Assessing the Economics of Genomic Medicine

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Workshop: Background

- Low cost genome sequencing are being considered for routine clinical use
- Tension exists between experts who feel obtaining this data before having a clear clinical indication is premature and those who feel that this information will empower HCP/patients for proactive decision making
- Available sequencing data could also be used at POC

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Workshop: Structure

- Workshop aimed at addressing one aspect of this debate:
  - Economic issues that may arise in the course of integrating genomic data into health care
- Assumptions
  - WGS costs are acceptable and fixed (this does not address interpretation costs)
  - Data storage costs are acceptable and fixed (this does not imply that electronically stored data is transportable)
  - These tests are available in a health care encounter

Workshop: Structure

- Three case scenarios: Followed one individual over three life events over a 15 year span
- Three different models:
  - Targeted mutation analysis: current standard of care
  - WGS with provision of data only relevant to the clinical situation and a few actionable variants
  - WGS with provision of data relevant to the clinical situation, actionable variants and other potentially significant secondary findings including lower effect size variants
- Identify research needs that arise from Day 1

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Workshop: Structure

- Overview of Genomic Medicine and Health Economics
- Case scenarios: three different stakeholder perspectives
  - Clinician
  - Futurist
  - Patient/consumer
- Economics panel discussion

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Promise of Genomic Medicine

- Potential to shed light on the genetic underpinnings of every disease
- Assessing risk of common diseases
  - And doing something about it
- Pre-emptive delineation of select PGx variants
- As an adjunct to newborn screening
- Finding those relatively unusual individuals who are at high risk of preventable disease
- Enabling a variety of reproductive decisions

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Genomic Scorecard

- ★ Powerful diagnostic tool for patients with primary genetic disorders
- X Broad preemptive PGx application
- ★ Improved treatment of cancer through genomic somatic analysis
- X Prevention of common diseases through genomic risk assessment
- ★ Prevention of rare diseases through selective genomic discovery of highly penetrant mutations
- ★ Utility in newborn screening
- ★ Preconception screening to inform reproductive choice

Courtesy of Jim Evans

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Health Economics

Types of Economic Evaluation in Health Care				
Study Design	**Costs Measured?**	**Outcomes Measured?**	**Strengths**	**Weaknesses**
Cost-minimization	Yes	Not necessary	Easy to perform	Useful only if outcomes are the same for both interventions
Cost-benefit	Yes	Yes, in monetary terms	Good theoretical foundation; can be used within health care and across sectors of the economy	Less commonly accepted by health care decision makers; evaluation of benefits methodologically challenging
Cost-effectiveness	Yes	Yes, in clinical terms (events, life years)	Relevant for clinicians; Easily understandable	Cannot compare interventions across disease areas when using disease specific endpoints.
Cost-utility	Yes	Yes, in **quality-adjusted life-years (QALY)**	Incorporates quality of life; Comparable across disease areas and interventions; Standard	Requires evaluation of patient preferences; Can be difficult to interpret

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Health Economics is Truly About Measuring Value

- Cost effectiveness analysis evaluates not only cost but also benefits of a health care intervention to assist in decision making
  - Is the improved clinical outcome enough to justify the intervention?
- Also assesses downstream consequences

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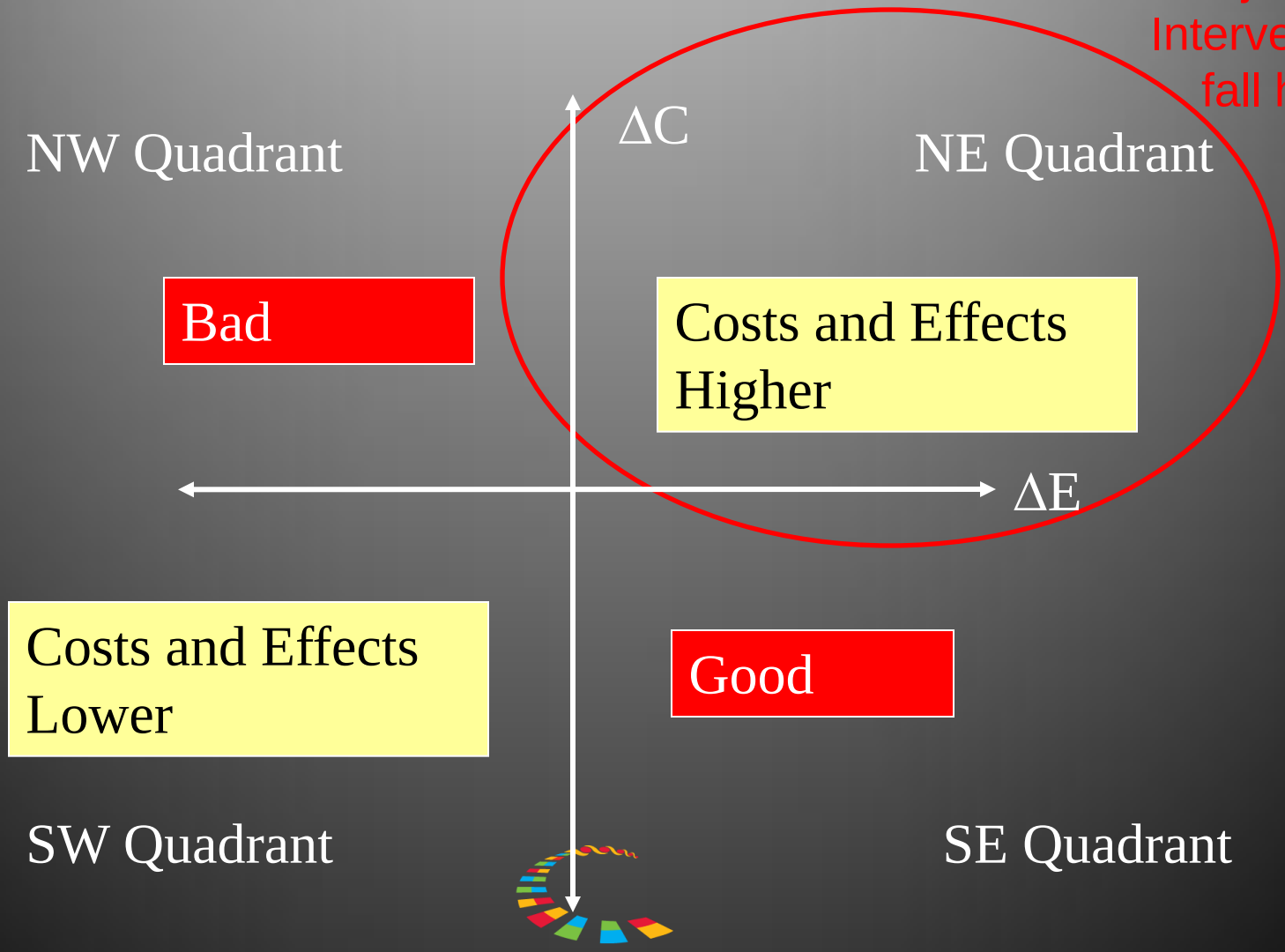
Interpretation of CEA results



Simple Misconceptions

1. ‘Cost-effective’ = ‘Cost-saving’
2. Expensive interventions are not cost-effective.
3. Inexpensive interventions are cost-effective.

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Health Economics Summary

- Helping people to understand what's at stake – what's the decision
- Careful CEA is about analyzing decisions
  - Clarify assumptions
  - Evaluate uncertainties
  - Not primarily about costs, but about trade-offs

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Is NextGen Sequencing Cost Effective?

- It's not about the cost, as much as …

  what is the outcome being measured?
  - base pairs sequenced
  - number of variants identified
  - diagnoses
  - clinical actions
  - patient outcomes – morbidity and mortality
- … and what is the comparator?

How do we determine the effect of genomics on the health care system?

What do we have to address in order to make this assessment?

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Assessing the Needs

- Requires a spectrum of expertise/perspectives
- Some are strictly economic research, most are not
  - Technology development – ongoing
  - Epi research
  - Behavioral research
  - ELSI/education
  - Health Services

I. Evidence – Comparative Effectiveness Research (CER)

- Need for evidence base development – collaboration, infrastructure with clinical trials groups
- Need for innovative approaches to CER prioritization.
- Determining if and how genomic sequence information modifies healthcare provision and patient outcomes.
- Impact of increasing accuracy of sequencing on patient outcomes and costs.
- Evaluation of proper use of family history to guide medical decision making, integrated into HIT infrastructure.

II. Health Economics Methods

- Need better (quicker) approaches and frameworks to performing health economic evaluations of genomic testing.
- Evaluation of evidence thresholds for data in hand versus data that must be obtained, and cost of further research.
- Divergence of economic assessment models in public health, clinical care, and academics.
- In the setting of a disruptive technology and a zero sum game/ shrinking pool of resources what/who will be replaced and how to fund genomic interventions?

III. Health Economics Applications

- When is genomic sequencing cost-effective? E.g., NBS scenario with data being used over the lifespan.
- Better education of genomic scientists regarding economic analysis/integration of economic analysis and on-going studies.
- Methods/infrastructure (including informatics) in health systems to follow downstream consequences of providing sequence data.
- Is cost reduction demonstrable? Do ACO's provide a possible mechanism for more efficient health care delivery of genomic technologies?
- Study of provider preferences for provision of genomic medicine – evaluation of barriers to implementation.
- Economic incentives for test and evidence development with value-based and specific pricing versus old system (CPT stacking)
- Determination of relative contribution of environment/setting on cost-effectiveness.

IV. Patient-Centered Outcomes

- Developing outcomes data on informed consent/study of efficient methods for patient education regarding informed consent.
- Stakeholder engagement; methodology to increase participation in clinical trials.
- Development of improved methods for assessing value/personal utility /patient preference in economic analysis.
- Potential for genomic medicine to exacerbate disparities, including applicability of information to minority populations and SES disadvantages. Focus on interventions.

Discussion Points

- Zero sum gain: shrinking pool of resources, how to fund genomic interventions?
- Need new ways to obtain evidence
  - Improved methods for assessing value/personal utility/patient preference
- Real world versus academic exercise
- Access issues
- Burdon of additional information that is poorly understood

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Assessing the Economics of Genomic Medicine

- Workshop Chair: Greg Feero, MD, PhD
  - Co-chair: Cathy Wicklund, MS, CGC
  - Clinical Practice and Public Health small group
- IOM Project Staff
  - Adam Berger, PhD, Roundtable Director
  - Claire Giammaria, MPH, Research Associate
  - Tonia Dickerson, Senior Program Assisant

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