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Clinical Sequencing Exploratory Research

Healthcare Utilization, Economics and Value: Challenges and Opportunities

David L. Veenstra, PharmD, PhD
University of Washington
Seattle, WA

Outline

- Costs vs. Value
- Economic data collection within CSER
- Challenges
- Opportunities and future directions

Cost ≠ Value

- Interventions can be expensive and good value, or inexpensive and poor value
- Value - how much health can we buy for $ spent?
  - health measured in QALYs (Quality-Adjusted Life-Years)
  - calculate incremental cost/incremental QALYs
- But of course payers care about costs!
  - We measure 'healthcare resource utilization' (HRU) then assign costs to utilization
- Measure effectiveness using clinical events, QoL, LE, … and estimate QALYs
- Goal: Improve patient outcomes in a cost effective (or cost saving) manner

CSER Healthcare Utilization Outcomes by Site: Data

Type of Outcome	Baylor	BWH MedSeq	ClinSeq	Columbia	DFCI	Kaiser	Mayo/ UCSF/ UMN	Seattle Children's	UNC	U Wash
Medical care visits		X	X	X	X	X	X	X	X	X
Mental health care visits		X				X		X		X
Procedures		X	X			X				X
Screening tests	X	X	X			X				X
Drug use		X	X		X	X			X	X
OTC drug use		X							X	X
Health insurance		X				X	X	X		X
Life, disability, or long-term care insurance	X	X		X			X			X
Testing uptake of family members	X	X					X			X
Other				X[1,2]	X[3]					X[4]
Approx. Number by July 2015	240	60-202	200+	200	40			131	520-560	150

[1]Reproductive decisions [2]Job, moving, marriage [3]Clinical trial participation [4]Not specified

CSER Healthcare Utilization Outcomes by Site: Methods

Method of Data Collection	Baylor	BWH MedSeq	ClinSeq	Columbia	DFCI	Kaiser	Mayo/ UCSF/ UMN	Seattle Children's	UNC	U Wash
NHANES (dietary survey)							X	X	X	
BRFSS (behavior survey)		X								
Patient survey (HRU)		X	X	X	X		X	X		X
Medical record evaluation	X	X			X	X				
Provider survey	X	X			X					
Participant interviews	X							X		

*no data collection by patient diary, insurance data

What is our goal?

Help healthcare systems and payers make informed coverage and reimbursement decisions for clinical sequencing

Challenge 1
What evidence do decision makers need?

- We don't know because…
- they don't know
  - or, at least it takes a lot of work to figure it out

Challenge 2:
Broad utility of clinical sequencing

- We don't need evidence for 'WGS'…we need evidence for specific applications
- But generating evidence for every type of test for every setting for multiple types of patients is not feasible
- We need information on all aspects of clinical delivery of new tests (not just the cost of the test)
  - time of genetics providers
  - impact on treatment decisions

Challenge 3: Comparative data

- Study design considerations
  - RCTs? Yes, but not necessarily
  - Comparative? Yes – need control groups
  - Historical control groups less than ideal
    - Concurrent controls

Challenge 4: Sample Size

- Sample size considerations
  - Diagnostic yield (incremental)
    - Selected populations: 100's -> 1,000
    - Non-selected populations: 1,000's -> 10,000's
  - Primary screening incremental impact
    - 10K - 100K
- How do we achieve this efficiently?

Opportunity 1:
Payer needs

- Ask payers and healthcare systems
- Consortium payer advisory board
- Need to be (very) indication specific
- Better to focus on types of evidence – what's most important?
  - Evidence prioritization

Opportunity 2:
Indication Foci within Consortium

- Diagnosis
  - impact on family direct and indirect costs
  - healthcare cost of diagnostic odyssey
- Treatment
  - treatment decisions
- Screening, both primary and secondary*
  - actions individuals take
    - positive and 'not-positives'
  - family communication, actions

*consortium opportunity for pooling across all sites, e.g., incidental findings

Opportunity 3: Study Designs and Data Collection

- Study design
  - Comparative as feasible
  - Sample size: power for most common clinical action
- Data collection
  - Patient and family-centered costs
  - Efficient use of EMRs
  - Develop novel 'test-attributable' cost surveys
    - for actions/outcomes with strong hypotheses, moderate need for control group and large sample size
    - share with other NHGRI consortia

Opportunity 4:
Policy Models

- Provide framework for decision making
- Helpful for synthesizing existing and new data
- Can ‘fill’ evidence gaps to some degree
- Inform both developers and policy makers regarding evidence prioritization

Summary

Consortium opportunities

- payer and decision maker input
- develop, validate, and implement common economic measures
- data pooling across sites with similar clinical settings
- develop policy frameworks to guide efforts

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