Cost-Effectiveness Evaluation for a New Diagnostic Test Considering also Costs for False Negative and False Positive Diagnoses at Various Prevalence Rates

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OBJECTIVES
To evaluate the cost-effectiveness of a new diagnostic device for which no gold standard data are available. An example is given for the evaluation of capsule endoscopy (CE) in diagnosing obscure gastrointestinal bleeding (OGIB) from a health care payer perspective in Switzerland.

METHODS

Clinical Data:
- 7 controlled clinical trials
- n = 184 patients with OGIB
- Comparator: push enteroscopy (PE)
- Effectiveness parameters: sensitivity and specificity values, correctly diagnosed patients

Sensitivity:
- Per patient, location in small intestine only
- All CE positives are true positives
- CE positive finding, PE no finding → CE true positive, PE false negative
- CE no finding, PE positive finding → CE false negative
- Both positive findings → true positive findings for both tests

Specificity:
- PE literature data
- CE study data

Cost Data:
- Procedure cost of CE and PE
- Cost of diagnostic failure:
  - due to false positive diagnosis (FP)
  - due to false negative diagnosis (FN)
- For FP cost an assumption of unnecessary treatment was made
- For FN cost diagnostic procedures performed two years prior to study start were considered and allocated according prevalence in the model

Modeling:
- Micro-simulation model incorporating first- and second-order Monte Carlo simulation
- Simulation of 10,000 patients
- Pretest probability (prevalence) from 10 to 90%
- Breakdown of FN cost into 9 cycles
- Min, max, mean FN cost per cycle, depending on prevalence
- Incremental cost-effectiveness (ICE): costs per correctly diagnosed patient depending on prevalence

RESULTS
- Mean future costs after a false negative diagnosis can range from 7,644 € (Minimum 2,555; Maximum 22,993) at a disease prevalence of 10% (cycle 1) to 3,129 € (Minimum 2,555; Maximum 3,613) at a disease prevalence of 50% (cycle 9) in the patient population (Table 1).
- Sensitivity and specificity value calculations have meanwhile been confirmed by several, independent study results, comparing CE to intraoperative endoscopy, which is close to be regarded as gold standard.

Table 1: FN Costs – Prevalence Dependent

<table>
<thead>
<tr>
<th>Pretest Probability</th>
<th>Costs (EUR)</th>
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<tbody>
<tr>
<td></td>
<td>Minimum</td>
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<td>10%</td>
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<td>90%</td>
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* Mean expected value, log-normal distribution

CONCLUSIONS
- Prevalence dependent ICE reveals cost saving potential of CE when used at a prevalence of 10% or higher. This corresponds with application of CE after negative upper and lower gastroscopy (Figure 1).
- Greatest savings are observed for a prevalence rate of 50%. At higher prevalences – i.e. at a later stage in the diagnostic path – cost savings decrease due to increase of false positive diagnoses.

REFERENCES