

Economic Value of Whole Genome Sequencing

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How Do We Assess Value?

- Economic Evaluation
 - Cost effectiveness: Cost per health outcome
 - Cost utility: Cost per QALY
 - Cost benefit: Net cost
- Cost effective means a service provides reasonable value
 - Does NOT mean cost saving
 - Cost effective is cost additive



Cost Effectiveness

$$\frac{\text{Cost}}{\text{Quality-Adjusted Life Year}}$$

Cost = Net cost from a societal perspective

QALYs = Net health benefit



Costs

- Direct Costs
 - Medical Costs
 - Non Medical Costs
- Indirect Costs (Productivity Costs)
- Intangible Costs (e.g., pain, grief, suffering)



- Typical direct medical costs
 - Cost of a test
 - Cost of visits and hospitalization
 - Cost of follow up tests
 - Cost of treatment



Models of Clinical Use of WGS

SCENARIO 1: Focused Clinical Use

Testing, archiving, and extracting information as needed for management of specific clinical conditions

SCENARIO 2: Screening

Testing, reporting, and using the information in an asymptomatic patient



Scenario 1: Focused Clinical Use

Economics are largely the same as for any laboratory test

What does the incremental information gleaned contribute to better decisions, e.g., ending a diagnostic odyssey, selection of treatment, and understanding prognosis?

EXCEPT

1. Once WGS is done, it is a sunk cost; additional focused uses may increase health benefits at little incremental testing cost
2. There are data storage, other data handling, and clinical data support costs



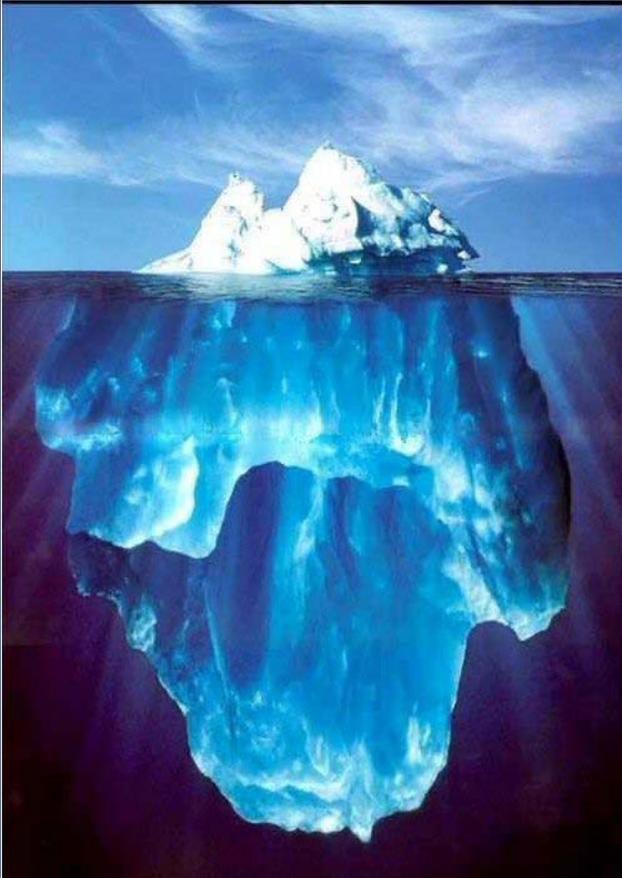
Focused Clinical Use

Used appropriately where WGS information provides reasonable clinical value, the issue is likely to be **FINANCIAL** not **ECONOMIC**, i.e.,

- Who pays for initial testing and long-term data management and access costs?
- How to costs get shared among payers for first testing and subsequent use?
- How are clinical decision support systems maintained?



Tip of the Iceberg



For *all* diseases, that which is clinically apparent without “looking beneath the surface” is just the tip of the iceberg.

By screening, I mean identifying those who are asymptomatic, beneath the surface.

Scenario 2: Screening

The problem:

- Early detection \neq better outcome
- Too much information may lead to
 - too many errors
 - too much follow up
 - too little benefit
 - too much cost
- The challenge: Securing the most benefit with the least harm



Looking beneath the surface

**WHAT ARE THE SIX
POSSIBLE OUTCOMES OF
SCREENING?**



Looking Beneath the Surface: Screening Outcome # 1

- Screening test negative...
 - but the patient *has the disease* - **false negative** - inappropriately reassured
 - Ignoring a new breast lump because mammogram was normal
 - **Decreases health benefit**
 - **May increase cost**



Looking Beneath the Surface: Screening Outcome # 2

- Screening test negative and the patient *does not* have the disease
 - **True negative.** No health benefit since patient does not have the disease
 - though patient reassured – is that always good?
Knowing you may be at lower risk for diabetes may lead to suboptimal behaviors
 - **Increases cost**



Looking Beneath the Surface: Screening Outcome # 3

- Screening test positive...
 - But patient does not have disease
 - **False positive** – subject to risks/costs of further testing and anxiety
 - e.g. maternal serum testing for Down syndrome/Trisomy 18 is calibrated to label 5% of women abnormal
 - **Increases cost**
 - **May increase harms**



Looking Beneath the Surface: Screening Outcome # 4

- Screening test positive and patient does have disease...
 - but is not destined to suffer morbidity or mortality related to the disease
 - treated unnecessarily
 - e.g., 25% of men in age range for prostate cancer screening have prostate cancer. Life time risk of death is 3%. How many of those detected by screening are treated for disease that would never have made it to the surface?
 - Increases cost
 - May decrease health benefit



Looking Beneath the Surface: Screening Outcome # 5

- Test positive and the patient is destined to suffer morbidity or mortality related to the disease
 - but outcomes of treatment in asymptomatic stage are no different from treatment after symptoms are present
 - we simply lengthen the treatment time
 - e.g. what morbidity do we really prevent by screening for COPD with spirometry ?
 - No net health benefit
 - May increase cost



Looking Beneath the Surface: Screening Outcome # 6

- Test positive
 - Patient destined to suffer morbidity or mortality related to the disease – and treatment in asymptomatic stage prevents complications that would develop if treatment not started until after symptoms are present
 - e.g. screening for colon cancer and treating in asymptomatic stage has clearly been shown to save lives
 - Health benefit
 - May save costs



Screening Outcomes: Keeping Score?

- For 5 of 6 outcomes, there can be NO health benefits to the patient
 - These 5 outcomes are not just costly – patients incur the harms of screening and treatment
- For 1 of 6 outcomes, there can be health benefits to the patient,
 - but no assurances that the benefits will exceed the harms of screening and treatment across screened populations



Challenges with WGS and Providing Information in a Screening Context

- The challenge is the overwhelming number of tests being done simultaneously
- So multiply the benefits and harms by the number of observations
 - Inevitably many positive findings
 - Inevitably many concerns to follow up
 - Harms are likely to exceed benefits
 - Costs are likely to be substantial



Screening

We should screen when good evidence demonstrates that the benefits of detection of a disease in an asymptomatic phase exceed the harms associated with diagnosis and treatment *across screened populations*



WE ARE SWIMMING UPSTREAM



June 29, 2008
NY Times

“It’s incumbent on the community to dispense with the need for evidence-based medicine,” he said. “Thousands of people are dying unnecessarily.”

Cardiologist from
Manhattan, NY

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THE EVIDENCE GAP
Weighing the Costs of a CT Scan's Look Inside the Heart



Josh Haner/The New York Times

Last month, Robert Franks, 59, received a CT angiogram at Lenox Hill Hospital in Manhattan.

By ALEX BERENSON and REED ABELSON
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E-MAIL

**THE FORCES FOR PROVIDERS
TO “DO” ARE ENORMOUSLY
GREATER THAN THE FORCES
TO “NOT DO”**



Forces To “Do”

- A noble ambition to do good, and the failure to recognize (or the ability to ignore) harm
- A cultural expectation that medical care can only do good, not harm, and that more care is always better than less
- The public and the medical profession have faith in technology



Forces To “Do”

- There are disease advocacy organizations that have substantial sway over the opinions of the public and medical profession
- Fear of litigation
- “Failure to detect”



Forces To “Do”

- Quality Measures
- Current PQRI quality measures include 13 specific measures that include the word “screening”
- Every one requires screening
- Not one single measure addresses use of unnecessary screening services



Forces To “Do”

- Payment
- “Every dollar spent on health care is a dollar of income for someone”
- In the debates of health care reform past and present: it is “immoral” to pay physicians to “withhold care”



What Not to Do: Overuse Genomics Screening Services

If WGS translates to unbridled use of screening, then in the process of promoting prevention we will do much harm and health care costs will increase.



Securing Value for WGS

- Deliver services that have demonstrated health benefits and provide good value
- Develop financing, coverage, and reimbursement systems to cover costs
- Develop systems to assure appropriate use



THANKS!!!

