clinical use of genetic technologies. Also, better systems of oversight and regulation must be implemented, an exploration of the type of evidence that is sufficient to demonstrate clinical validity and utility should be undertaken, and coverage of clinically useful PM applications should be considered by insurers. Our American Medical Association (AMA) recognizes the importance of genomic-based PM in the delivery of care and will continue to develop educational resources and point-of-care tools to assist in its clinical implementation. Our AMA also will continue to represent physicians’ voices and interests in national policy discussions of issues pertaining to the clinical implementation of genomic-based PM.

RECOMMENDATIONS

The Council on Science and Public Health recommends that the following statements be adopted and the remainder of this report be filed:

1. That our American Medical Association reaffirm Directives D-460.976, “Genomic and Molecular-based Personalized Health Care,” and D-480.987, “Direct-to-Consumer Marketing and Availability of Genetic Testing.” (Reaffirm HOD Policy)
2. That our AMA acknowledge the increasingly important role of genomic-based personalized medicine applications in the delivery of care, and will continue to assist in informing physicians about relevant personalized medicine issues. (New HOD Policy)
3. That our AMA continue to develop educational resources and point-of-care tools to assist in the clinical implementation of genomic-based personalized medicine applications, and will continue to explore external collaborations and additional funding sources for such projects. (Directive to Take Action)
4. That our AMA continue to represent physicians’ voices and interests in national policy discussions of issues pertaining to the clinical implementation of genomic-based personalized medicine, such as genetic test regulation, clinical validity and utility evidence development, insurance coverage of genetic services, direct-to-consumer genetic testing, and privacy of genetic information. (New HOD Policy)