insufficient evidence...

Evaluating Medical Tests

Colonoscopy

Fecal hemoglobin testing
### Test Evaluation: Three questions

<table>
<thead>
<tr>
<th>Question</th>
<th>Feature</th>
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<tbody>
<tr>
<td>Is it true?</td>
<td>Technical Performance</td>
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<tr>
<td>Is it meaningful?</td>
<td>Clinical Performance</td>
</tr>
<tr>
<td>Is it useful?</td>
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1. **Technical Performance**
   - Is it true?
### 2. Clinical Performance

Is it meaningful?

#### Diagnostic Accuracy Study

<table>
<thead>
<tr>
<th>Medical Test</th>
<th>Gold Standard</th>
</tr>
</thead>
</table>

#### The results

<table>
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<tr>
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<td><strong>BioMarker</strong></td>
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<tr>
<td>Positive</td>
<td>45</td>
<td>76</td>
</tr>
<tr>
<td>Negative</td>
<td>74</td>
<td>1,061</td>
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Diagnostic Accuracy Study

- 1,256 Patients
- iFOBT
- Colonoscopy
- Cross-classification

Measures of Diagnostic Test Accuracy

- Sensitivity & Specificity 38% 93%
- Predictive Values 37% 93%
- Likelihood Ratios 5.66 0.67
- Diagnostic Odds Ratio 8.5

New interventions should

- Extend life
- Reduce morbidity
- Maintain health
- Reduce costs
- Reduce risks
- Make things simpler

3. Clinical Effectiveness

Is it useful?
Testing should
- extend life
- reduce morbidity
- maintain health
- reduce costs
- reduce risks
- make things simpler

Medical Tests
- should be treated like other interventions in EBM
- should be evaluated like other interventions (up to a point...)

Value of Medical Tests

Essentialism
the theory that
the value of a marker or a medical test
should be judged
by the trueness of its results

Consequentialism
the theory that
the value of a marker or a medical test
should be judged
by the value of its consequences

Two views on tests

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Consequences of Testing
Consequences of Testing

Population → Study Group → Randomize

TEST → Outcome

Control → Outcome

Randomized Clinical Trial

Population → Study Group → Randomize

Active → Outcome

Control → Outcome

Medical Test RCT

Population → Study Group → Randomize

TEST → Outcome

Control → Outcome

Clinical Effectiveness

Explanation

Health Outcome: Health outcomes that matter to patients and society: to prevent premature death, to restore or maintain functional health.

Probabilistic: Not all outcomes will be observed in everyone tested; evaluations will be made at the group level, and expressed in terms of a distribution of outcomes.

Comparative: Clinical utility from a testing or marker based strategy is defined relative to a comparator strategy: current best standard practice.
Meta-analysis CRC Screening RCT

Relative Risk CRC Mortality: 0.84
(95% CI: 0.77 to 0.93)
Three questions

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Decisions about Tests

- Guided by consequences
- Technical and Clinical Performance not sufficient
- But...
- Often can be redefined as necessary (and sufficient) conditions for effectiveness

Meta-analysis CRC Screening RCT

Relative Risk CRC Mortality: 0.84
(95% CI: 0.77 to 0.93)
Fecal hemoglobin testing

RCT Screening

Meta-analysis CRC Screening RCT

RCT Screening

Random Comparison of Guaiac and Immunohistochemical Fecal Occult Blood Tests for Colorectal Cancer in a Screening Population
Fecal hemoglobin testing

RCT Screening

Early Detection

Disease
Take Home Messages

- Technical Performance, Clinical Performance, Clinical Effectiveness

- Decisions about medical tests are based on consequences, not on performance (only).

- Performance requirements can - and should - be defined as necessary conditions for effectiveness.

Medical Tests in EBM

- Should be treated like other interventions
- Should be evaluated like other interventions
  (up to a point...)

Oxford - Diagnostics Forum