

EUnetHTA Core Model Questionnaire

Appendix 5

Unimportant Elements

(≥ 3 out of 5 Countries w/o Canada)



Overall Unimportant Elements for at least 3 Countries (w/o Canada)

4 = very important
 3 = somewhat important
 2 = somewhat unimportant
 1 = very unimportant
 u = uncertain

2. Description and technical characteristics of technology

Training and information needed to use the technology

| ID | Assessment Element | Count Countries | F | D | I | NL | UK |
|-------|---|-----------------|---|---|---|----|----|
| B0012 | What kind of qualification and quality assurance processes are needed for the use or maintenance of the technology? | 4 | 4 | 2 | 2 | 1 | 2 |
| B0015 | What information of the technology should be provided for patients outside the target group and the general public? | 4 | 1 | 2 | u | 1 | 2 |

3. Safety

Environmental safety

| ID | Assessment Element | Count Countries | F | D | I | NL | UK |
|-------|--|-----------------|---|---|---|----|----|
| C0040 | What kind of risks for public and environment may occur when using the technology? | 5 | 2 | 2 | 2 | 1 | 2 |

3. Safety

Safety risk management

| ID | Assessment Element | Count Countries | F | D | I | NL | UK |
|-------|--|-----------------|---|---|---|----|----|
| C0063 | How can one reduce safety risks for professionals (including technology-, user-, and patient-dependent aspects)? | 3 | 3 | 2 | u | 1 | 2 |
| C0064 | How can one reduce safety risks for environment (including technology-, user-, and patient-dependent aspects)? | 3 | 1 | 3 | u | 1 | 2 |

4. Clinical Effectiveness

Mortality

| ID | Assessment Element | Count Countries | F | D | I | NL | UK |
|-------|--|-----------------|---|---|---|----|----|
| D0003 | What is the effect of the technology on the mortality due to causes other than the target disease? | 3 | 2 | 3 | 1 | 1 | 3 |

4. Clinical Effectiveness

Patient satisfaction

| ID | Assessment Element | Count Countries | F | D | I | NL | UK |
|-------|---|-----------------|---|---|---|----|----|
| D0017 | Was the use of the technology worthwhile? | 3 | 2 | 3 | 1 | 1 | 4 |

6. Ethical Analysis

Autonomy

| ID | Assessment Element | Count Countries | F | D | I | NL | UK |
|-------|---|-----------------|---|---|---|----|----|
| F0007 | Does the implementation or withdrawal of the technology challenge or change professional values, ethics or traditional roles? | 3 | 1 | 3 | 2 | 3 | 1 |

6. Ethical Analysis

Respect for persons

| ID | Assessment Element | Count Countries | F | D | I | NL | UK |
|-------|--|-----------------|---|---|---|----|----|
| F0009 | Does the implementation or use of the technology affect the user's moral, religious or cultural integrity? | 3 | 1 | 2 | u | 1 | 3 |

6. Ethical Analysis

Justice and Equity

| ID | Assessment Element | Count Countries | F | D | I | NL | UK |
|-------|---|-----------------|---|---|---|----|----|
| F0013 | How are technologies with similar ethical issues treated in the health care system? | 3 | 2 | 3 | 2 | 1 | 3 |

7. Organizational aspects

Health delivery process

| ID | Assessment Element | Count Countries | F | D | I | NL | UK |
|-------|---|-----------------|---|---|---|----|----|
| G0012 | How is the quality assurance and monitoring system of the new technology organized? | 3 | 2 | 3 | 4 | 2 | 2 |

7. Organizational aspects

Structure of health care

| ID | Assessment Element | Count Countries | F | D | I | NL | UK |
|-------|--|-----------------|---|---|---|----|----|
| G0005 | How do decentralization or centralization requirements influence the implementation of the technology? | 3 | 2 | 2 | 4 | 4 | 2 |

8. Social aspects

Individual

| ID | Assessment Element | Count Countries | F | D | I | NL | UK |
|-------|--|-----------------|---|---|---|----|----|
| H0100 | What kind of changes do patients or citizens expect? | 3 | 1 | 3 | 3 | 1 | 2 |

8. Social aspects

Major life areas

| ID | Assessment Element | Count Countries | F | D | I | NL | UK |
|-------|---|-----------------|---|---|---|----|----|
| H0011 | What kinds of reactions and consequences can the introduction of the technology cause at the overall society level? | 3 | 1 | 2 | 4 | 1 | 4 |

8. Social aspects

Information exchange

| ID | Assessment Element | Count Countries | F | D | I | NL | UK |
|-------|---|-----------------|---|---|---|----|----|
| H0007 | What is the knowledge and understanding of the technology in patients and citizens? | 3 | u | 2 | 2 | 4 | 2 |
| H0013 | What are the social obstacles or prospects in the communication about the technology? | 5 | 1 | 2 | 2 | 1 | 2 |

9. Legal aspects

Autonomy of the patient

| ID | Assessment Element | Count Countries | F | D | I | NL | UK |
|-------|---|-----------------|---|---|---|----|----|
| I0002 | What kind of legal requirements are there for providing appropriate information to the user or patient? | 3 | 1 | 3 | 2 | 4 | 2 |
| I0005 | What kind of legal requirements are there to obtain informed consent from the user or patient? | 3 | 1 | 3 | 2 | 4 | 2 |
| I0034 | Who is allowed to give consent for minors and incompetent persons? | 3 | 1 | 3 | 2 | 4 | 2 |

9. Legal aspects

Privacy of the patient

| ID | Assessment Element | Count Countries | F | D | I | NL | UK |
|-------|--|-----------------|---|---|---|----|----|
| I0009 | What do laws/ binding rules require from appropriate measures for securing patient data? | 3 | 1 | 3 | 2 | 4 | 2 |

9. Legal aspects

Ownership and liability

| ID | Assessment Element | Count | F | D | I | NL | UK |
|----|--------------------|-------|---|---|---|----|----|
|----|--------------------|-------|---|---|---|----|----|

| | | Countries | | | | | |
|-------|--|-----------|---|---|---|---|---|
| I0019 | What should be known about the intellectual property rights and potential licensing fees? | 3 | 1 | 2 | 3 | 4 | 2 |
| I0021 | What should be known of the legal or binding rules about the width, depth and length of the manufacturers guarantee? | 4 | 1 | 2 | 2 | 4 | 2 |

9. Legal aspects

Regulation of the market

| ID | Assessment Element | Count Countries | F | D | I | NL | UK |
|-------|--|-----------------|---|---|---|----|----|
| I0024 | What kind of regulations are there for acquisition and use of the technology? | 3 | 2 | 3 | 2 | 4 | 2 |
| I0025 | What legal restrictions are there for marketing the technology to the patients? | 4 | 1 | 2 | 2 | 4 | 1 |
| I0026 | What should be known about the legal issues in cases of new technologies where the current legislation is not directly applicable? | 3 | 1 | 2 | 3 | 4 | 1 |
| I0027 | Are there relevant concerns of conflicts of interest concerning the preparation of binding rules and their implementation? | 3 | 4 | 2 | 2 | u | 2 |