

**EUnetHTA Core Model Questionnaire
Appendix 3 –October 2014**

*Overall Important Elements
(≥ 4 out of 5 Countries) that are
Overall Transferable
(≥ 4 out of 5 Countries)
w/o Canada*



Overall Important Elements for at least 4 Countries that are Overall Transferable for at least 4 Countries w/o Canada

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	Importance
		4	x	0	x	x	x	Transferable

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	Importance
		5	x	x	x	x	x	Transferable
A0003	What are the known risk factors for the disease or health condition?	4	3	4	4	4	1	Importance
		5	x	x	x	x	x	Transferable
A0004	What is the natural course of the disease or health condition?	5	4	3	4	4	3	Importance
		5	x	x	x	x	x	Transferable
A0005	What are the symptoms and burden of disease for the patient at different stages of the disease?	5	4	4	4	4	4	Importance
		4	x	x	x	0	x	Transferable
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	Importance
		4	x	x	x	0	x	Transferable
A0009	What aspects of the consequences / burden of disease are targeted by the technology?	5	4	4	4	4	4	Importance
		5	x	x	x	x	x	Transferable

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	Importance
		4	x	x	x	0	x	Transferable
A0018	What are the other typical or common alternatives to the current technology?	5	4	3	4	4	4	Importance
		4	x	x	x	0	x	Transferable
A0024	How is the disease or health condition	4	4	3	4	4	1	Importance

currently diagnosed according to published guidelines and in practice?	4	x	x	x	0	x	Transferable
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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	Importance
		5	x	x	x	x	x	Transferable
A0021	What is the reimbursement status of the technology across countries?	5	4	3	4	4	3	Importance
		4	x	x	x	0	x	Transferable

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	Importance
		4	x	x	x	0	x	Transferable
B0002	What is the approved indication and claimed benefit of the technology and the comparator(s)?	5	4	4	4	4	4	Importance
		4	x	0	x	x	x	Transferable
B0003b	What is the phase of development and implementation of the technology and the comparator(s)?	4	4	2	4	4	3	Importance
		4	x	0	x	x	x	Transferable
B0004	Who performs or administers the technology and the comparator(s)?	5	3	3	4	3	4	Importance
		4	x	0	x	x	x	Transferable
B0005	In what context and level of care are the technology and the comparator used?	5	3	3	4	3	4	Importance
		4	x	0	x	x	x	Transferable

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	
B0011	What kinds of registers are needed to monitor the use of the technology and comparator?	5	3	3	4	4	3	Importance
		4	x	x	x	0	x	Transferable

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	Importance
		5	x	x	x	x	x	Transferable

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	Importance
		5	x	x	x	x	x	Transferable
C0002	Are the harms related to dosage or frequency of applying the technology?	5	4	3	4	4	4	Importance
		5	x	x	x	x	x	Transferable
C0004	How does the frequency or severity of harms change over time or in different settings?	4	4	3	u	4	3	Importance
		5	x	x	x	x	x	Transferable
C0005	Are there susceptible patient groups that are more likely to be harmed through use of the technology?	4	2	4	4	4	4	Importance
		5	x	x	x	x	x	Transferable
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	Importance
		4	x	0	x	x	x	Transferable
C0008	How safe is the technology in relation to the comparator(s)?	5	4	4	4	4	4	Importance
		5	x	x	x	x	x	Transferable

4. Clinical Effectiveness

Function

ID	Assessment Element	Count Countries	F	D	I	NL	UK	
D0011	What is the effect of the technology on patients' body functions?	5	4	4	3	4	4	Importance
		5	x	x	x	x	x	Transferable
D0016	How does use of the technology affect activities of daily living?	5	4	3	3	4	4	Importance
		5	x	x	x	x	x	Transferable

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	Importance
		5	x	x	x	x	x	Transferable
D0013	What is the effect of the technology on disease specific quality of life?	5	4	4	3	4	4	Importance
		5	x	x	x	x	x	Transferable

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	Importance
		5	x	x	x	x	x	Transferable
D0002	What is the expected beneficial effect on the disease-specific mortality?	5	4	3	3	3	4	Importance
		4	x	0	x	x	x	Transferable

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	Importance
		5	x	x	x	x	x	Transferable
D0006	How does the technology affect the progression (or recurrence) of the target condition?	5	4	3	4	4	4	Importance
		5	x	x	x	x	x	Transferable

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	Importance
		4	x	0	x	x	x	Transferable

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	Importance
		4	x	x	x	0	x	Transferable

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	Importance
		5	x	x	x	x	x	Transferable

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	Importance
		4	0	x	x	x	x	Transferable

9. Legal aspects

Authorization and safety

ID	Assessment Element	Count Countries	F	D	I	NL	UK	
I0017	What are the legal requirements for safety of the technology and are they fulfilled in practice?	4	3	4	4	4	2	Importance
		5	x	x	x	x	x	Transferable