



Secretary's Advisory Committee on
Genetics, Health, and Society
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March 26, 2009

Harold Sox, M.D.
The Committee on Comparative Effectiveness Research Priorities
Institute of Medicine
500 Fifth Street, N.W.
Washington, DC 20001

Dear Dr. Sox:

I am writing on behalf of the Secretary's Advisory Committee on Genetics, Health, and Society (SACGHS) to suggest that your Committee identify genetic/genomic tests as a high priority for comparative effectiveness research.

Genomic tests are expected to become increasingly prevalent in the coming years. The hope is that these tests will enable early diagnosis of common diseases and guide preventive measures tailored to each individual's genotype. Similarly, pharmacogenomics tests are expected to enable more tailored treatment. Given the promise and potential value of genomic tests in reducing the burden of common diseases, these tests warrant careful study to assess their clinical utility.

Only a few systematic reviews have been conducted to date on the effectiveness of widely applicable genomic tests. Much of this work has been carried out by the Centers for Disease Control and Prevention's Evaluation of Genomic Applications in Practice and Prevention (EGAPP) working group. EGAPP has produced studies on tests designed to guide screening, drug dosing, and cancer treatment. It is currently working on a report on genomic profiling for cardiovascular disease. While EGAPP efforts are important, the working group does not have sufficient resources to keep pace with new and anticipated genomic tests. Thus, other government resources are needed to support the primary studies of these tests and disseminate their results.

Like genomic information, family health history can provide clues to a patient's inherited risk for common diseases. This test is already commonly used in clinical care but, for the most part, providers lack evidence-based guidance on how to use the information in clinical decision-making. Comparative effectiveness studies of family health history would provide needed guidance on how to incorporate this low-cost clinical tool into health care practice.

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SACGHS has made recommendations to the Secretary of Health and Human Services about the need for the establishment and support of a program to conduct studies on the clinical utility of genomic tests. In our view, such assessments are key to the successful translation of genomic discoveries into clinically useful tests. SACGHS reports and recommendations are available at http://oba.od.nih.gov/SACGHS/sacghs_documents.html

Thank you for your consideration and our best wishes to your Committee in carrying out your important task.

Sincerely,

A handwritten signature in black ink, appearing to read "Steven Teutsch". The signature is written in a cursive, flowing style.

Steven Teutsch, M.D., M.P.H.
SACGHS Chair