

EUnetHTA Core Model Questionnaire
Appendix 4
Important Elements
(≥ 4 out of 5 Countries w/o Canada)



Overall Important Elements for at least 4 Countries (w/o Canada)

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

1. Health Problem and Current Use of the Technology

Target population

ID	Assessment Element	Count Countries	F	D	I	NL	UK
A0007	What is the target population in this current assessment of the technology?	5	4	4	4	4	4
A0023	How many people belong to the target population?	5	4	4	4	4	3

1. Health Problem and Current Use of the Technology

Target condition

ID	Assessment Element	Count Countries	F	D	I	NL	UK
A0002	What is the disease or health condition in the scope of this assessment?	5	4	3	4	4	4
A0003	What are the known risk factors for the disease or health condition?	4	3	4	4	4	1
A0004	What is the natural course of the disease or health condition?	5	4	3	4	4	3
A0005	What are the symptoms and burden of disease for the patient at different stages of the disease?	5	4	4	4	4	4
A0006	What are the consequences of the disease or the health condition for the society (i.e. the burden of the disease)?	5	4	4	3	4	3
A0009	What aspects of the consequences / burden of disease are targeted by the technology?	5	4	4	4	4	4

1. Health Problem and Current Use of the Technology

Current management of the condition

ID	Assessment Element	Count Countries	F	D	I	NL	UK
A0017	What are the differences in the management for different stages of the disease or health condition?	5	4	4	4	4	3
A0018	What are the other typical or common alternatives to the current technology?	5	4	3	4	4	4
A0024	How is the disease or health condition currently diagnosed according to published guidelines and in practice?	4	4	3	4	4	1
A0025	How is the disease or health condition currently	5	4	4	4	4	3

managed according to published guidelines and in practice?

1. Health Problem and Current Use of the Technology

Utilization

ID	Assessment Element	Count Countries	F	D	I	NL	UK
A0001	For which health conditions and for what purposes is the technology used?	5	4	4	4	4	4
A0011	How much is the technology utilized currently and in the future?	5	4	3	4	4	3
B0003	What is the phase of development and implementation of the technology and the comparator(s)?	4	4	2	3	4	3
F0001	Is the technology a new, innovative mode of care, an add-on to or modification of a standard mode of care or replacement of a standard mode of care?	5	4	3	4	4	3

1. Health Problem and Current Use of the Technology

Regulatory status

ID	Assessment Element	Count Countries	F	D	I	NL	UK
A0020	What is the marketing authorization status of the technology?	5	4	4	4	4	4
A0021	What is the reimbursement status of the technology across countries?	5	4	3	4	4	3

2. Description and technical characteristics of technology

Features of the technology

ID	Assessment Element	Count Countries	F	D	I	NL	UK
B0001	What are this technology and the comparator(s)?	5	4	3	4	4	4
B0002	What is the approved indication and claimed benefit of the technology and the comparator(s)?	5	4	4	4	4	4
B0003b	What is the phase of development and implementation of the technology and the comparator(s)?	4	4	2	4	4	3
B0004	Who performs or administers the technology and the comparator(s)?	5	3	3	4	3	4
B0005	In what context and level of care are the technology and the comparator used?	5	3	3	4	3	4

2. Description and technical characteristics of technology

Investments and tools required to use the technology

ID	Assessment Element	Count Countries	F	D	I	NL	UK
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B0009	What equipment and supplies are needed to use the technology and the comparator?	5	4	3	3	3	3
B0010	What kind of data and records are needed to monitor the use of the technology and the comparator?	4	3	3	4	3	2
B0011	What kinds of registers are needed to monitor the use of the technology and comparator?	5	3	3	4	4	3

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
B0013	What kind of training and information is needed for the personnel/carer using this technology?	4	3	3	3	3	2

2. Description and technical characteristics of technology

Other

ID	Assessment Element	Count Countries	F	D	I	NL	UK
A0022	Who manufactures the technology?	5	4	3	4	4	4

3. Safety

Patient safety

ID	Assessment Element	Count Countries	F	D	I	NL	UK
C0001	What kind of harms can use of the technology cause to the patient; what are the incidence, severity and duration of harms?	5	4	4	4	4	4
C0002	Are the harms related to dosage or frequency of applying the technology?	5	4	3	4	4	4
C0004	How does the frequency or severity of harms change over time or in different settings?	4	4	3	u	4	3
C0005	Are there susceptible patient groups that are more likely to be harmed through use of the technology?	4	2	4	4	4	4
C0007	Are there special issues in the use of the technology that may increase the risk of harmful events?	4	4	3	4	2	3
C0008	How safe is the technology in relation to the comparator(s)?	5	4	4	4	4	4

4. Clinical Effectiveness

Function

ID	Assessment Element	Count Countries	F	D	I	NL	UK
D0011	What is the effect of the technology on patients?	5	4	4	3	4	4

	body functions?						
D0014	What is the effect of the technology on work ability?	4	4	3	3	2	3
D0015	What is the effect of the technology on return to previous living conditions?	5	4	3	3	4	3
D0016	How does use of the technology affect activities of daily living?	5	4	3	3	4	4

4. Clinical Effectiveness

Health-related Quality of life

ID	Assessment Element	Count Countries	F	D	I	NL	UK
D0012	What is the effect of the technology on generic health-related quality of life?	5	4	4	4	4	4
D0013	What is the effect of the technology on disease specific quality of life?	5	4	4	3	4	4

4. Clinical Effectiveness

Benefit-harm balance

ID	Assessment Element	Count Countries	F	D	I	NL	UK
D0029	What are the overall benefits and harms of the technology in health outcomes?	4	4	4	2	4	4

4. Clinical Effectiveness

Mortality

ID	Assessment Element	Count Countries	F	D	I	NL	UK
D0001	What is the expected beneficial effect of the intervention on overall mortality?	5	3	4	4	4	4
D0002	What is the expected beneficial effect on the disease-specific mortality?	5	4	3	3	3	4

4. Clinical Effectiveness

Morbidity

ID	Assessment Element	Count Countries	F	D	I	NL	UK
D0005	How does the technology affect symptoms and findings (severity, frequency) of the target condition?	5	4	4	4	4	4
D0006	How does the technology affect the progression (or recurrence) of the target condition?	5	4	3	4	4	4

4. Clinical Effectiveness

Change-in management

ID	Assessment Element	Count Countries	F	D	I	NL	UK
D0010	How does the technology modify the need for hospitalization?	5	4	3	3	3	3
D0023	How does the technology modify the need for other technologies and use of resources?	4	4	3	2	3	4

5. Costs and economic evaluation

Resource utilization

ID	Assessment Element	Count Countries	F	D	I	NL	UK
E0001	What types of resources are used when delivering the assessed technology and its comparators (resource-use identification)?	5	4	3	3	4	4
E0002	What amounts of resources are used when delivering the assessed technology and its comparators (resource-use measurement)?	5	4	3	3	4	4
E0009	What were the measured and/or estimated costs of the assessed technology and its comparator(s) (resource-use valuation)?	4	4	4	4	1	4

5. Costs and economic evaluation

Measurement and estimation of outcome(s)

ID	Assessment Element	Count Countries	F	D	I	NL	UK
E0005	What is (are) the measured and/or estimated health-related outcome(s) of the assessed technology and its comparator(s)?	4	4	2	3	4	4

5. Costs and economic evaluation

Examination of costs and outcomes

ID	Assessment Element	Count Countries	F	D	I	NL	UK
E0006	What are the estimated differences in costs and outcomes between the technology and its comparator(s)?	5	4	3	3	4	4

5. Costs and economic evaluation

Characterizing uncertainty

ID	Assessment Element	Count Countries	F	D	I	NL	UK
E0010	What are the uncertainties surrounding the costs and economic evaluation(s) of the technology and its comparator(s)?	4	4	2	3	4	4

5. Costs and economic evaluation

Characterizing heterogeneity

ID	Assessment Element	Count Countries	F	D	I	NL	UK
E0011	To what extent can differences in costs, outcomes, or 'cost effectiveness' be explained by variations between any subgroups using the technology and its comparator(s)?	4	4	2	3	3	4

5. Costs and economic evaluation

Validity of the model(s)

ID	Assessment Element	Count Countries	F	D	I	NL	UK
E0012	To what extent can the estimates of costs and outcomes or from economic evaluation(s) be considered as providing valid descriptions of the technology and its comparator(s)?	4	4	2	3	4	4

6. Ethical Analysis

Beneficence/nonmaleficence

ID	Assessment Element	Count Countries	F	D	I	NL	UK
F0100	What is the severity level of the health condition that the technology is directed to?	4	3	3	4	4	1
F0010	What are the known and estimated benefits and harms for patients when implementing or not implementing the technology?	4	4	4	3	4	u

6. Ethical Analysis

Autonomy

ID	Assessment Element	Count Countries	F	D	I	NL	UK
F0004	Does the implementation or use of the technology affect the patient's capability and possibility to exercise autonomy?	4	3	3	4	3	1

6. Ethical Analysis

Justice and Equity

ID	Assessment Element	Count Countries	F	D	I	NL	UK
H0012	Are there factors that could prevent a group or person from gaining access to the technology?	4	4	3	4	1	3

6. Ethical Analysis

Ethical consequences of the HTA

ID	Assessment Element	Count Countries	F	D	I	NL	UK
F0017	What are the ethical consequences of the choice of endpoints, cut-off values and comparators/controls in the assessment?	5	3	4	4	4	3

7. Organizational aspects

Health delivery process

ID	Assessment Element	Count Countries	F	D	I	NL	UK
G0001	How does the technology affect the current work processes?	4	3	2	4	4	3
G0100	What kind of patient/participant flow is associated with the new technology?	5	3	3	3	4	3

7. Organizational aspects

Structure of health care system

ID	Assessment Element	Count Countries	F	D	I	NL	UK
G0101	What are the processes ensuring access to care of the new technology for patients/participants?	4	2	3	4	4	4

7. Organizational aspects

Process-related costs

ID	Assessment Element	Count Countries	F	D	I	NL	UK
G0006	What are the processes related costs for purchasing and setting up the new technology?	4	3	3	4	4	2
G0007	What are the likely budget impacts of implementing the technologies being compared?	5	4	4	4	4	3

7. Organizational aspects

Management

ID	Assessment Element	Count Countries	F	D	I	NL	UK
G0009b	Who decides which people are eligible for the technology and on what basis?	5	4	3	4	4	4

7. Organizational aspects

Culture

ID	Assessment Element	Count Countries	F	D	I	NL	UK
G0011	How are the other interest groups taken into account in the planning / implementation of the technology?	4	3	3	3	4	2

8. Social aspects

Individual

ID	Assessment Element	Count Countries	F	D	I	NL	UK
H0002	Who are the important others that may be affected in addition to the individual using the technology?	4	3	2	3	4	3
H0003	What kind of support and resources are needed for the patient or citizen as the technology is introduced?	4	4	3	3	4	1
H0004	What kind of changes may the use of the technology generate in the individual's role in the major life areas?	4	3	3	4	u	4
H0012b	Are there factors that could prevent a group or persons to participate?	4	1	3	3	4	4

9. Legal aspects

Equality in health care

ID	Assessment Element	Count Countries	F	D	I	NL	UK
I0012	What are the consequences of various EU level and national regulations to the equal access to the technology?	4	2	3	3	4	3

9. Legal aspects

Authorization and safety

ID	Assessment Element	Count Countries	F	D	I	NL	UK
I0015	What authorizations and register listings does the technology have?	5	3	3	3	4	4
I0017	What are the legal requirements for safety of the technology and are they fulfilled in practice?	4	3	4	4	4	2