



Workshop # 2: Securing the evidence of clinical utility for genetic testing

Objectives for Workshop # 2: December 3-5, 2008

The Report from Workshop #1, October 29-31, 2007, concludes as follows:

“The evolution of the U.S. health care system tells us that change, if at all, arrives slowly and fitfully. But all systemic change is precipitated by recognition of a problem: a practice, a program or a process that can be better done. Two years ago, maybe as little as one year ago, the problem we addressed at the Workshop [emphasis added] might not have been conceived as a problem. Now it is. The Workshop was obviously only a first step toward finding answers; in fact, its purpose was more to get the questions right... Much more work lies ahead. Plans are now being formulated for another Workshop with an agenda designed to start where this first Workshop ended”.

Our Objectives for Workshop# 1:

Our Objectives for Workshop # 1 focused on identification and assessment of the perspectives of key health care system stakeholders as to why, and then how, to determine the clinical utility of genetic tests (out of the larger category of molecular diagnostics). The Report summarized those perspectives for six key stakeholder groups: clinicians, payers, researchers, developers and manufacturers, public agencies, and consumers. More specifically, our objective was to sufficiently explicate the relative positions of the stakeholders in order to identify the next steps to undertake to establish clinical utility. That goal was achieved: a number of such steps were identified. Now, building on this work, the challenge for this next Workshop is to undertake a more detailed analysis of these key steps: what “tools” are available; who could or should do what; how the work should be done, and, finally, how the work will be financed.

Our Objectives for Workshop # 2:

Though there are a number of challenges associated with the integration of genetic testing into health care, no issue is more pivotal than clinical utility, primarily because demonstrating the clinical utility of a test is a necessary pre-condition to its comprehensive translation into medical care practice, and concomitantly, its reimbursement. Our overall objective for this next Workshop then is to seek consensus on appropriate levels and types of evidence to establish clinical utility (which may vary with the nature and proposed use of a test), how we will go about collecting evidence for it, viz., public/private partnerships, and what analytic tools, such as decision modeling or risk-benefit analysis, should be used to establish it. We will also address the means by which such testing can be added to the clinical armamentarium of providers to enhance medical practice and improve patient outcomes.