EARLY ASSESSMENT OF MEDICAL DEVICES
Systematic Literature Review of Papers and Methods in Use

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INTRODUCTION
The development process of medical devices is a costly and uncertain undertaking, with sharp competition for restricted resources. Assessment conducted early in the development can increase the likelihood of success, by curtailing the diffusion or influencing the development in a simple and inexpensive manner. “Early assessment of medical devices” can be defined as an early examination of the medical, economic, social and ethical implications of the medical device to determine the potential for incremental value in health care. Early assessment starts from initial idea generation up to stage I of clinical trials (Fig.1).

(objectives) Objectives of the studies:
9 papers → To develop the methods for cost-effectiveness analysis early in development;
9 papers → To include stakeholder perspectives for the early assessment of devices in development;
9 papers → To propose or develop a framework (i.e. sequence of methods to assess different aspects of technology) for early assessment;
5 papers → To estimate the cost-effectiveness of a new technology early in development;
4 papers → To support decisions in new technology development through analytical decision support techniques;
4 papers → To propose a methodology for the early identification of emerging technologies;
1 paper → To estimate the clinical outcomes and potential harms of a new technology early in development;

METHODS
(1) Systematic Literature Review (1990-2012);
(2) Extract:
- a. Study Characteristics;
- b. Objectives of the studies;
- c. Methods of early assessment;

More popular keywords used: (early) HTA, medical device*, innovati*, product development, technology assessment, decision*, model*, project management

RESULTS
(1) Searching for relevant papers:
4412 publications found – 43 publications included

(2a) Study Characteristics:
* 15 application papers + 10 theoretical papers with an example to illustrate the theory + 13 theoretical papers + 5 systematic/narrative reviews;
* majority of papers originates from European countries + visible international collaboration;
* the variety of journals that published selected articles reflects the multidisciplinary nature of the early assessment of medical devices.

(2b) Methods of early assessment:
Table 1: Numbers (n) of Quantitative (QN) and Qualitative (QL) methods used in the early assessment of medical devices according to the stage of development and for different target audience.

<table>
<thead>
<tr>
<th>Target audience</th>
<th>Stage of development</th>
<th>Decision makers on coverage and reimbursement</th>
<th>Policy Makers</th>
<th>Developers</th>
<th>Other</th>
</tr>
</thead>
<tbody>
<tr>
<td>Basic research on mechanisms</td>
<td>2QN</td>
<td></td>
<td></td>
<td></td>
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<tr>
<td>Targeting for specific product</td>
<td>3QN, 1QL</td>
<td></td>
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<tr>
<td>Proof of principle</td>
<td>2QN, 2QL</td>
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<tr>
<td>Prototype product development</td>
<td>3QN, 7QL, 3QN, 3QL</td>
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<tr>
<td>First clinical trials</td>
<td>4QN, 3QL, 1QN, 4QL</td>
<td></td>
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<tr>
<td>Not specified</td>
<td>3QN, 1QN, 3QL, 1QN, 5QL</td>
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</tbody>
</table>

CONCLUSIONS
➢ Medical devices developers – the most involved target audience (lack of expertise in assessment performance);
➢ The most frequent study area: early modelling of cost-effectiveness;
➢ Many important aspects of early assessment are unexplored (e.g. the potential of quantifying user needs and preferences);
➢ Need for a higher level of structure and specifications to communicate the benefit to intended audience;
➢ Basic classification and harmonization of methods is necessary;
➢ Efforts to overcome those barriers are on-going.