Applying Evidence-Based Medicine to Laboratory Test Selection

Robert Schmidt MD, PhD, MBA
Motivation

• Value for money
  – Improved outcomes
  – Lower costs
• Changes in health care management
Impact of Laboratory Testing

Laboratory tests account for 3% of medical costs but affect 70% of medical decisions.
Webinar Topics

- Hierarchy of evidence in test evaluation
- How to evaluate the utility of tests
- Gaps in evidence
- Identification of misused tests
  - examples
Hierarchy of Effectiveness

- Societal Impact
- Cost effectiveness
- Clinical effectiveness
- Clinical performance
- Analytical performance
Analytical Performance

- Limit of detection
- Precision
- Linear Range
- Accuracy
- Interferences
- Cost
- Operational capability
  - Reliability/maintainability/durability
  - Turnaround time
Hierarchy of Effectiveness

1. Societal Impact
2. Cost effectiveness
3. Clinical effectiveness
4. Clinical performance
5. Analytical performance
Clinical Performance

• Diagnostic Accuracy

• Does the test discriminate those with disease from those without?
What is a Diagnostic Test Accuracy Study?

- **Population**
- **Index Test**
- **Comparator (Reference Test)**
- **Outcome**
- **Timing**
- **Setting**
Basic Accuracy Statistics

<table>
<thead>
<tr>
<th>Index Test</th>
<th>Reference Test</th>
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</thead>
<tbody>
<tr>
<td></td>
<td>Positive</td>
<td>Negative</td>
<td></td>
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<tr>
<td>Positive</td>
<td>TP</td>
<td>FP</td>
<td></td>
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<tr>
<td>Negative</td>
<td>FN</td>
<td>TN</td>
<td></td>
</tr>
</tbody>
</table>

Sensitivity = TP / (TP + FN)

Specificity = TN / (TN + FP)

Positive Predictive Value = PPV = TP / (TP + FP)

Negative Predictive Value = NPV = TN / (TN + FN)
Framework for Study Evaluation

Study Value

Internal Validity

Do the results of this study actually measure what they purport to measure?

External Validity

Are the results of this study applicable to my clinical question?
Threats to Validity

Study Value

- Internal Validity
  - Precision
  - Bias
- External Validity
  - Real Differences

Do the results of this study actually measure what they purport to measure?

Are the results of this study applicable to my clinical question?
Threats to Validity

Study Value

- Internal Validity
  - Precision
  - Bias
- External Validity
  - Real Differences

Sources of Variation
Bias

Precision

External Validity
External Validity

Clinical Problem

- Population
- Index Test
- Reference Test
- Outcome

Potentially Relevant Study

- Population
- Index Test
- Reference Test
- Outcome
Variability of Study Results

65 DTA studies of parotid gland FNA

malignant vs benign neoplastic

Bias?
Precision?
Real Differences?

Patient Factors

(Beta-D glucan for Diagnosis of Invasive Fungal Disease)

Study A
120 heme patients
Measure BDG
EORTC criteria

Study B
100 culture positive pts (cases)
100 medical students (controls)
Measure BDG
Patient Spectrum

Study A
- 120 heme onc patients
- Measure BDG
- EORTC criteria

Study B
- 100 culture positive pts (cases)
- Measure BDG
- 100 medical students (controls)
What factors affect patient spectrum?
Impact of referral patterns on patient spectrum

Primary Care

"Easy" Diagnoses

Specialist
Index Test

• Applicability
  – Definition of the test

• Sources of Bias
  – Test Review Bias
  – Reading Order Bias
  – Incorporation Bias
Index test Definition

• What is the test?
  – Isolated index test?
  – Isolated index test plus clinical information?
  – Isolated test plus previous testing?
Test Definition: Impact of Additional Information
Reference Test

Misclassification Bias

• Error in the reference standard
  – (Brass Standard vs Gold Standard)

  – Nondifferential misclassification
    • Error rate independent of index test result
    • Almost always reduces sensitivity and specificity

  – Differential misclassification
    • Error rate depends on index test result
      – (e.g. errors higher for cases with a positive result)
    • Impact on accuracy statistics difficult to predict
Example: Nondifferential Misclassification

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<tr>
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<th>Histopathology</th>
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<tr>
<td></td>
<td>Positive</td>
<td>Negative</td>
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</tr>
<tr>
<td>FNA</td>
<td>900</td>
<td>100</td>
<td></td>
<td>1000</td>
</tr>
<tr>
<td>Positive</td>
<td>90</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Negative</td>
<td>100</td>
<td>900</td>
<td></td>
<td>1000</td>
</tr>
</tbody>
</table>

Sensitivity = 90%
Specificity = 90%

Sn = 90%
Sp = 90%

10% Misclassification Rate

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<tr>
<th></th>
<th>Histopathology</th>
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<th></th>
<th>Total</th>
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<tbody>
<tr>
<td></td>
<td>Positive</td>
<td>Negative</td>
<td></td>
<td></td>
</tr>
<tr>
<td>FNA</td>
<td>820*</td>
<td>180</td>
<td></td>
<td>1000</td>
</tr>
<tr>
<td>Positive</td>
<td></td>
<td></td>
<td></td>
<td></td>
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<tr>
<td>Negative</td>
<td>180</td>
<td>820</td>
<td></td>
<td>1000</td>
</tr>
</tbody>
</table>

Sensitivity = 82%
Specificity = 82%

Sn = 82%
Sp = 82%

*Example: 820 = 900 (1 - 0.1) + 0.1 (100)
Verification Bias

α = positive verification rate
β = negative verification rate
Example of Verification Bias:
1000 people with a lump
Prevalence of neoplasia = 20%
FNA Sensitivity = 90%
FNA Specificity = 90%
90% of positive cases get histologic follow-up
10% of negative cases get histologic follow-up

<table>
<thead>
<tr>
<th></th>
<th>Study Population</th>
<th>Verified Population</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Positive</td>
<td>Negative</td>
</tr>
<tr>
<td>FNA Positive</td>
<td>180</td>
<td>80</td>
</tr>
<tr>
<td>FNA Negative</td>
<td>20</td>
<td>720</td>
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</tbody>
</table>

Actual Sensitivity = 90%
Actual Specificity = 90%

Observed Sensitivity = 99%
Observed Specificity = 50%
Impact of partial verification on bias

\[ R = \frac{\beta}{\alpha} \]
Differential Verification Bias
(Work-up bias)

Patients

Positive

Index Test

Negative

Reference Test 1

Histopathology

Reference Test 2

Clinical Follow-up
Example: Differential verification bias
1000 people with a lump
Prevalence of neoplasia = 20%
FNA Sensitivity = 90%
FNA Specificity = 90%
positive cases get histologic follow-up (error rate: 0.01%)
positive cases get clinical follow-up (error rate: 10%)

<table>
<thead>
<tr>
<th>True Results</th>
<th>Reference Test</th>
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</thead>
<tbody>
<tr>
<td></td>
<td>Positive</td>
</tr>
<tr>
<td>FNA Positive</td>
<td>180</td>
</tr>
<tr>
<td>FNA Negative</td>
<td>20</td>
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</table>

Actual Sensitivity = 90%
Actual Specificity = 90%

<table>
<thead>
<tr>
<th>Observed Results</th>
<th>Reference Test</th>
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<tbody>
<tr>
<td></td>
<td>Positive</td>
</tr>
<tr>
<td>FNA Positive</td>
<td>179</td>
</tr>
<tr>
<td>FNA Negative</td>
<td>90</td>
</tr>
</tbody>
</table>

Observed Sensitivity = 66%
Observed Specificity = 89%

Usually causes negative bias in sensitivity
## Indeterminate Results

- How should they be included?
- How do they affect accuracy statistics?

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<table>
<thead>
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<tbody>
<tr>
<td><strong>Study A</strong></td>
<td><strong>Reference Test</strong></td>
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<tr>
<td></td>
<td><strong>Total</strong></td>
<td><strong>POS</strong></td>
<td><strong>IND</strong></td>
<td><strong>NEG</strong></td>
</tr>
<tr>
<td>POS</td>
<td>100</td>
<td>80</td>
<td>1</td>
<td>19</td>
</tr>
<tr>
<td>IND</td>
<td>10</td>
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<td>5</td>
<td>2</td>
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<td>NEG</td>
<td>100</td>
<td>13</td>
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</tr>
<tr>
<td>Total</td>
<td>210</td>
<td>96</td>
<td>8</td>
<td>106</td>
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<p>| | | | | |</p>
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<tbody>
<tr>
<td><strong>Study B</strong></td>
<td><strong>Reference Test</strong></td>
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</tr>
<tr>
<td></td>
<td><strong>Total</strong></td>
<td><strong>POS</strong></td>
<td><strong>IND</strong></td>
<td><strong>NEG</strong></td>
</tr>
<tr>
<td>POS</td>
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<tr>
<td>IND</td>
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<td>15</td>
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<td>19</td>
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<tr>
<td>NEG</td>
<td>86</td>
<td>1</td>
<td>0</td>
<td>85</td>
</tr>
<tr>
<td>Total</td>
<td>210</td>
<td>96</td>
<td>8</td>
<td>106</td>
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</tbody>
</table>
## Impact of Indeterminate Rate on Accuracy

### Scenario A

<table>
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<th>Index Test</th>
<th>Reference Test</th>
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<tbody>
<tr>
<td></td>
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<tr>
<td>POS</td>
<td>80</td>
<td>1</td>
</tr>
<tr>
<td>IND</td>
<td>3</td>
<td>5</td>
</tr>
<tr>
<td>NEG</td>
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<td>2</td>
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<tr>
<td>Total</td>
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</table>

### Scenario B

<table>
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<td>IND</td>
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<td>8</td>
</tr>
<tr>
<td>NEG</td>
<td>1</td>
<td>0</td>
</tr>
<tr>
<td>Total</td>
<td>96</td>
<td>8</td>
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</tbody>
</table>
Other Problems With Accuracy Studies

• Inaccurate Reporting
• Tests are viewed independently
  – Key question: how does test information impact likelihood of disease?
• Heterogeneity
Variability of Study Results

65 DTA studies of parotid gland FNA

malignant vs benign neoplastic

Bias?

Precision?

Real Differences?

Hierarchy of Evidence for Clinical Studies

Cochrane Reviews

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Meta-Analysis of DTA studies

The State of Nature

As revealed by experiments:

As revealed by publications:

As selected for review:

Systematic Review:

Quality Search Strategy
Sensitive
Multiple data bases
Unpublished sources
Well Defined Criteria
Inclusion
Exclusion
Defined a priori
Reproducible

Meta-Analysis

As synthesized
The State of Nature

As revealed by experiments:

As revealed by publications:

As selected for review:

As synthesized
The State of Nature

As revealed by experiments:

As revealed by publications:

As selected for review:

As synthesized
The outcome of abstracts presented at the United States and Canadian Academy of Pathology annual meetings

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Abstract

Many abstracts presented at scientific meetings are never published as articles in peer-reviewed journals. Using PubMed search and custom computer programs, we retrospectively reviewed all 4824 abstracts presented at the United States and Canadian Academy of Pathology annual meetings from 2005 to 2007, and found an overall publication rate of 36% for a 3-year maximal follow-up. This rate is comparable with that of other medical societies with published data. The publication rate varied from 10 to 62% among different subspecialties. The format of presentation, either platform or poster, was also a significant predictor of outcome, with 42–50% publication rate for platform abstracts and 32–36% for poster abstracts. Country of origin and the use of statistical methods did not seem to affect outcome significantly. The average time from abstract submission to article publication was 18 months. Seven journals accounted for over half of all publications, and the top three journals were American Journal of Surgical Pathology (16.2%), Modern Pathology (9.1%), and American Journal of Clinical Pathology (8.3%).
Comparison of outcomes of published vs registered RCTs

Simes J Stat Med; 1987
## Effect of various outcomes on publication rate

<table>
<thead>
<tr>
<th>Study or sub-category</th>
<th>Positive n/N</th>
<th>Negative n/N</th>
<th>OR (fixed) 95% CI</th>
<th>Weight %</th>
<th>OR (fixed) 95% CI</th>
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</thead>
<tbody>
<tr>
<td>01 Positive versus negative or no difference</td>
<td></td>
<td></td>
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<tr>
<td>Bardy 1998</td>
<td>52/111</td>
<td>16/77</td>
<td>35.13 [3.36, 3.65]</td>
<td>35.13</td>
<td>3.36 [1.73, 6.53]</td>
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<tr>
<td>Subtotal (95% CI)</td>
<td>111</td>
<td>77</td>
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<tr>
<td>Total events: 52 (Positive), 16 (Negative)</td>
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<tr>
<td>Test for heterogeneity: not applicable</td>
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</tr>
<tr>
<td>Test for overall effect: Z = 3.57 (P = 0.0004)</td>
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<tr>
<td>02 Significant versus not significant</td>
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<tr>
<td>Dickersin 1992</td>
<td>84/96</td>
<td>52/72</td>
<td>25.98 [2.69, 5.96]</td>
<td>5.66</td>
<td>7.04 [1.90, 26.16]</td>
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<tr>
<td>Dickersin 1993</td>
<td>121/124</td>
<td>63/74</td>
<td>32.66 [3.18, 6.99]</td>
<td>146</td>
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<td>Subtotal (95% CI)</td>
<td>220</td>
<td>146</td>
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<td>Total events: 205 (Positive), 115 (Negative)</td>
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<td>Test for heterogeneity: Chi² = 1.51, df = 1 (P = 0.22), I² = 34.0%</td>
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<td>Test for overall effect: Z = 3.74 (P = 0.0002)</td>
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<tr>
<td>03 Positive (or favours experimental arm) versus negative (or favours control arm)</td>
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<tr>
<td>Subtotal (95% CI)</td>
<td>27</td>
<td>39</td>
<td></td>
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<td></td>
</tr>
<tr>
<td>Total events: 20 (Positive), 16 (Negative)</td>
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<tr>
<td>Test for heterogeneity: not applicable</td>
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<tr>
<td>Test for overall effect: Z = 2.58 (P = 0.010)</td>
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<tr>
<td>04 Significant versus non-significant trend or no difference</td>
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<td></td>
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<td></td>
<td></td>
</tr>
<tr>
<td>Subtotal (95% CI)</td>
<td>78</td>
<td>54</td>
<td></td>
<td></td>
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<tr>
<td>Total events: 55 (Positive), 18 (Negative)</td>
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<td></td>
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<tr>
<td>Test for heterogeneity: not applicable</td>
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<td></td>
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<td></td>
<td></td>
</tr>
<tr>
<td>Test for overall effect: Z = 4.29 (P &lt; 0.0001)</td>
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<td></td>
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<td></td>
<td></td>
</tr>
<tr>
<td>Total (95% CI)</td>
<td>434</td>
<td>316</td>
<td></td>
<td>100.00</td>
<td>3.90 [2.68, 5.68]</td>
</tr>
<tr>
<td>Total events: 332 (Positive), 165 (Negative)</td>
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<td></td>
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</tr>
<tr>
<td>Test for heterogeneity: Chi² = 2.40, df = 4 (P=0.66), I² = 0%</td>
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<tr>
<td>Test for overall effect: Z = 7.12 (P &lt; 0.0001)</td>
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</tbody>
</table>
Bottom line

- Lots of deficiencies in the literature
  - Incomplete reporting (STARD)
  - Biased results
  - Inaccurate reporting of results
- Problems with meta-analysis
  - Publication bias (for clinical studies)
  - Meta-analysis of non-comparative studies
  - Heterogeneity
  - GIGO
  - Relatively few available
- Accuracy is a Surrogate Measure: Not Linked to Value
Hierarchy of Effectiveness

- Societal Impact
- Cost effectiveness
- Clinical effectiveness
- Clinical performance (diagnostic accuracy)
- Analytical performance
Clinical Utility

• Degree to which a test is associated with improved outcomes

• Do tests change outcomes that matter to patients?
Components of Utility

• Medical Impact
  – Change in management:
    • stop, start, modify or withdraw treatment
  – Effect of test on patients (adverse events)
• Emotional Impact
• Social Impact

A test can have clinical utility without medical impact
Characteristics of Clinical Utility

• Probabilistic
  – Outcome is not assured even if test is perfect

• Relative
  – No absolute scale
  – Defined relative to an alternative

• Contextual
  – Utility depends on:
    • Available treatments
    • Alternative tests

• Constantly changing
Measurement of Utility

• Utility Scale
  – Dead = 0
  – Best possible health = 1
  – Intermediate health states: between 0 and 1

• Quality adjusted life years (QALY)
  – Accounts for:
    • Quantity of life (years)
    • Quality of life (Utility)
Measuring Utility

Perfect Health (Utility=1)

Dead Utility = 0

COPD (Utility=?)

Expected Utility of COPD = \( p \times 1 + (1-p) \times 0 = p = 0.7 \)?
Measuring Utility

Expected Utility of COPD = p*1 + (1-p)*0 = p = 0.999?
Add up QALYs over life

• Life after test A: expected QALYs = 9.5
• Life after test B: expected QALYs = 8.0

• Test A provides a benefit of 1.5 QALYs relative to Test B
Where does data come from?

- Randomized Clinical Trials
  – Best Evidence for Utility

- Modeling
Diagnostic Randomized Controlled Trial

Patients → R → Test A
- Positive: Treatment → Outcomes
- Negative: No Treatment → Outcomes

Patients → R → Test B
- Positive: Treatment → Outcomes
- Negative: No Treatment → Outcomes
Problems with DRCTs

- Costly
- Time consuming
- Inefficient
- Indirect
Evidence from DRCTs

• Very few published studies
  – 37 DRCTs per year
  – 11,000 RCTs
Do we need DRCTs?

- Not always
- Combine evidence from test performance with evidence from therapeutic trials
Do we always need DRCTs?

• Test A has utility relative to Test B if:
  – Better sensitivity but same specificity
  – Better specificity but same sensitivity
  – Same sensitivity and specificity but fewer adverse events
Modeling

Information required:
• List of states
• Utility of each state
• Transition probabilities

Output:
• QALYs
Expected QALYs
Hierarchy of Effectiveness

- Societal Impact
- Cost effectiveness
- Clinical effectiveness
- Clinical performance
- Analytical performance
## Cost Effectiveness Modeling

<table>
<thead>
<tr>
<th>Alternative</th>
<th>QALYs</th>
<th>Total Cost</th>
</tr>
</thead>
<tbody>
<tr>
<td>Test A</td>
<td>11.0</td>
<td>$25,000</td>
</tr>
<tr>
<td>Test B</td>
<td>9.0</td>
<td>$15,000</td>
</tr>
<tr>
<td>Difference</td>
<td>2.0</td>
<td>$10,000</td>
</tr>
</tbody>
</table>

Incremental Cost Effectiveness Ratio (ICER) = Value for Money

\[
\frac{COST_A - COST_B}{QALY_A - QALY_B} = \frac{\Delta Cost}{\Delta Utility} = \frac{\$10,000}{2.0 \text{ QALY}} = \frac{\$5000}{\text{QALY}}
\]
Cost Effectiveness Plane

$\Delta QALY$

$\Delta COST$
Winners

Losers:

$ΔCOST$

$ΔQALY$

Slope = ICER

A $5000/QALY
WTP = $50,000
ICER = $5,000
Which new tests do you choose?

ΔCOST

ΔQALY

WTP = $50,000
\[ \Delta COST \]

\[ \Delta QALY \]

WTP = $50,000

Test

Other Project
Modeling

- Faster, less expensive than DRCTs
- Won’t find the unexpected
- Requires many assumptions
- Low output of studies
  - 147 of 2000 cost effectiveness studies were on diagnostic testing
Hierarchy of Effectiveness

1. Societal Impact
2. Cost effectiveness
3. Clinical effectiveness
4. Clinical performance
5. Analytical performance
Many steps to evaluate tests:

- Societal Impact
- Cost effectiveness
- Clinical effectiveness
- Clinical performance
- Analytical performance
Limited Incremental Cost Effectiveness

- Advanced Cardiac Markers
Ordering Errors

- 1, 25 dihydroxy vitamin D vs 25 hydroxy vitamin D
New Tests with better performance

- Celiac Disease
  - ttG vs endomysial antibody
- Helicobacter pylori infection
  - Stool antigen vs serology
- Pheochromocytoma
  - Metanephrines vs catecholamines
Tests with limited clinical use

- rT3
- Vitamin D2 and D3
- Phosphatidylserine antibodies for APS
- MBP for multiple sclerosis
Deviations from guidelines

• Free PSA when total PSA > 10 or PSA < 2.5 ng/mL
• PSA screening in men over 75
• Over testing
  – IgA and IgG ttG for celiac disease

• Wrong context
  – IgG subclasses by non-specialists

• Odd patterns
  – Hospital X accounts for 3% of our volume but 70% of the orders for Test Y
Utilization Iceberg

Easy cases

Defensive Medicine

Tests without followup

Ineffective ordering

Failure to test

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Conclusion

• Many paths to low utility
• Evidence base is poor
  – Poor link between testing and outcomes
  – Few clinical trials or modeling studies
  – Problems with accuracy studies
• New tests are developed faster than they can be evaluated
  – “omics” tsunami
• Findings are transient
Future

- Evidence base is accelerating
- Diagnostic accuracy literature is improving
- Need for efficient use of comparative effectiveness studies
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