Early technology assessment

From concept to successful innovation

User involvement
Medical Technology Development

• Improved efficiency of health care market

• At present:
  – High development costs and high failure rate of MT
  – High lump sum start-up costs at implementation
  – Increased need for medical devices to demonstrate value to different stakeholders (government, capital investors, industry, insurance companies)
Early Assessment

First contact with end users

Ijzerman & Steuten 2011
Issues in MT development

• Product specification: potential of the technology in different types of interventions, clinical settings or disease indications
• Identifying the potential for differentiation from competitors
• Efficient use of research and development resources
• Building persuasive argument for outside investors
The user as starting point

- Clinical Case Analysis
  - What is the intended aim and who are the user stakeholders?
- Unfulfilled medical needs
  - What are the user needs that the innovation must meet
- Requirement Analysis
  - What is the potential for improvement of the new innovation
Public preferences for colorectal cancer screening using new genome-based nanotechnologies.

• Jilles M. Fermont, Karin G.M Groothuis-Oudshoorn, Janine A. van Til and Maarten J. IJzerman
Case Example

- http://www.utwente.nl/onderzoek/themas/health/en/lab-on-a-chip/lab-on-a-chip/nanopill.docx/
Background

- European Technology Platform on Nanomedicine
  - Personalized Nanodiagnosticstics, e.g. nanopill

- Perceived benefits of nanodiagnosticstics in CRC screening
  - Avoid handling of stool in current iFOBT) testing
  - Non-invasive, yet good diagnostic performance
The user as starting point

- Clinical Case Analysis
  - Use of nanopill as CRC screening tool
- Unfulfilled medical needs
  - Perceived value of current (iFOBT) screening and identifying gaps
- Requirement Analysis
  - What is the required performance for the Nanopill to demonstrate incremental value
Methods

- Discrete choice experiment (DCE)
- General population sample
- Attribute selection: Based on literature review on characteristics of current diagnostic methods in CRC:
  - iFOBT
  - sigmoidoscopy,
  - colonoscopy
  - nanopill
<table>
<thead>
<tr>
<th>Preparation</th>
<th>Technique</th>
<th>Specificity</th>
</tr>
</thead>
<tbody>
<tr>
<td>No preparation</td>
<td>Take Pill</td>
<td>70%</td>
</tr>
<tr>
<td>Laxatives</td>
<td>Collect Stool</td>
<td>80%</td>
</tr>
<tr>
<td>Enemas</td>
<td>Short tube being inserted</td>
<td>90%</td>
</tr>
<tr>
<td>Diet plus laxatives</td>
<td>Long tube being inserted with sedation</td>
<td>100%</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Complication rate</th>
<th>Frequency</th>
<th>Sensitivity</th>
</tr>
</thead>
<tbody>
<tr>
<td>None</td>
<td>Every year</td>
<td>70%</td>
</tr>
<tr>
<td>1/10000</td>
<td>Every two years</td>
<td>80%</td>
</tr>
<tr>
<td>1/1000</td>
<td>Every 5 years</td>
<td>90%</td>
</tr>
<tr>
<td>1/100</td>
<td>Every 10 years</td>
<td>100%</td>
</tr>
</tbody>
</table>
Design

- Full profile CBC D-Efficient design generated with Sawtooth
  - 16 choice tasks per respondent (14 random, 2 hold-out)
  - Triplets (3 scenarios per choice set), 6 attributes with 4 levels each
  - Fractional factorial design with balanced overlap
  - 999 unique questionnaires

- Dual-Response None Option

- Conditional Logit Additive Model
Data Collection

- Survey Sampling International
- Men and women, 50-74 years
- UK and NL
- Sample size ≥800 per country
Imagine that you can choose how you will be screened for colorectal cancer. Please look at the screening tests below and select the test you prefer by clicking the button below this test.

How do you need to prepare?
Before the test you need to take laxatives which cause diarrhoea to empty your colon.

How is the test done?
A short flexible tube with a small camera is inserted through the anus into the last part of the colon. This test is done at a hospital.

How many out of 10 people with cancer, would the test correctly identify?
7 out of 10

How many out of 10 people without cancer, would the test correctly identify?
7 out of 10

How many out of 10,000 people who take this test have a complication?
None

How often do you need to take the test?
Every 5 years

For 3 days you need to alter your diet and medication. Before the test you need to take enemas which cause diarrhoea to empty your colon.

A long flexible tube with a small camera is inserted through the anus into the full colon. During the examination you will be sedated. This test is done at a hospital.

How many out of 10 people with cancer, would the test correctly identify?
8 out of 10

How many out of 10 people without cancer, would the test correctly identify?
10 out of 10

How many out of 10,000 people who take this test have a complication?
10 out of 10,000

How often do you need to take the test?
Every year

You need to swallow a pill that leaves your body through faeces after several hours. Your test results are wirelessly sent to your physician. This test is done at home.

How many out of 10 people with cancer, would the test correctly identify?
9 out of 10

How many out of 10 people without cancer, would the test correctly identify?
9 out of 10

How many out of 10,000 people who take this test have a complication?
10 out of 10,000

How often do you need to take the test?
Every 10 years

If you could choose between the test you chose or not to be screened for colorectal cancer, what would you prefer?

- I would still prefer the test I chose above
- I would prefer not to be screened
Study sample n=884

UK
- 1100 invited
- 870 responded (79%)
- 15 excluded (2%)
- 855 eligible (98%)
- 92 incomplete (11%)
- 179 inconsistent (23%)
- 763 complete (89%)

NL
- 1125 invited
- 779 responded (69%)
- 16 excluded (2%)
- 763 eligible (98%)
- 593 complete (78%)
- 170 incomplete (22%)
- 293 inconsistent (49%)
- 300 consistent (51%)
Importance of test characteristics

- Preparation
- Technique
- Sensitivity
## Nanopill vs. IFOBT

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<th>nanopill</th>
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<td>Stool</td>
<td>Take stool sample</td>
</tr>
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<td><strong>Sensitivity</strong></td>
<td>80%</td>
<td>?</td>
</tr>
<tr>
<td><strong>Specificity</strong></td>
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<td>?</td>
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## Nanopill vs. IFOBT BASECASE

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Preferences for Screening Method
Current Gaps: The potential of increasing sensitivity?

Sensitivity: Needs to be 100% to have equal preference share
Current Gaps: The potential of increasing specificity?

Even with 100% specificity higher preference for nanopill
Potential for improvement

“Fixed” Attributes

“Unknown” Attributes
Method: discrete choice experiment

- Literature on early stage consumer research and new product development:
  - Better understanding consumer needs (Van Kleef et al. 2004)
  - Quality improvement of products and services (Garmer et al. 2004)
  - Reduced time to market, prevent wasting of resources on inappropriate prototype (Martin et al. 2011)
  - Preferences for not yet available services or technologies can be estimated. Optimize screening uptake (Marshall et al. 2007)
Discussion & Conclusion

- No costs included in early assessment
- Difference iFOBT and nanopill is small
- Nanopill needs to show improved adherence to screening, better test performance and more efficient screening process to increase potential in bowel cancer screening
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- Dr. Lotte Steuten
- Dr. Marjan Hummel
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