Personalized Medicine: Perspectives on the New Science of Genetic Testing and Molecular Diagnostics

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Accelerating ease and lower cost of human genome sequencing, SNP genotyping and DNA analysis via microarrays

Explosive growth in correlation analysis in molecular medicine

Increased appreciation of: HTE (heterogeneity of treatment effects) in traditional RCTs and throughout EBM; gene/environment interactions;

Other disciples connecting to molecular medicine: Bioinformatics, Computational Biology, POC Diagnostics, Wireless Medicine

Clinical Applications are emerging, notably in Oncology, Transplant, Pharmacogenomics

DATA DUMP
The number of gene-expression data sets in publicly available databases has climbed to nearly one million over the past decade.

Source: NATURE | VOL 487 | 19 JULY 2012
The Increasing Complexity of the Central Dogma of Molecular Biology

Current Environment

- Estimates suggest that there are between 1,000 to 1,300 genetic tests currently available.
- Currently genetic testing is thought to be available for about 2,500 conditions, both rare and common.
- Genetic tests have the potential to benefit more than 60 percent of the population.

  » According to one estimate, clinical laboratory tests influence about 70 percent of health care decisions.

Key question: where are we in the eyes of consumers, physicians and other stakeholders, including payers?

Sources:
3) AdvaMed, “Harnessing Advanced Diagnostics Technology for Early Diagnosis and Prevention.”
New national survey on consumers’ perceptions of genetic testing

Finding: Consumers are cautiously optimistic about the promise these tests hold for the future of medicine

Consumers are optimistic

Three-quarters of American consumers believe that genetic testing:

1) helps doctors diagnose preventable conditions
2) offer more personalized treatment options

Consumers believe use of tests will increase in the next five years, but do not expect to get tests themselves

74 percent of American consumers believe that use of genetic testing in the U.S. will increase

80 percent of American consumers believe that the number of different kinds of genetic testing available will increase

Only 4 percent of respondents expect to get a test in the next five years

Sources:
1) UnitedHealth Center for Health Reform & Modernization/Harris Interactive survey of consumers, January 2012.
New national survey on physicians’ perceptions of genetic testing

Finding: Physicians are also cautiously optimistic about the promise these tests hold for the future of medicine

Physicians believe tests could be helpful

- Three-quarters of physicians say there are patients who have not yet had a genetic test but who would benefit from having one

However, physicians are concerned about cost to patients and to the health care system

- Approximately 60 percent of physicians are concerned about the cost of genetic tests to their patients
- 56 percent of physicians believe genetic testing will increase health care costs in the future

Physicians cite numerous barriers to incorporating genetic testing into their practice

- Cost of Tests / Reimbursement
- Lack of familiarity with tests
- Questions about the validity of tests
- Lack of evidence of test effectiveness / utility
- Less or not relevant to practice
- Questions about patient ability to understand results

Sources:
1) UnitedHealth Center for Health Reform & Modernization/Harris Interactive survey of physicians, January 2012
Between 2008 and 2010, average annual spending increased 14 percent

Per person spending on genetic testing for UnitedHealthcare’s Medicare and Medicaid members was higher than for UnitedHealthcare’s employer-sponsored and individually insured population by 16 percent and 24 percent, respectively

Finding: UnitedHealthcare data and claims suggest the cost of genetic testing for members was about $500 million in 2010
Estimated number of test procedures per 1,000 UnitedHealthcare members, 2010

Sources:
1) UnitedHealth Center for Health Reform & Modernization, 2012
Estimated U.S. spending by payer on molecular diagnostics and genetic testing, 2010

Sources:
1) UnitedHealth Center for Health Reform & Modernization, 2012
Issues in Establishing the Value Proposition of Personalized Medicine

• Current State: often “promising but unproven”; or proven but with narrow clinical utility.

• Often unclear:
  ▪ Analytic validity
  ▪ Definitions of appropriate patients
  ▪ Impact on clinical care process or outcome
  ▪ Role in care compared to current practice

• Difficult to study with traditional methods

• Sometimes more fervor than science
  ▪ Confusing association with causality
  ▪ Genetic determinism vs. complex system thinking

• Even proven tests often used inappropriately (BRCA)
Evidence in a PM World—New Data, Methods, Insights

- Increased use of modeling/simulation approaches
- The opportunity created by “Big Data”—sophisticated analysis of observational data
- Need for new (and large) data sets: phenotypes, functional status, patient-reported outcomes
- Sorry, but we still need to do prospective trials…
- Closing the gap between typical care and optimal care
## Practical recommendations

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<tr>
<th>Recommendations</th>
<th>Consumers</th>
<th>Physicians</th>
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<tbody>
<tr>
<td>1 Protecting, supporting, and informing patients through data confidentiality, non-discrimination, and decision-support</td>
<td>✓</td>
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<td>2 Benefiting patients by developing the clinical evidence base to determine which tests work</td>
<td>✓</td>
<td>✓ ✓</td>
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<td>3 Stimulating future progress by encouraging the development of tests that are proven to work</td>
<td>✓</td>
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<td>4 Monitoring care through more transparent coding and reporting</td>
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<td>5 Protecting patients by ensuring that lab tests are performed safely and accurately</td>
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<td>6 Making it easier for health professionals to stay up-to-date as genetic science evolves</td>
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Thank you!

All UnitedHealth Center for Health Reform Working Papers are available here:

www.unitedhealthgroup.com/reform/