eunethta

HTA Core Model® Online

Assessment element tables

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Assessment element tables of *HTA Core Model Application for Medical and Surgical Interventions (1.1)*

Contents

1 Health Problem and Current Use of the Technology

ID	Topic	Issue	Clarification	Im.	Tr.	Information sources	Reference	Relations	Core
A0001	Target Condition	Which disease/health problem/potential health problem will the technology be used for?	Definition (naming) of the condition, health problem, disease for which the technology is intended.	3	3	Medical literature, at the best systematic reviews on mechanism of disease, risk factors, course and prognosis. Developers/ manufacturers view on the potential targets and what they expect/claim from the technology.	Burls et al. 2001, Busse et al. 2002, Liberati et al. 1973 Imaz-Iglesia et al. 1998, Kristensen et al. 2009		Yes
A0002	Target Condition	What, if any, is the precise definition/ characterization of the target disease? Which diagnosis is given to the condition and according to which classification system (e.g. ICD-10)?	Characteristics of the condition which allow a precise diagnostic and differentiation of the indication for the use of the technology	3	3	Medical literature, at the best systematic reviews on mechanism of disease, risk factors, course and prognosis.	Burls et al. 2001, Busse et al. 2002, Liberati et al. 1973 Imaz-Iglesia et al. 1998, Kristensen et al. 2009	Choice of "Patient" component of the PICO for effectiveness assessment Subgroups or indications are also considered under Clinical Effectiveness	Yes
A0003	Target Condition	Which are the known risk factors for acquiring the condition?		2	2	Medical literature, at the best systematic reviews on mechanism of disease, risk factors, course and prognosis.	Burls et al. 2001, Busse et al. 2002, Liberati et al. 1973 Imaz-Iglesia et al. 1998, Kristensen et al. 2009	Identification of alternative (i. e. preventive) approaches	Yes
A0004	Target Condition	What is the natural course of the condition?	For example stages of the disease which can be object of different interventions.	3	3	Medical literature, at the best systematic reviews on mechanism of disease, risk factors, course and prognosis.	Burls et al. 2001, Busse et al. 2002, Liberati et al. 1973 Imaz-Iglesia et al. 1998, Kristensen et al. 2009	Choice of outcome parameter for effectiveness assessment (PICO). Disease path can be used to construct economic models	Yes
A0005	Target Condition	What are the symptoms of the disease?		2	3	Medical literature, at the best systematic reviews on mechanism of disease, risk factors, course and prognosis.	Burls et al. 2001, Busse et al. 2002, Liberati et al. 1973 Imaz-Iglesia et al. 1998,	Choice of outcome component of the PICO for effectiveness assessment.	Yes

ID	Topic	Issue	Clarification	Im.	Tr.	Information sources	Reference	Relations	Core
							Kristensen et al. 2009		
A0006	Target Condition	What are the consequences of the condition?	Qualitative description of the burden of disease for the individual (e.g. disability, pain)	3	2	Medical literature, at the best systematic reviews on mechanism of disease, risk factors, course and prognosis.	Burls et al. 2001, Busse et al. 2002, Liberati et al. 1973 Imaz-Iglesia et al. 1998, Kristensen et al. 2009	Choice of outcome parameter for effectiveness assessment (PICO). Disease path can be used to construct economic models	Yes
A0007	Target Condition	How many people belong at the moment (will belong) to the specific target group (describe according to sex, age)?	Incidence and/or prevalence of the target condition or the indication for use of the technology	3	1	Systematic reviews of epidemiological studies such as cross-sectional Studies (prevalence), cohort studies (incidence), routine statistics. Own analysis of: Disease register, administrative databases (discharge databases, reimbursement claims databases)	Burls et al. 2001, Busse et al. 2002, Liberati et al. 1973 Imaz-Iglesia et al. 1998, Kristensen et al. 2009	Data can be used when constructing models, however only if they are really generalisable/transferable	Yes
A0008	Target Condition	What is the burden of disease (mortality, disability, life years lost)?	Disease-specific mortality. Prevalence of disability or disabling symptoms caused by the condition. Prevalence/Incidence of early retirement due to the condition	3	2	Systematic reviews of epidemiological studies such as cross-sectional Studies (prevalence), cohort studies (incidence), routine statistics. Own analysis of: Disease register, administrative databases (discharge databases, reimbursement claims databases)	Burls et al. 2001, Busse et al. 2002, Liberati et al. 1973 Imaz-Iglesia et al. 1998, Kristensen et al. 2009	Data can be used when constructing models, however only if they are really generalisable/transferable	Yes
A0009	Target Condition	What aspects of the burden of disease are targeted by the technology, i.e. are expected to be reduced by the technology?	The application of the technology may target only one aspect of the burden of disease, eg. disability but not mortality. Or mortality but not symptomatligy	3	3				Yes
A0011	Utilisation	How much is the technology being used?		2	1	Utilisation reviews, audits,studies on praxis-variation. Own primary analysis of: Disease register, procedure	Burls et al. 2001, Busse et al. 2002, Liberati et al. 1973		No

ID	Topic	Issue	Clarification	Im.	Tr.	Information sources	Reference	Relations	Core
						register, device register, administrative data (DRG, dicharge databases, reimbursement claims database).	Imaz-Iglesia et al. 1998, Kristensen et al. 2009		
A0012	Utilisation	Describe the variations in use across countries/regions/settings, if any?		2	2	Utilisation reviews, audits,studies on praxis-variation. Own primary analysis of: Disease register, procedure register, device register, administrative data (DRG, dicharge databases, reimbursement claims database).	Burls et al. 2001, Busse et al. 2002, Liberati et al. 1973 Imaz-Iglesia et al. 1998, Kristensen et al. 2009		Yes
A0013	Current Management of the Condition	How is the disease/health condition currently being diagnosed?	Self-explaining.	3	1	Surveys, utilisation reviews. If such information is lacking: Expert surveys / expert interviews		Findings can be used to assess whether technology could add anything in the managament of the disease. Findings can be used when constructing CE-Models comparing to alternatives. Different diagnostic techniques are applied by different professional groups, thus this item is also relevant for organisational domain.	Yes
A0014	Current Management of the Condition	According to published algorithms/guidelines (if any), how should the condition be diagnosed?	Asssessment of this allows to draw conclusions on how far the current management is optimal.	3	2	Clinical guidelines, recommendations, appraising their quality with for example AGREE Instrument. If such information is lacking: expert surveys / expert interviews, textbooks.		Findings can be used to assess whether the technology could add anything in the managament of the disease.	Yes
A0015	Current Management of the Condition	How is the disease/health condition currently being managed?		3	1	Surveys, utilisation reviews. If such information is lacking: Expert surveys / expert interviews	Burls et al. 2001, Busse et al. 2002, Liberati et al. 1973 Imaz-Iglesia et al. 1998, Kristensen et al. 2009	Findings can be used to assess whether technology could add anything in the managament of the disease. Findings can be used when constructing CE-Models comparing to alternatives	Yes
A0016	Current Management of the	According to published algorithms/guidelines (if any), how should the condition be managed?	Asssessment of this allows to draw conclusions on how far the current management	3	2	Clinical Guidelines, recommendations. If such information is lacking: Expert	Burls et al. 2001, Busse et al. 2002, Liberati et	Findings can be used to assess whether the technology could add anything in the managament of the disease.	Yes

ID	Topic	Issue	Clarification	Im.	Tr.	Information sources	Reference	Relations	Core
	Condition		is optimal.			surveys / expert interviews, textbooks.	al. 1973 Imaz-Iglesia et al. 1998, Kristensen et al. 2009		
A0017	Current Management of the Condition	What are the differences in the management for different stages of disease, if any?	Identification of practice variations which point out differences in the quality of health care	2	2	Surveys, utilisation reviews, clinical guidelines, recommendations. If such information is lacking: Expert surveys / expert interviews	Burls et al. 2001, Busse et al. 2002, Liberati et al. 1973 Imaz-Iglesia et al. 1998, Kristensen et al. 2009		Yes
A0018	Current Management of the Condition	What are the other evidence-based alternatives to the current technology, if any?		3	2	Clinical guidelines, recommendations, systematic reviews	Burls et al. 2001, Busse et al. 2002, Liberati et al. 1973 Imaz-Iglesia et al. 1998, Kristensen et al. 2009	Choice of comparator for effectiveness assessment (PICO) Choice of comparator for cost-effectiveness assessment	Yes
A0019	Life-Cycle	In which phase is the development of the technology (experimental, emerging, routine use, obsolete)?	This is related to the question whether there is enough evidence or experiences on the use of the technology on the condition.	3	2	Horizon scanning databases, ongoing research databases. Information from manufacturers.	Burls et al. 2001, Busse et al. 2002, Liberati et al. 1973 Imaz-Iglesia et al. 1998, Kristensen et al. 2009	Status determines the kind of information which can be expected on other domains (specially in long-term safety, effectiveness). Uncertainity grade	Yes
A0020	Regulatory Status	Which approval status has the technology in other countries, or international authorities?		3	3	Drugs: EMEA, FDA, National Authorities. Devices: CE-Approval, National Authorities. Manufacturers should be contacted in order to identify which steps have they taken/ are they planning to take concerning Market-Approval	Burls et al. 2001, Busse et al. 2002, Liberati et al. 1973 Imaz-Iglesia et al. 1998, Kristensen et al. 2009	Legal Domain	Yes
A0021	Regulatory Status	Has the technology been included in / excluded from the benefit basket of any country? How is the coverage of the technology across countries? (e.g.	Are there co-payments, to what extent?	2	3	Lists of benefits / services of the National Health Services / Sickness Funds, inquiry of technical officers from MoH.	Burls et al. 2001, Busse et al. 2002, Liberati et al. 1973	Legal Domain	Yes

ID	Topic	Issue	Clarification	Im.	Tr.	Information sources	Reference	Relations	Core
		full-coverage, co-payments, coverage under special circumstances/conditional coverage?)				Manufacturers. Literature on Benefit Basket (Comparative policy studies)	Imaz-Iglesia et al. 1998, Kristensen et al. 2009		
A0022	Other	Who manufactures the technology?		2	2		Burls et al. 2001, Busse et al. 2002, Liberati et al. 1973 Imaz-Iglesia et al. 1998, Kristensen et al. 2009	Related to Organisational or Social domain	Yes

2 Description and technical characteristics of technology

ID	Topic	Issue	Clarification	Im.	Tr.	Information sources	Reference	Relations	Core
B0001	Features of the technology	What is this technology?	Provide a short technical description: Type of device, operation, imaging, etc. Biological rationale and mechanism of action of the technology.	3	3	Manufacturer, effectiveness studies, clinical experts, studies in basic science, textbooks		Current use	Yes
B0002	Features of the technology	Why is this technology used?	Describe the aim of using the technology: How is it expected to be an improvement as compared to previous technologies used for the same health problem?	3	2	Manufacturer, effectiveness studies, clinical experts		Current use	Yes
B0003	Features of the technology	Phase of the technology: When was it developed or introduced in health care?	Is it a truly novel one, or has it been used earlier for this or some other purpose? Is the technology fully developed or in its early stages? Most technologies will be introduced at approximately the same time in several countries. If an HTA has been done more than a few months before using it, the technology might have been studied in more detail and moved into another phase (with more published trials, for example).	3	2	Manufacturer, effectiveness studies		Current use. Effectiveness	Yes
B0004	Features of the technology	Who will apply this technology?	What types of professionals (nurses, doctors, other professionals) or patients (all with a certain disease, narrowly defined groups) will be using this technology?	3	2	Manufacturer, effectiveness studies, clinical experts, legislation. National or local judgement		Current use, Organisational	Yes
B0005	Features of the technology	What is the place and context for utilising the technology	At which level(s) of health care (self-care, primary, secondary, tertiary) will the technology be used?	3	1	Manufacturer, effectiveness studies, clinical experts, legislation. National or local judgement		Current use, Organisational	Yes
B0006	Features of the technology	Are there any special features relevant to this technology?	Any points where this technology is different from its predecessors (other technologies used for similar purposes); new aspects that need to be considered when applying it.	3	2	Manufacturer, effectiveness studies, clinical experts		Effectiveness, Safety	Yes
B0007	Investments and tools required to use the technology	What material investments are needed to use the technology?	Devices, machinery, computer programs, etc. Those parts of the technology that need to be purchased (and often installed) by an organization in order to use the technology. Includes need for back-up investment to cover for breakdowns in use.	3	2	Manufacturer, applicability studies, clinical experts, user information. National or local judgement		Current use, Organisational	Yes
B0008	Investments and tools required to use the technology	What kind of special premises are needed to use the technology?	Many technologies require purpose-built premises within organizations, such as radiation-secured areas, Faraday cages, etc. Typical premises in primary or secondary care may differ markedly from country to country. A clear description of necessary facilities, training etc. is needed instead of lump statement (e.g. to be used in hospitals only)	3	2	Manufacturer, applicability studies, clinical experts, user information. National or local judgement		Current use Organisational, Legal	Yes
B0009	Investments and tools required to use the	What equipment and supplies are needed to use the technology?	Syringes, needles, medicines, fluids, bandages etc. All disposable items necessary for using the technology	3	3	Manufacturer, applicability studies, clinical experts, user information. National or local		Current use	Yes

ID	Topic	Issue	Clarification	Im.	Tr.	Information sources	Reference	Relations	Core
	technology					judgement			
B0010	Investments and tools required to use the technology	What kind of data and records are needed to monitor the use the technology?	What kind of data needs to be collected about the use of this technology regarding care processes, professionals involved, patients and their health outcomes?	3	1	Clinical experts, administrative experts, legislation. National or local judgement		Current use, Legal	Yes
B0011	Investments and tools required to use the technology	What kind of registers is needed to monitor the use the technology?	Are there existing registries that should be used, or should a registry be established, to collect the necessary data?	3	1	Clinical experts, administrative experts, legislation. National or local judgement		Current use, Legal	Yes
B0012	Training and information needed for utilizing the technology	What kind of qualification, training and quality assurance are needed for the use or maintenance of the technology?	Training materials: writing and/or translation, other adaptation? Personal training: individual and/or group sessions, number and length of sessions, number and qualifications of trainers	3	2	Manufacturer, effectiveness studies, observational studies, applicability studies, clinical experts, user information. National or local judgement		Current use, Organisational, Legal	Yes
B0013	Training and information needed for utilizing the technology	What kind of training is needed for the personnel treating or investigating patients using this technology?	Training materials: writing and/or translation, other adaptation? Personal training: individual and/or group sessions, number and length of sessions, number and qualifications of trainers. If the technology requires a specific skill that is developed over a period of time using the technology (learning curve) it should be estimated how many cases a professional needs to treat (as a basis or per year) in order to reach acceptable quality	2	1	Manufacturer, effectiveness studies, observational studies, applicability studies, clinical experts, user information. National or local judgement		Current use, Organisational, Legal	No
B0014	Training and information needed for utilizing the technology	What kind of training and information are needed for the patients receiving or using this technology & their families?	Training materials: writing and/or translation, other adaptation? Personal training: individual and/or group sessions, number and length of sessions, number and qualifications of trainers	3	1	Manufacturer, effectiveness studies, observational studies, applicability studies, clinical experts, user information, patient organisations. National or local judgement		Current use, Organisational, Ethical, Legal	Yes
B0015	Training and information needed for utilizing the technology	What information do patients outside the target group and the general public need on the technology?	Training materials: writing and/or translation, other adaptation?	3	1	Manufacturer, effectiveness studies, observational studies, applicability studies, clinical experts, user information, patient organisations. National or local judgement		Current use, Organisational, Ethical, Legal	Yes

3 Safety

ID	Topic	Issue	Clarification	Im.	Tr.	Information sources	Reference	Relations	Core
C0001	Patient safety	What kind of harms can use of the technology cause to the patient and what is the incidence, severity and duration of harms?	Are the harms intrinsic to the technology (primary effect) or application dependant (secondary effects) or an unrelated event consequent on its use?	3	2		Ref 1, 2, 4		Yes
C0002	Patient safety	What is the dose relatedness of the harms to patients?	Here one should consider also the accumulated harm due to repeated testing	3	3	Research articles, manufacturers' product data sheets, safety monitoring databases			Yes
C0003	Patient safety	What is the timing of onset of harms to patients: immediate, early or late?	The onset of the harm will be different dependant on the mechanism of action and type of technology. Some harms may not be detected because the duration of follow up is not sufficiently long.	3	3	Manufacturers/ medical literature/ grey literature/ registries/ national or international safety monitoring systems			Yes
C0004	Patient safety	Is the incidence of the harms to patients likely to change over time?	For some technologies the occurrence of harms may change over time and be dependant on the experience or training of the operator?	3	2	Medical literature/ grey literature/ professional societies/ registries	Ref 1	Current use/ Clinical effectiveness/ Economic evaluation	Yes
C0005	Patient safety	Are there susceptible patient groups that are more likely to be harmed through use of the technology?		2	3	Research articles, manufacturers' product data sheets, safety monitoring databases	4		Yes
C0006	Patient safety	What are the consequences of false positive, false negative and incidental findings brought about using the technology to the patients from the viewpoint of patient safety?		3	2	Research articles		Accuracy	Yes
C0007	Patient safety	What are the special features in using (applying/interpreting/maintaining) the technology that may increase the risk of patient safety?	Is there evidence for operator dependent harms? Is there a learning curve and what is its consequence? Is there is a big intra- or inter-observer variation in the reading of test results, what is its consequence?	2	2	Research articles, manufacturers' product data sheets, safety monitoring databases		Description	Yes
C0008	Patient safety	What is the safety of the technology in comparison to alternative technologies used for the same purpose?	Relative impact of harms comparative to alternative treatment(s) for individual patients, populations, service delivery & cost effectiveness	1	2	Other HTA reports or systematic reviews of main comparators. Manufacturer or regulators information		Current use/ organisational aspects/ costs, economic evaluation	No
C0020	Occupational safety	What kind of occupational harms may exist through using the technology?		2	3	Research articles, manufacturers' product data sheets, safety monitoring databases			Yes

ID	Topic	Issue	Clarification	Im.	Tr.	Information sources	Reference	Relations	Core
C0040	Environmental safety	What kind of environmental risks may use of the technology cause?		1	2	Research articles, manufacturers' product data sheets, safety monitoring databases			No
C0060	Safety risk management	How does the safety profile of the technology vary between different generations, versions or products?		3	3	Research articles, manufacturers' product data sheets, safety monitoring databases		Description and Technical Characteristics	Yes
C0061	Safety risk management	Is there evidence that harms increase or decrease in different organizational settings?		3	3	Accuracy and effectiveness research, epidemiological risk research		Current use, Accuracy	Yes
C0062	Safety risk management	How can one reduce safety risks for patients (including technology-, user-, and patient-dependent aspects)?	Is there a requirement for specific training, use of a protocol or guideline or restricting use to specialist centres, providing patient information, etc. may all reduce the occurrence or severity of harm.	2	2			Organisational aspects	Yes
C0063	Safety risk management	How can one reduce safety risks for professionals (including technology-, user-, and patient-dependent aspects)?		2	2	Research in occupational health and safety			Yes
C0064	Safety risk management	How can one reduce safety risks for environment (including technology-, user-, and patient-dependent aspects)?		2	2	Research articles, manufacturers' product data sheets			Yes

4 Clinical Effectiveness

ID	Topic	Issue	Clarification	Im.	Tr.	Information sources	Reference	Relations	Core
D0001	Mortality	What is the effect of the intervention on overall mortality?	Use of technology may have an impact on patients' life expectancy.	3	2	Systematic reviews of RCTs (Randomised controlled trials) or CTs (controlled trials), if not available RCTs or CTs itself. If these not available, non-controlled studies and respective systematic reviews. Health care register data.	Several sources, see the Reference list.		Yes
D0002	Mortality	What is the effect of the intervention on the mortality caused by the target disease?	Use of technology may have an impact on mortality caused by the target disease.	3	2	Systematic reviews of RCTs (Randomised controlled trials) or CTs (controlled trials), if not available RCTs or CTs itself. If these not available, non-controlled studies and respective systematic reviews. Health care register data.	Several sources, see the Reference list.		Yes
D0003	Mortality	What is the effect of the intervention on the mortality due to other causes than the target disease?	Use of technology may have an impact on the mortality due to other causes than the target diseas.	3	2	Systematic reviews of RCTs (Randomised controlled trials) or CTs (controlled trials), if not available RCTs or CTs itself. If these not available, non-controlled studies and respective systematic reviews. Health care register data.	Several sources, see the Reference list.		Yes
D0004	Mortality	What is the mortality related to the technology studied?	Use of technology may have an impact on mortality related to the intervention studied.	3	2	Systematic reviews of RCTs (Randomised controlled trials) or CTs (controlled trials), if not available RCTs or CTs itself. If these not available, non-controlled studies and respective systematic reviews. Health care register data.	Several sources, see the Reference list.	Safety domain	Yes
D0005	Morbidity	How does the intervention modify the severity and frequency of symptoms and findings?	Use of technology may have an impact on patients' symptoms.	3	2	Systematic reviews of RCTs (Randomised controlled trials) or CTs (controlled trials), if not available RCTs or CTs itself. If these not available, non-controlled studies and respective systematic reviews.	Several sources, see the Reference list.		Yes
D0006	Morbidity	How does the intervention modify the progression of disease?	Use of technology may have an impact on course of the illness.	3	2	Systematic reviews of RCTs (Randomised controlled trials) or CTs (controlled trials), if not available RCTs or CTs itself. If these not available, non-controlled studies and respective systematic reviews.	Several sources, see the Reference list.		Yes
D0007	Morbidity	How does the intervention modify the recurrence of symptoms and findings?	Use of technology may have an impact on course of the illness.	3	2	Systematic reviews of RCTs (Randomised controlled trials) or CTs (controlled trials), if not available RCTs or CTs itself. If these not available, non-controlled studies and respective systematic reviews.	Several sources, see the Reference list.		Yes
D0008	Morbidity	What is the morbidity related to the intervention?	Use of technology may have an impact on morbidity related to the intervention.	3	2	Systematic reviews of RCTs (Randomised controlled trials) or CTs (controlled trials), if not available RCTs or CTs itself. If these not available, non-controlled studies and respective systematic reviews.	Several sources, see the Reference list.	Safety domain	Yes

ID	Topic	Issue	Clarification	Im.	Tr.	Information sources	Reference	Relations	Core
D0010	Change-in management	How does the technology modify the need for hospitalization?	Use of technology may have an impact on morbidity related to the need for hospitalizations.	3	2	Systematic reviews of RCTs (Randomised controlled trials) or CTs (controlled trials), if not available RCTs or CTs itself. If these not available, non-controlled studies and respective systematic reviews.	Several sources, see the Reference list.		Yes
D0023	Change-in management	How does the technology modify the need for other technologies and use of resources?		2	2			Economic & Organisation domains	Yes
D0011	Function / HRQL (Health-related quality of life)	What is the effect of the intervention on global improvement of function?	Use of technology may have an impact on functional ability	3	2	Systematic reviews of RCTs (Randomised controlled trials) or CTs (controlled trials), if not available RCTs or CTs itself. If these not available, non-controlled studies and respective systematic reviews.	Several sources, see the Reference list.		Yes
D0012	Function / HRQL (Health-related quality of life)	What is the effect of the technology on health-related quality of life?	Use of technology may have an impact on quality of life	3	2	Systematic reviews of RCTs (Randomised controlled trials) or CTs (controlled trials), if not available RCTs or CTs itself. If these not available, non-controlled studies and respective systematic reviews.	Several sources, see the Reference list.		Yes
D0013	Function / HRQL (Health-related quality of life)	What is the effect of the intervention on disease specific quality of life?	Use of technology may have an impact on quality of life	3	2	Systematic reviews of RCTs (Randomised controlled trials) or CTs (controlled trials), if not available RCTs or CTs itself. If these not available, non-controlled studies and respective systematic reviews.	Several sources, see the Reference list.		Yes
D0014	Function / HRQL (Health-related quality of life)	What is the effect of the intervention on return to work?	Use of technology may have an impact on working ability.	3	2	Systematic reviews of RCTs (Randomised controlled trials) or CTs (controlled trials), if not available RCTs or CTs itself. If these not available, non-controlled studies and respective systematic reviews.	Several sources, see the Reference list.		Yes
D0015	Function / HRQL (Health-related quality of life)	What is the effect of the intervention on return to previous living conditions?	Use of technology may have an impact on ability to return to previous living conditions.	3	2	Systematic reviews of RCTs (Randomised controlled trials) or CTs (controlled trials), if not available RCTs or CTs itself. If these not available, non-controlled studies and respective systematic reviews.	Several sources, see the Reference list.	Social domain	Yes
D0016	Function / HRQL (Health-related quality of life)	How does the use of technology affect activities of daily living?	Use of technology may have an impact on ability to perform daily activities.	3	2	Systematic reviews of RCTs (Randomised controlled trials) or CTs (controlled trials), if not available RCTs or CTs itself. If these not available, non-controlled studies and respective systematic reviews.	Several sources, see the Reference list.	Social domain	Yes
D0017	Patient satisfaction	Was the use of technology worth it?	Patients overall assessment of the worthiness of the intervention.	3	2	Systematic reviews of RCTs (Randomised controlled trials) or CTs (controlled trials), if not available RCTs or CTs itself. If these not available, non-controlled studies and respective systematic reviews.	Several sources, see the Reference list.		Yes
D0018	Patient satisfaction	Would the patient be willing to use the technology again?	Patients overall assessment of the worthiness of the intervention.	3	2	Systematic reviews of RCTs (Randomised controlled trials) or CTs (controlled trials), if not available RCTs or CTs itself. If these not available, non-controlled studies	Several sources, see the Reference list.		Yes

ID	Topic	Issue	Clarification	Im.	Tr.	Information sources	Reference	Relations	Core
						and respective systematic reviews.			

5 Costs and economic evaluation

ID	Topic	Issue	Clarification	Im.	Tr.	Information sources	Reference	Relations	Core
E0001	Resource utilization	What types of resources are used when delivering the assessed technology and its comparators (resource use identification)?	In order to do an economic evaluation all types of resource utilization must be identified. The study perspective determines what kinds of resource utilization must be identified. A societal perspective implies identifying all kinds of resource utilization irrespective of who pays for the resources. If a health care provider perspective is applied, then resource utilization paid for by the patient is not relevant	3	2	Health care registers, RCT's with resource utilization data, reimbursement databases, micro-level costing studies/ABC-costing studies	Guidelines for economic evaluation of Health Technologies: Canada, 3rd edition, 2006, Guidelines for Pharmacoeconomic. Evaluations in Belgium, 2008		Yes
E0002	Resource utilization	What amounts of resources are used when delivering the assessed technology and its comparators (resource use measurement)?	For all types of resource utilization the amounts of resources used when delivering the assessed technology as well as when delivering the comparator technologies must be measured	3	2	Health care registers, RCT's with resource utilization data, reimbursement databases, micro-level costing studies/ABC-costing studies	Guidelines for economic evaluation of Health Technologies: Canada, 3rd edition, 2006, Guidelines for Pharmacoeconomic. Evaluations in Belgium, 2008		Yes
E0003	Unit costs	What are the unit costs of the resources used when delivering the assessed technology and its comparators?	Ideally unit cost estimates should be (proxies for) opportunity costs. By the opportunity cost is understood the (lost) health gains that could have been achieved from an alternative technology, which, however, cannot be introduced or retained, because the resources e.g. manpower, are used on the new technology. Market prices are often used as proxies for opportunity costs.	3	1	Market prices, companies, hospital accounting systems, reimbursement databases, micro level costing studies/ABC-costing studies	Guidelines for economic evaluation of Health Technologies: Canada, 3rd edition, 2006, Guidelines for Pharmacoeconomic. Evaluations in Belgium, 2008.		Yes
E0004	Indirect Costs	What is the impact of the technology on indirect costs?	Indirect costs include costs to society of lost production. This can be due to patient's temporary absence from work due to illness, reduced working capacity due to illness and disablement, or lost production due to an early death	2	2	Different registers e.g. register on sick leave, sickness allowance, patient administration systems/ clinical databases, earlier studies, cost diaries.	Kristensen 2007	Overlap with social domain.	Yes
E0005	Outcomes	What are the incremental effects of the technology relative to its comparator(s)?	The calculation of an incremental cost-effectiveness ratio requires the estimation of the incremental effectiveness/utility/benefit of a technology relative to its comparator(s).	3	2	Estimation of the incremental effects can be based on information provided in the effectiveness domain (e.g. mortality data). Additional information collection may be needed (e.g. on health-related quality of life indices). The		Overlap with effectiveness domain	Yes

ID	Topic	Issue	Clarification	Im.	Tr.	Information sources	Reference	Relations	Core
						incremental effectiveness may result from an economic model, where inputs from the effectiveness domain are used (amongst others)			
E0006	Cost-effectiveness	What is the incremental cost-effectiveness ratio?	The result of the economic analysis will most often be an incremental cost-effectiveness ratio eg. costs/QALY if quality-adjusted life years is used as the main outcome indicator. The incremental cost-effectiveness ratio does not in itself determine that a technology is desirable. Decision makers need – implicitly or explicitly – to weigh the benefits of a technology against the costs. The concept of a cost-effectiveness threshold is one way of expressing decision-makers willingness-to-pay for health benefits. If other types of economic evaluation is chosen, eg. cost benefit analysis, other types of measures are used to express results of the analysis, but most current economic analysis within HTA's are done within the cost-effectiveness/cost-utility framework	3	1	Sources of data used are specified under relevant issues under domains safety, effectiveness and costs. The ICER estimate might result from the economic model, using inputs from the safety and effectiveness domain.		In addition to the resource utilization and unit costs specified below the economic evaluation uses information from all types of outcomes specified under the domains safety and effectiveness (mortality, morbidity, HRQoL etc.)	Yes

6 Ethical analysis

ID	Topic	Issue	Clarification	Im.	Tr.	Information sources	Reference	Relations	Core
F0001	Principal questions about the ethical aspects of technology	Is the technology a new, innovative mode of care, an add-on to or modification of a standard mode of care or a replacement of a standard?	The consequences of totally new models of care are likely to be more difficult to predict than the consequences of replacing an old technology (for individual values, attitudes and expectations as well as for health care systems). Novel, innovative treatment modes may require extra emphasis on ethical analysis, although the literature and research base on the topic may be narrow.	3	2	Literature search. Expert opinion	Mitcham 2004	technology description, organizational	Yes
F0002	Principal questions about the ethical aspects of technology	Can the technology challenge religious, cultural or moral convictions or beliefs of some groups or change current social arrangements?	It is important to identify those groups within the society for whom the use of the technology may pose serious challenges due to their beliefs, convictions or current social arrangements (e.g. need of blood transfusion adjunct to the use of the technology, contraception). Identification of these conflicts and finding other, acceptable possibilities to treat the condition in these groups is important. Identifying the conceptions behind the beliefs and values may help put them in perspective, when considering the overall acceptability of the technology. Technology may also change generally accepted social arrangements by challenging traditional conceptions (e.g. assisted reproductive technologies have separated the concept of genetic, biological and social motherhood).	3	2	Literature search. Expert opinion. Stakeholder hearing	Ogletree 2004	Social	Yes
F0003	Principal questions about the ethical aspects of technology	What can be the hidden or unintended consequences of the technology and its applications for different stakeholders.	In addition to intended use, the technology may be used for other purposes and have side-effects in addition to those following from the intended use. Unintended consequences are obviously difficult to predict, but the intended purpose and uses of the technology should be evaluated against the likely uses and consequences of the technology in the real world. New technologies tend to lead to new areas of inventions and give rise to new ethical questions (e.g. IVF and development of genetic testing has led to questions of preimplantation genetic diagnostics (PGD). As presymptomatic and prenatal genetic tests have become available, the health care system has to be prepared to handle moral issues raised by true positive and false negative findings.) Many treatments have indirect effects also on relatives.	3	2	Literature search. Expert opinion. Stakeholder	Ogletree 2004, Hofmann 2005b, Hofmann 2002b		Yes
F0004	Autonomy	Does the implementation or use of the technology challenge patient autonomy?	Patients have in most cases a right to autonomy, i.e. right to be self-governing agents. This requires the right to decide about things of importance to oneself on one hand, but also relevant information and a capability to understand the information,	3	2	Literature search. Expert opinion. Stakesholder	Miller 2004		Yes

ID	Topic	Issue	Clarification	Im.	Tr.	Information sources	Reference	Relations	Core
			consider it in relation to personal values and decide accordingly. Thus, technologies and health systems may interfere with patient's right to autonomy directly or indirectly by influencing the decisional capacity. For example, a technology that does not allow itself to be understandably explained to the patient (e.g. gene therapy for dementia) is potentially problematic, as are treatments that require patients to behave in a certain way (e.g. liver transplants given conditional to not drinking).			hearing			
F0005	Autonomy	Is the technology used for patients/people that are especially vulnerable?	The right and justification to use the technology for persons who are vulnerable (critically ill or have otherwise reduced decision making capacity, like children, mentally retarded, patients that have due to their illness/state limited decision making capacity, pregnant women etc) has to be clarified. Who has the right to balance the benefit against possible harm in these situations? On what grounds can these decisions be made? Is the technology so valuable, as to justify its use on people who can not give informed consent to it?	3	3	Literature search. Expert opinion. Stakeholder hearing	Miller 2004		Yes
F0006	Autonomy	Can the technology entail special challenges/risk that the patient/person needs to be informed of?	Is the common professional practice of discussing the treatments with patients enough, or is special care needed with this technology? The technology to be used in life-threatening situations may have life-threatening side effects (e.g. invasive techniques). Technology used to get exact information may have unexpected severe side-effects (e.g. miscarriage due to amniocentesis).	3	3	Literature search. Expert opinion. Registers	Miller 2004	Safety	Yes
F0007	Autonomy	Does the implementation challenge or change professional values, ethics or traditional roles?	Technologies may change the relationship between physician and patient, challenge professional autonomy or otherwise interfere with professional ethics and values. The patient-physician relationship is traditionally based on mutual trust, confidentiality and professional autonomy so that individual treatment decisions can be made in the best interest of the patient. Technologies that interfere with core virtues and principles of medical and professional ethics challenge the professional integrity of the physicians or other health care professionals. Technologies that align with professional ethics are more likely to be implemented successfully.	3	2	Expert opinion	Hofmann 2005b. Medical Professionalism Project 2002	Organisational. Technology description	Yes
F0008	Human Dignity	Does the implementation or use of the technology affect human dignity?	Especially technologies that are applied for persons with reduced autonomy may violate a person's dignity (children, mentally impaired, severely ill), i.e. challenge the idea that all human beings have intrinsic moral value, and should thus not be seen as	3	2	Literature search. Expert opinion. Stakeholder	Kilner 2004		Yes

ID	Topic	Issue	Clarification	Im.	Tr.	Information sources	Reference	Relations	Core
			means to others ends.			hearing			
F0009	Human integrity	Does the implementation or use of the technology affect human integrity?	"Technology can challenge human integrity by preventing (or even tempting) people (patients or professionals) to live according their moral convictions, preferences or commitments. This is especially important for vulnerable patient groups. Integrity can also be seen as a coherent image or identity of oneself. Thus, for example, prenatal diagnostics might challenge the integrity of people who value new life as gift; cochlear implants are problematic for those, who do not see deafness as a disability. Institutions that discourage honesty or ethical conduct more generally are detrimental to integrity (for example, systems where lying about ones health state might lead to better treatment than being honest). "	3	2	Literature search. Expert opinion. Stakeholder hearing	Kilner 2004		Yes
F0010	Beneficence/nonmaleficence	What are the benefits and harms for patients, and what is the balance between the benefits and harms when implementing and when not implementing the technology? Who will balance the risks and benefits in practice and how?	The decision to implement new technology requires careful decision on the balance between benefit and harm, cost-effectiveness, reallocation of resources etc. When this decision has been made the decision on individual patient level rests on both the professional who offers the technology and the patient who autonomously accepts the use of technology in her/his situation. The individual decision has to be based on objective information on possible benefit and risks. Risks are only justified to the extent they are needed to create benefits. If not proven otherwise, the individual patient is generally to be seen as the best judge of risks and benefits for her/himself.	3	2	Literature search. Expert opinion. Stakeholder hearing	Autti-Rämö 2007	Safety. Effectiveness	Yes
F0011	Beneficence/nonmaleficence	Can the technology harm any other stakeholders? What are the potential benefits and harms for other stakeholders, what is the balance between them? Who will balance the risks and benefits in practice and how?	Some technologies have the potential to unfold unwanted or harmful effects not only on the patients that the technology is directly applied to but also indirectly on other stakeholders (relatives, other patients, organisations, commercial entities, society etc.) Benefits and harms to individuals must be balanced with benefits and harms that can befall society as a whole (social utility, maximizing public health). These harmful effects may manifest in the physical, social, financial or even other domains of life. For example results of genetic tests may negatively interfere with the family planning and social life of not only the individual being tested but also of his or her relatives. Table 2 in the process description can be used to describe benefits and harms.	3	2	Literature search. Expert opinion. Stakeholder hearing	Autti-Rämö 2007 Beauchamp and Childress 2001	Organisational. Social	Yes
F0012	Justice and Equity	What are the consequences of implementing / not	A new intervention may require reallocation of human resources, funding and training. A large reallocation of resources may seriously jeopardize other patient groups (e.g. new technology	3	2	Literature search. Expert opinion.	Sterba 2004 Daniels 2001	Cost-effectiveness. Organisational. Social	Yes

ID	Topic	Issue	Clarification	Im.	Tr.	Information sources	Reference	Relations	Core
		implementing the technology on justice in the health care system? Are principles of fairness, justness and solidarity respected?	that requires human resources in acute care). How this reallocation affects the existing health care system has to be studied for all stakeholders? Can the technology be applied in a way that there is equal access to those in equal need? How can this be guaranteed? Could potential discrimination or other inequalities (geographic, gender, ethnic, religious, employment, insurance) prevent access? Are specific safeguards needed? How will possible caregivers' burden and well-being be influenced? Potential inequalities and discrimination should be justified.			Stakeholder hearing			
F0013	Justice and Equity	How are technologies presenting with relevantly similar (ethical) problems treated in health care system?	Clearly presenting how relevantly similar technologies are treated in a health care system may help to adopt coherent and just health policies, either by applying past precedents to current cases, or showing that past cases need reconsideration. Similarity is to be defined individually for each technology. The idea is to concentrate only on the similarities relevant for solving the ethical problems found important for the current HTA project. The similarity may be, for example, of medical, technological, economical, ethical, social, organisational or legal nature.	3	2	Littrature search. Expert opinion	Hofmann 2005b		Yes
F0014	Rights	Does the implementation or use of the technology affect the realisation of basic human rights?	Human rights exist both in ethics and legislation, most notably in the United Nations declarations and related statements, like the European Council Biomedicine convention. Basic human rights are universal and consider the most important goods, protections and freedoms. Classes of rights are civil and political rights, social rights, minority and group rights and environmental rights. For HTA, perhaps the most relevant are the rights to equality, non-discrimination, safety, adequate standard of living and health care. For example: -Right to life, liberty and security of person. -Right to a standard of living adequate for the health and well-being of himself and of his family, including medical care and necessary social services, and the right to security in the event of sickness, disability or old age. -Right of the child to the enjoyment of the highest attainable standard of health and to facilities for the treatment of illness and rehabilitation of health.	3	3	Literature search. Law, rules and regulations. Expert opinion. Stakeholder hearing	Marks 2004	Social. Legal	Yes
F0016	Legislation	Is legislation and regulation to use the technology fair and adequate?	Technology may lead to ethical problems that make current regulation inadequate (e.g. ethical reflection is needed when considering what kind of regulation is needed. This consideration is done on the basis and in combination with the legal domain. Emphasis should be put on considering the ethically relevant aspects and consequences of current law, needs for legal regulation that have arisen from the ethical analysis, and a global	2	1	Law, rules and regulations. Stakeholder hearing. Expert opinion	Capron 2004	Legal	No

ID	Topic	Issue	Clarification	Im.	Tr.	Information sources	Reference	Relations	Core
			assesment of the adequacy of the legislation based on all available information.						

7 Organisational aspects

ID	Topic	Issue	Clarification	Im.	Tr.	Information sources	Reference	Relations	Core
G0001	Process	What kind of work flow and patient flow processes are needed?	A new technology could change current work tasks and processes (including also quality control). Work and patient processes should be described, and it should be explained what kind of activities a new technology might replace or reduce in the target organisation. Patient flow and changes required in patient path should be taken to account when implementing new technology. It is essential to know the change the use of the new technology generates to the performance of care.	3	2	Systematic reviews (and other studies), annual reports and statistics of the hospital, other qualitative research methods	Kristensen 2001, Kristensen 2007	(Current use)	Yes
G0002	Process	What kind of patient and relative involvement in treatment or care has to be mobilized?	A new technology may require changes in the distribution of tasks among the people involved in the treatment and care. Patients and their important others may be more actively involved in own care and treatment – or tasks they used to carry out may be taken over by health professionals.	2	1		Kristensen 2007		No
G0003	Process	What kind of staff, training and other human resources is required?	It has to be clarified what kind of staff is needed, and whether the existing staff can be trained or extra staff must be brought in. A new technology can bring along the need for extra staff when extending the ongoing activities in the organisation or when there is a demand for special expert knowledge. It must be considered if there will be a need to increase or decrease the amount of the staff. The implementation of a new innovation can mean change in job satisfaction. It could make some tasks monotonous or bring along new boring job descriptions. It is crucial that there is not just one person familiar with the new technology. If just one person has been trained for a new technology, there is a risk of loosing know-how when he/she leaves the organisation (or moves to other tasks).	3	2	Systematic reviews (and other studies), reports of the hospital or hospital districts and other qualitative research methods	Busse 2002, Kristensen 2001, Kristensen 2007	Description	Yes
G0004	Process	What kind of co-operation and communication of activities have to be mobilised?	The use of technology can presume new co-operation and communication with other parts of the structure (e.g. other units) or outside the structure (e.g. other hospitals, pharmacies). The type of technology 'determines' the frequency of need for information exchange between different actors. Also interaction and communication with patients and their important others will change.	2	2	Systematic reviews (and other studies), reports of the hospital or hospital districts and other qualitative research methods	Kristensen 2001, Kristensen 2007, Senter för Medisinsk metodevurdering (SMM) 2003		Yes
G0005	Structure	What consequences the implementation of the new technology will have in respect of decentralisation or centralisation?	The location of use of the technology (primary - secondary - tertiary care) could vary between different countries depending on the system of organisational systems. (De)centralisation could have some economical and qualitative benefits. Centralisation could make a new technology more difficult to access. For example some expensive technologies are centralized to tertiary care units.	3	2	Systematic reviews (and other studies), reports of the hospital or hospital districts and other qualitative research methods	Busse 2002, Kristensen 2001, Kristensen 2007, Senter för Medisinsk metodevurdering (SMM) 2003	Current use, Description	Yes
G0006	Structure	What kinds of investments are needed (material or premises)?	The new technology could require many changes in the organisation e.g. premises must be according to the directions of the manufacturer. This could be very costly for the organisation. High costs of the new technology can	3	2	Systematic reviews (and other studies), reports of the hospital or hospital	Kristensen 2007	Description	Yes

ID	Topic	Issue	Clarification	Im.	Tr.	Information sources	Reference	Relations	Core
			influence the decision of purchasing the new technology. It is important to know which organisation(s) participate in the investments of a new technology and to what extent the other organisations take part in the running costs.			districts and other qualitative research methods. Information from manufacturers			
G0007	Structure	What is the likely budget impact of the implementation of the technology for the payers (e.g. government)?	When a new technology is introduced, the question about reimbursement quickly arises. Whenever a technology is reimbursed, there will be an impact on the health care budget. Budget impact analysis examines the likely impact of the reimbursement of a new technology on financial outlays from the perspective of the payers (e.g. government).	3	1	Systematic reviews (and other studies), reports of the hospital or hospital districts and other qualitative research methods			Yes
G0008	Management	What management problems and opportunities are attached to the new technology?	The issue concerns the administrative / managerial questions of the new technology: management of resources (e.g. investments), co-ordination (in relation to different levels), establishment of objectives, monitoring and control, evaluation and sanctioning.	2	2		Kristensen 2007		Yes
G0009	Management	Who decides which patients are to undergo a treatment and on what basis?	Procedurals about decisions about the patients who receive care could vary.	3	2	Systematic reviews (and other studies), reports of the hospital or hospital districts and other qualitative research methods	Kristensen 2007		Yes
G0010	Culture	How is the new technology accepted?	Acceptance should bee looked at by different perspectives: by organisation, by personnel and by patients. A new technology could consist of elements which don't suit the image of the organisation. Also, the alternative ways to introduce a new technology into the organisation could influence problems e.g. resistance among staff and dysfunction of processes. Patients are usually very technologically-oriented. However, patients can resist a new technology itself or its implementation. Objective and understandable information on a new technology is important.	2	2	Systematic reviews (and other studies), qualitative research methods	Finohta's EUnetHTA workshop 2006, Kristensen 2007	Ethical, Social	Yes
G0011	Culture	How will the other interest groups of the new technology be taken into account in the planning / implementation of the new technology?	It may be useful to know who are the possible stakeholders of the particular technology, as well as what kind of co-operation there has been and what kind of interaction is needed. The stakeholders could be e.g. the pharmaceutical industry and companies offering new technologies, authorities (national / regional), administrative parties, municipalities, policy makers / decision makers, staff groups and patient organisation. One can also ask: Has the patient organisation taken part into the process? Has it been involved from the beginning (in the planning) or in the later stages for example as commentator? Furthermore, it is interesting to figure out what kind of co-operation exists between hospitals and companies offering new technologies and what kind of co-operation is needed.	3	1	Systematic reviews (and other studies), qualitative research methods	Kristensen 2001, Kristensen 2007, Senter för Medisinsk metodevurdering (SMM) 2003	Ethical	Yes

8 Social aspects

ID	Topic	Issue	Clarification	Im.	Tr.	Information sources	Reference	Relations	Core
H0001	Major life areas	Which social areas does the use of the technology influence?	Map the major life areas of the patient and the important others (family life, day care, school, work, leisure time, lifestyle, or other daily activities), where the technology is going to be used or where its use may have a direct or indirect influence.	3	2	Search for or conduct a literature review or, if relevant data is not available, conduct a primary study; if there's no time for primary study, the opinion of health care professionals and content experts can be consulted.			Yes
H0002	Major life areas	Who are the important others that the use of the technology may affect in addition to the patient?	Describe who are the important other people that are involved in the use of technology in addition to the patients (parents, children, friends, people at work place etc)	3	2	Search for or conduct a literature review or, if relevant data is not available, conduct a primary study; if there's no time for primary study, the opinion of health care professionals and content experts can be consulted.			Yes
H0003	Major life areas	What kind of support and resources are needed or might be released as the technology is put to use?	This issue is about any kind of support and resources (practical, physical, emotional, personal social, nurturing, financial etc.) that need to be mobilized, and organized - or might be released - in order for the patient to use the technology with satisfactory results. It covers all arrangements or adjustments that may be needed in the major life areas (e.g. alteration of special tasks, working time, adjustments in the physical environment, emotional support).	3	2	Search for or conduct a literature review or, if relevant data is not available, conduct a primary study; if there's no time for primary study, the opinion of health care professionals and content experts can be consulted.	ICF(32) environmental factors: support and relationships (chapter 3: e310-399); activities and participation, chapter 6: d698, structural arrangements of patient's environment (10, 12, 13)	Organisational	Yes
H0004	Major life areas	What kinds of changes does the use of the technology generate in the patient's role in the major life areas?	This issue is about the patient's social roles and ability to manage and maintain relations with other people in a socially appropriate manner in major life areas.	3	2	Search for or conduct a literature review or, if relevant data is not available, conduct a primary study; if there's no time for primary study, the opinion of health care professionals and content experts can be consulted.	ICF(32) activities and participation, interpersonal interactions and relationships (chapter 7, d710-779), community, social and civic life (chapter 9:d910-d999), (5, 7, 33, 34)	Ethical. Effectiveness, safety	Yes
H0005	Major life areas	What kind of changes does the implementation and use of the technology mean for the patients physical and psychological functioning in	This issue is about the physical and psychological consequences the use of the technology may generate in the patient's main life areas e.g. on person's body functions and structures, activities on daily living, or performance at work, school, home or leisure time. This	3	2	Search for or conduct a literature review or, if relevant data is not available, conduct a primary study; if there's no time for primary study, the	ICF(32),(15)	Effectiveness. Safety	Yes

ID	Topic	Issue	Clarification	Im.	Tr.	Information sources	Reference	Relations	Core
		his or her major life areas?	issue covers whether, from a patient perspective, the technology leads to improvements or harms (a cross reference to effectiveness, safety domain issues), or generates any other unexpected effects on functioning.			opinion of health care professionals and content experts can be consulted.			
H0006	Individual	How do patients and important others react and act upon the technology?	This issue is about the patients and her important others' attitudes, perceptions, preferences, satisfaction and relations to the technology. This covers whether, from a patient perspective, any positive or negative issues arise as a consequence of using the technology e.g. feelings of unity or empowerment and existential experiences (e.g. insecurity, worries, hope, anxiety, stigmatisation, person's value as a human being or social status, courage to face life, satisfaction, changes in self-conception).	3	2	Search for or conduct a literature review or, if relevant data is not available, conduct a primary study; if there's no time for primary study, the opinion of health care professionals and content experts can be consulted.	ICF(32) body functions: mental functions (chapter 1:b110-b199) environmental factors: attitudes (chapter 4:, e410-499) , (3)	Effectiveness	Yes
H0007	Communication	What is patients' and important others' knowledge and understanding of the technology?	This issue explores the patient's and important others' understanding of the technology in order to describe and decide what guidance and help (e.g. patient information leaflets, counselling processes, need of follow up consultation or help from other professionals) they need before, during and after the use of the technology.	3	2	Search for or conduct a literature review or, if relevant data is not available, conduct a primary study; if there's no time for primary study, the opinion of health care professionals and content experts can be consulted.		Current use. Safety	Yes
H0008	Communication	How is the information regarding the use of the technology processed and exchanged?	This issue is about the exchange of information from a patient's perspective. What are patients' and significant others' questions? How do they receive answers? How is information provided and received?	3	2	Search for or conduct a literature review or, if relevant data is not available, conduct a primary study; if there's no time for primary study, the opinion of health care professionals and content experts can be consulted.		Organisational	Yes
H0009	Communication	What are the consequences in decision making?	This issue clarifies the possible implications from the patient's perspective to decision making e.g. limitations (dependent, passive user) and possibilities (empowered, active user) as a consequence of using the technology.	3	2	Search for or conduct a literature review or, if relevant data is not available, conduct a primary study; if there's no time for primary study, the opinion of health care professionals and content experts can be consulted.		Organisational. Ethical	Yes

9 Legal aspects

ID	Topic	Issue	Clarification	Im.	Tr.	Information sources	Reference	Relations	Core
I0002	Autonomy of the patient	Can patients understand the implications of using/not using the technology?	It is important to provide information on the (evermore complex) technologies in such a manner that the patient can truly understand it.	3	2				Yes
I0003	Autonomy of the patient	Are there relevant optional technologies that future patients should be allowed to consider?	The concept of informed consent includes also the possibility to consider other therapeutic options, if these are available.	3	2				Yes
I0004	Autonomy of the patient	Is it possible to give future patients enough time to consider their decisions?	It is usually advised that the patient is given some time to think over the treatment decision, especially if the decision involves assimilating complex technical information or a tough weighing of risks and benefits of the procedure. It should be assessed beforehand if a given technology allows such time for consideration.	2	2				Yes
I0005	Autonomy of the patient	Is it possible to obtain an advance directive on the use of the technology?	If it is expected that the technology may be used in an emergency situation in the future it is advised that the patient is consulted beforehand and her opinion is recorded to the medical file as an advance directive on the use of a given technology.	2	1				No
I0009	Privacy of the patient	Can the access to the patient data secured properly?	At the era of computer-based patient records it is crucial that the health care unit has taken appropriate measures to secure the patient databases. Negligence may lead to liability.	2	1		Directive 95/46/EC	Organisational aspects	No
I0010	Privacy of the patient	What levels of access to which kind of patient information exist in the chain of care?	During the therapeutic process many people may either need to get access or semi-accidentally get access to the personal medical data of patients. The delicacy of the information depends on the technology in question. Health care unit must be organised so that it minimises the number of people having access to patient data. Also other measures to minimise the risk of information leakage from health care unit must be taken.	1	1			Organisational aspects	No
I0011	Equality in health care	Is the technology equally accessible to all needing members in a given society?	This topic operates both at national and international level. In general, equality in health care is spoken out in the EU Charter of Fundamental Rights and it is also one of the central principles of the Biomedicine Convention. In many Constitutions equality of citizens covers also access to health care.	3	2		EU FR Charter Art 35, Biomedicine Convention Article 3, CM RecommendationR (2006) 18	Social domain	Yes

ID	Topic	Issue	Clarification	Im.	Tr.	Information sources	Reference	Relations	Core
I0012	Equality in health care	Is the technology subsidized by the society?	Governmental interventions or the lack of them may affect to the expected number of patients.	2	1			Societal aspects, organisational aspects, economical aspects	No
I0013	Equality in health care	Is there a wide variation in the acceptability of the technology across Europe?	Varying legal regimes may lead to health-care tourism across the borders, especially if the technology in question is controversial.	3	3	Europe-wide legal comparison		Social domain	Yes
I0014	Equality in health care	Is health-care tourism expected from/to other European countries?	Varying legal regimes may lead to health-care tourism across the borders.	2	3	C-158/96 (ECJ), C-372/04 (ECJ), Europe-wide legal comparison		Social domain	Yes
I0015	Authorisation & safety	Has the technology national/EU level authorisation?	Patient safety as expressed in product safety is one domain of health care technology assessment which clearly falls under the mandate of the European Union	3	3			Safety aspects	Yes
I0016	Authorisation & safety	Does the technology need to be listed in a national/EU register?	A European database of medical devices (EUDAMED) is under construction.	2	2			Safety aspects	Yes
I0017	Authorisation & safety	Does the technology fulfil product safety requirements?	The implication of findings in the safety domain should be discussed against the relevant European or national legal frameworks to ensure patient safety from using the technology:	3	3		Directive 93/42/EEC, Directive 95/2001/EC	Safety aspects	Yes
I0018	Authorisation & safety	Does the technology fulfil tissue safety requirements?	Many novel health technologies may utilise human cells or tissue (so called advanced therapy medicinal products). These products must fulfil the safety requirements issued by EC Directive 2004/23/EC.	3	3	COM 567 (2005) final	Directive 2004/23/EC	Safety aspects	Yes
I0019	Ownership & liability	Does the technology infringe some intellectual property right?	Issues in this topic are to be considered by the health care unit when considering the acquisition of a new technology. The wording of acquisition contract may affect liability sharing between the manufacturer and health care unit.	2	3	Manufacturer, patent data bases	EPO Web site, European patent convention, national elgislation		Yes
I0020	Ownership & liability	Does the introduction of the technology presume some additional licensing fees to be paid?	As novel technologies build up on existing knowledge, the use of the technology may involve the payment of some additional fees to additional patent holders etc. In principle, the manufacturer should be able to clarify this to the health care unit/health care system in question.	2	2	Manufacturer, patent data bases			Yes
I0021	Ownership & liability	What are the width, depth and length of the	The terms of the manufacturers guarantee are of importance to the health care unit as well as to the society's health care sector	3	3	Manufacturer			Yes

ID	Topic	Issue	Clarification	Im.	Tr.	Information sources	Reference	Relations	Core
		manufacturers guarantee?	when considering whether it is economically and/or liabilitywise advantageous to introduce the technology or not.						
I0022	Ownership & liability	Is the user guide of the technology comprehensive enough?	The wording and clarity of the user guide of the technology can have legal effects on the liability issues in case the technology is not working as expected.	3	3	Manufacturer			Yes
I0023	Regulation of the market	Is the technology subject to price control?	As health care technology is essential to everyone at some point in their lives, its pricing may be regulated.	3	2	C-317/05 (ECJ), C-283/03 (ECJ)	Directive 1989/105/EEC		Yes
I0024	Regulation of the market	Is the technology subject to acquisition regulation?	Expensive technology is subject to acquisition regulation.	3	2		Directive 2004/18/EC		Yes
I0025	Regulation of the market	Is the marketing of the technology to the patients restricted?	As health care technology is essential to everyone at some point in their lives, the way by which it can be marketed to consumers may be regulated.	3	2	T-179/00 (ECJ)	Directive 1989/105/EEC, directive 1992/27/EEC		Yes
I0026	Legal regulation of novel/experimental techniques	Is the technology so novel existing legislation was not designed to cover its regulation?	Modern biomedical sciences produce novel technologies which may not always be unambiguously covered by existing provisions.	3	1				Yes
I0027	Legal regulation of novel/experimental techniques	How the liability issues are solved according to existing legislation?	If the current law does not provide a straightforward answer to the liability issues it may be advisible to consult a legal expert on the interpretation of the existing provisions with regard to the technology in question. This way the health care unit can prepare itself for the possible future legal proceedings.	3	1				Yes
I0028	Legal regulation of novel/experimental techniques	Are new legislative measures needed?	If the existing legislation is not satisfactory the introduction of a novel technology may require new legislative measures. At the level of a health care unit this may slow down the introduction, whereas at the level of the society it implies a need to use resources for preparing new laws.	2	1				No
I0029	Legal regulation of novel/experimental techniques	Is the voluntary participation of patients guaranteed properly?	Use of experimental technologies may not compromise patient safety. Patients must not be pressured into such treatments.	3	1		Biomedicine Convention Article 16		Yes