INSTITUTE OF MEDICINE
OF THE NATIONAL ACADEMIES

Board on Health Sciences Policy
Roundtable on Translating Genomic-Based Research for Health

Evidence Generation for Genomic Diagnostic Test Development: A Workshop

November 17, 2010
The Keck Center of the National Academies

Strategies for Moving Forward

EVIDENCE

- The FDA is our friend – safety & efficacy requirements lower than payer requirement of health outcomes evidence
- Close the gap between FDA & payers evidence requirements
- Analysis of cost-effectiveness of “analytic framework” process vs single good trial
- Must define adequate, not perfect, evidence that gets us to 85% ”B grade” certainty

Strategies for Moving Forward

REIMBURSEMENT & COVERAGE

- Discuss new economic models (reimbursement) that value tests which prevent therapy when not useful
- Implement system that does not pay for treatment if not supported by prognostic/predictive test

Strategies for Moving Forward

MEDICAL PRACTICE

- Determine if safety & efficacy is enough for clinical use of new genomic tests, in the context of medical practice
- Medical process ignores EBR recommendations because they can; no checks on medical practice; perception that EBR groups don't understand the biological variability of individual patients in clinical practice

Strategies for Moving Forward

CLINICALLY-FOCUSED RESEARCH

- Need a patient-centric research system to focus test research on clinically important questions
- Develop a cooperative arena for identifying the top 10 clinically important questions & resources/ mechanisms to collaboratively generate the evidence, ie GAPPNet
- Engage journal editors to only publish only test validation studies that meet quality study design criteria and regardless of whether result is positive or negative

Strategies for Moving Forward

ACCESS TO CLINICAL TRIAL SPECIMENS/DATA

- Establish single index of annotated clinical trial specimens and closed health systems available for genomic test development projects, being done through GAPPNet
- Extend NIDDK requirement for biobanked specimens from RCTs to all NIH institutes for future studies
- Further develop ClinicalTrials.gov to be more complete in listings and data included, for RCTs in process and RCTs with negative outcomes

Strategies for Moving Forward

ACADEMIA

- Engage AMC leadership to reassess and change the academic promotion & reward systems to value clinically valuable research outcomes and team work rather than grants and publications
- Develop a link between the academic R&D segments and the healthcare teams at AMCs to improve the health of patients in their system
- Need training system for investigators to teach them test development study design options and optimization

Strategies for Moving Forward

OUT OF THE BOX

- Develop models of data sharing for genomic tests; eg GAPPNet, Canadian drug development model
- Large groups of people to come together to analyze the available data to answer a clinical question
- Public education on evidence for clinical tests & practice

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