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HTA Core Model® Online

Assessment element tables

The EUnetHTA Joint Action is supported by a grant from the European Commission

Assessment element tables of *HTA Core Model Application for Screening Technologies (draft - work in progress)*

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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, narrative reviews, book chapters	Burls 2000, Busse 2002, Liberati 1997 Imaz-Iglesia 1998, Kristensen 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 allows a precise diagnostic and differentiation of the indication for the use of the technology.Subgroups or indications are considered under the Domain Clinical Effectiveness	3	3	WHO	Burls 2000, Busse 2002, Liberati 1997 Imaz-Iglesia 1998, Kristensen 2009	Clinical Effectiveness Domain	Yes
A0003	Target Condition	Which are the known risk factors for acquiring the condition?	The prevalence of different risk factors might be different in different geographic areas and among different groups of population. This element clarifies the identification of alternative (also preventive) management approaches.	3	2	Narrative and systematic reviews, book chapters	Burls 2000, Busse 2002, Liberati 1997 Imaz-Iglesia 1998, Kristensen 2009	Clinical Effectiveness Domain	Yes
A0004	Target Condition	What is the natural course of the condition?	Description of underlying mechanisms or pathophysiology. Possible relation between early diagnosis and better prognosis?	3	3	Registries	Burls 2000, Busse 2002, Liberati 1997 Imaz-Iglesia 1998, Kristensen 2009	Clinical Effectiveness and Costs Domains	Yes
A0005	Target Condition	What are the symptoms at different stages of the disease?	Symptoms by stage might give an idea of possible improvements, and provide proxy outcomes for effectiveness assessment.	2	3	Registries, quality of life studies, narrative and systematic reviews, book chapters	Burls 2000, Busse 2002, Liberati 1997 Imaz-Iglesia 1998, Kristensen 2009	Clinical Effectiveness Domain	Yes
A0006	Target Condition	What is the burden of the condition?	Prevalence or incidence of disease specific mortality, life years lost, disability	3	2	Registries and national statistics	Burls 2000, Busse 2002, Liberati 1997 Imaz-Iglesia 1998, Kristensen 2009	Clinical Effectiveness, Social and Costs Domains	Yes

ID	Topic	Issue	Clarification	Im.	Tr.	Information sources	Reference	Relations	Core
A0009	Target Condition	What aspects of the burden of disease are targeted by the technology?	The technology can affect only some aspects (e.g. mortality) and leave other aspects (e.g. quality of life) untouched. Screening may increase disease incidence due to early diagnosis and over diagnosis.	3	3	Deductive models (based on the natural history of the disease, test target and treatment target; epidemiological studies (if sufficient testing has been done)		Clinical Effectiveness, Social and Costs Domains	Yes
A0007	Target Population	What is the target population of the technology?	The technology may be used for all patients having the condition, or only those in early stages, or certain severity level, or people with moderate risk of having the condition. In screening and other preventive interventions the target population represent a defined subgroup of healthy or asymptomatic individuals. Who have defined the selected subgroup(s) and for which reasons?	3	2	Medical literature, narrative reviews, commentaries, editorials of scientific associations, guidelines, recommendations		Clinical Effectiveness Domain	Yes
A0023	Target Population	How many people belong to the target population?		3	1	National registries, statistics, systematic reviews			Yes
A0011	Utilisation	How much is the technology being used?	What is the current rate of screening adherence?	3	1	National statistics, surveys, disease management studies, manufacturer sales data	Burls 2000, Busse 2002, Liberati 1997 Imaz-Iglesia 1998, Kristensen 2009	Costs and Organisational Domains	Yes
A0012	Utilisation	What kind of variations in use are there across countries/regions /settings?		2	2	National statistics, surveys, disease management studies, manufacturer sales data	Burls 2000, Busse 2002, Liberati 1997 Imaz-Iglesia 1998, Kristensen 2009		Yes
A0013	Current Management of the Condition	How is the disease/health condition currently diagnosed or screened?	Properties of diagnostic or screening tests affect patient spectrum and thus the effectiveness of subsequent interventions. Different tests are applied by different professional groups. This information is needed e.g. in cost-effectiveness models.	3	1	Surveys, utilisation reviews. If such information is lacking: Expert surveys / expert interviews, web search	Burls 2000, Busse 2002, Liberati 1997 Imaz-Iglesia 1998, Kristensen 2009	Clinical Effectiveness, Costs and Organisational Domains	Yes
A0014	Current Management of the Condition	How should the condition be diagnosed or screened according to published algorithms/guidelines?		2	2	Guidelines	Burls 2000, Busse 2002, Liberati 1997 Imaz-Iglesia 1998, Kristensen 2009	Clinical Effectiveness, Costs and Organisational Domains	Yes

ID	Topic	Issue	Clarification	Im.	Tr.	Information sources	Reference	Relations	Core
A0015	Current Management of the Condition	How is the condition currently managed?	Deviation from eb-guidelines may hint over/under use of the technology and it may increase the burden of disease.Identification of practice variations may point out differences in the quality of health care.	2	1	Surveys, utilisation reviews. If such information is lacking: Expert surveys / expert interviews, audits		Clinical Effectiveness, Costs and Organisational Domains	No
A0016	Current Management of the Condition	How should the condition be managed according to published algorithms/guidelines?	An assessment of the main differences between guidelines and actual practice allows conclusions to be drawn on how optimal the current management is.	3	2	Review of clinical guidelines, recommendation. If such information is lacking: Expert surveys / expert interviews, textbooks		Clinical Effectiveness, Costs and Organisational Domains	Yes
A0017	Current Management of the Condition	What are the differences in the management for different stages of disease?		2	2	Surveys, utilisation reviews, clinical guidelines, recommendations. If such information is lacking: expert surveys / expert interviews		Organisational and Social Domains	Yes
A0018	Current Management of the Condition	What are the other evidence-based alternatives to the current technology?		3	2	Clinical guidelines, recommendations, systematic reviews	Burls 2000, Busse 2002, Liberati 1997 Imaz-Iglesia 1998, Kristensen 2009	Clinical Effectiveness, Costs and Organisational Domains	Yes
A0019	Life-Cycle	In which phase is the development of the technology?	It can be experimental, emerging, or routine use? Usually a new test for primary screening needs studies with very long follow up. Consequently new screening putative tests are usually very old tests. On the other hand a new triage test, therapy for positive individuals may be experimental. Finally we may have a new version of an old primary test, in this case it may be experimental.	3	2	Horizon scanning databases, ongoing research databases, information from manufacturers.	Burls 2000, Busse 2002, Liberati 1997 Imaz-Iglesia 1998, Kristensen 2009	Safety, Clinical Effectiveness, Ethical, Social and Legal Domains	Yes
A0020	Regulatory Status	Which market authorization status has the technology in other countries, or international authorities?	Imaging devices may require approval. Substances needed for obtaining images may require additional approval (e.g. radiotracers). In some cases the approval for primary screening is different to that for clinical use (FDA recently licensed tests explicitly for screening), but in most cases approval is obtained for diagnostic use and the test is proposed for screening without any other formal approval.	3	3	e.g. CE-Approval, EMEA, national authorities. Manufacturers should be contacted in order to identify which steps have they taken/ are they planning to take concerning market approval	Burls 2000, Busse 2002, Liberati 1997 Imaz-Iglesia 1998, Kristensen 2009	Legal Domain	Yes
A0021	Regulatory Status	What is the reimbursement status of the technology across countries?	The technology may be differently included in / excluded from the benefit basket of the countries. Reimbursement status may be different for different purposes: e.g	2	3	Lists of benefits / services of the national health services / sickness funds, inquiry of	Burls 2000, Busse 2002, Liberati 1997	Organisational and Legal Domains	Yes

ID	Topic	Issue	Clarification	Im.	Tr.	Information sources	Reference	Relations	Core
			treatment vs prevention, diagnosing vs screening or monitoring. Information of full-coverage, co-payments, coverage under special circumstances/conditional coverage is useful.			technical officers from MoH. Manufacturers. Literature on benefit basket (Comparative policy studies)	Imaz-Iglesia 1998, Kristensen 2009		

2 Description and technical characteristics of technology

No assessment elements

3 Description and technical characteristics of the technology

ID	Topic	Issue	Clarification	Im.	Tr.	Information sources	Reference	Relations	Core
B0001	Features of the technology	What is this technology?	Type of device, operation, imaging, etc. Biological rationale and mechanism of action of the technology. Technology may include a single device, a questionnaire, imaging or sequence of technologies. The HTA may address one or several similar technologies. Minor modifications between manufacturers/products need to be accounted for as these may affect performance.	3	2	Manufacturers´ sites, published literature including reviews, introduction sections of research articles.			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 over previous / existing technologies used for the same health problem?	2	3	Manufacturers´ sites, published literature including reviews, introduction sections of research articles, grey literature, hand-searches and conference proceedings.		A0009, A0018, D1019, C0008	Yes
B0004	Features of the technology	Who will apply this technology?	Which professionals (nurses, doctors, other professionals) use the technology?	3	2	Manufacturers´ sites, published literature including reviews, textbooks, handbooks, introduction sections of research articles, interviews with specialists, as well as grey literature, hand-searches and conference proceedings.		Current Use	Yes
B0016	Features of the technology	To what population(s) will this technology be used on?	The technology might behave differently in different patient groups. Define as many subgroups as possible. The technology might behave differently in different patient groups. Define as many relevant subgroups as possible (e.g., 'optimal' age group versus optional age groups). Are there specific populations that should not be recipients of the technology because of technical difficulties, inaccuracy, inconclusive results or because of safety issues? Does the population need to use the technology more than once? In that case how many times, and how frequently?	3	2	Manufacturers´ sites, published literature including reviews, textbooks, handbooks, introduction sections of research articles, interviews with specialists, as well as grey literature, hand-searches and conference proceedings.		A0007, C0005	Yes
B0003	Features of the technology	What is the phase of the technology?	Is the technology an innovation? When was it developed? Is the technology only partially innovative (i.e. a modification of an existing technology), and in that case, is it possible to specify the degree of innovation the technology may represent? When was the technology introduced into healthcare? Is the technology an already established one, but now used in a different way, for instance for a new indication? Most technologies will be introduced at approximately the same time in several countries. The evidence base (published trials etc) may change rapidly for technologies that are at an earlier stage in their development.	3	2	Manufacturers´ sites, published literature including reviews, introduction sections of research articles, grey literature, hand-searches and conference proceedings.		A0019, A0020, F0001	Yes

ID	Topic	Issue	Clarification	Im.	Tr.	Information sources	Reference	Relations	Core
B0017	Features of the technology	Is this technology field changing rapidly?	For end users it is useful to know if new versions or adaptations of the technology are expected in the near future.	2	3	Manufacturers´ sites, published literature including reviews, textbooks, handbooks, introduction sections of research articles, clinical trial sites, interviews with specialists, as well as grey literature, hand-searches and conference proceedings.			Yes
B0006	Features of the technology	Are there any special features relevant to this technology?	How does this technology differ from its predecessors (other technologies used for similar purposes)? Are there new aspects that may need to be considered when applying it? Is there evidence that the technology works (or is used) outside its current indication area or produces incidental findings that can have consequences relevant to effectiveness, safety, organisational, social and ethical domains.	2	2	Manufacturers´ sites, published literature including reviews, introduction sections of research articles, interviews with specialists, grey literature, hand-searches and conference proceedings.		A0018, C0007, C0060, D0022	Yes
B0005	Features of the technology	In what place and context is the technology intended to be used?	It can be primary care, secondary care or self care. Its role in the management pathway can be as a replacement, an add-on or for triage.	3	2	Manufacturers´ sites, published literature including reviews, textbooks, handbooks, introduction sections of research articles, interviews with specialists, as well as grey literature, hand-searches and conference proceedings.		Current Use, D1007, G001, G0005	Yes
B0018	Features of the technology	Are the reference values or cut-off points clearly established?	Are conflicting /varying definitions of an abnormal finding likely to affect the interpretation of the results?	2	2	Manufacturers´ sites, published literature including reviews, textbooks, handbooks, introduction sections of research articles, interviews with specialists, as well as grey literature, hand-searches and conference proceedings.			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 organisation in order to use the technology. Includes need for back-up investment to cover for breakdowns in use.	2	2	Manufacturers´ sites, published literature including reviews, textbooks, handbooks, introduction sections of research articles, interviews with specialists, as well as grey literature, hand-searches and conference proceedings.		E0001, E0002, G0006	Yes

ID	Topic	Issue	Clarification	Im.	Tr.	Information sources	Reference	Relations	Core
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 organisations, 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 is needed instead of general statement (e.g. to be used in hospitals only)	2	2	Manufacturers´ sites, approving authority, published literature including reviews, handbooks, textbooks, introduction sections of research articles, interviews with specialists, as well as grey literature, hand-searches and conference proceedings.		Organisational domain	Yes
B0009	Investments and tools required to use the technology	What equipment and supplies are needed to use the technology?	Syringes, needles, medicines, fluids, bandages etc. All disposable items necessary for using the technology	2	2	Manufacturers´ sites, including published literature such as reviews, introduction sections of research articles, interviews with specialists, as well as grey literature, hand-searches and conference proceedings.		E0001, E002	Yes
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? How is this collected?	2	2	HTA-reports, local authorities		G0008	Yes
B0011	Investments and tools required to use the technology	What kind of registers are needed to monitor the use the technology?	Are there existing registries that could be used, or should a registry be established to collect the necessary data?	2	1	HTA-reports, local authorities		G0008	No
B0012	Training and information needed to use the technology	What kind of qualification, training and quality assurance processes are needed for the use or maintenance of the technology?	We need to differentiate between the users who are. 1. applying the technology (could be different from those interpreting results) 2. interpreting the results and make treatment decisions. 3. taking care of service and maintenance. 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. Are regular or frequent standardisation or quality checks required? E.g. CME points.	3	2	Manufacturers´ sites, approving authority, published literature including handbooks, textbooks, reviews, HTA-reports, interviews with specialists, as well as grey literature, hand-searches and conference proceedings.		G0003, C0020, C0062, C0063	Yes
B0013	Training and information needed to use 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), an estimate should be provided of the number of patients a professional needs to treat (as a basis or per year) in order to reach an acceptable minimum standard	2	1	Manufacturer, effectiveness studies, observational studies, applicability studies, clinical experts, user information. National or local judgement.		C0062, C0063, D1008, G0003	No
B0014	Training and information	What kind of training and information	Training materials: writing and/or translation, other adaptation? Personal training: individual and/or group sessions, number and length of sessions,	2	2	Manufacturer data, effectiveness studies, observational studies,		C0001, C0003, C0005, C0007,	Yes

ID	Topic	Issue	Clarification	Im.	Tr.	Information sources	Reference	Relations	Core
	needed to use the technology	should be provided for the patient who uses the technology, or for his family/carer?	number and qualifications of trainers Informed consent regarding the risk / benefits of participation.			applicability studies, clinical experts, user information, HTA-reports.		C0062, F0004, F006 G0004, H0003, H0007, H0008, I0002	
B0015	Training and information needed to use the technology	What information of the technology should be provided for patients outside the target group and the general public?	Information materials: writing and/or translation, other adaptation? Informed consent for participating?	3	2	HTA-reports, manufacturers' sites, interviews, as well as grey literature, hand-searches and conference proceedings..		F0005, F0011, G0004, H0002, H0007, H0008, I0002, I0008	Yes

4 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; what are the incidence, severity and duration of harms?		3	3	Observational research, safety monitoring databases, registers, statistics	Loke Y 2006, 2007, Ioannidis 2001, 2004, Higgins 2006, Papanikolaou 2006Busse 2002Golder 2006, Mac Mahon 2001		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 dosage or testing	3	3	Research articles, manufacturers' product data sheets, safety monitoring databases	Aronson 2003		Yes
C0003	Patient safety	What is the timing of onset of harms to patients: immediate, early or late?		3	3	Research articles, manufacturers' product data sheets, safety monitoring databases	Aronson 2003		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		Current use, effectiveness, costs domains	Yes
C0005	Patient safety	Are there susceptible patient groups that are more likely to be harmed through use of the technology?		3	3	Research articles, manufacturers' product data sheets, safety monitoring databases	Aronson 2003	Ethical, F0005	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		Effectiveness, Social, Costs, Ethical and Legal domains	Yes
C0029	Patient safety	Does the existence of harms influence tolerability or acceptability of the technology?		2	2	Qualitative research articles, patient associations' web sites, Internet discussion forums		Effectiveness, Social, Ethical and Legal domains	Yes
C0007	Patient safety	What are the special features in using (applying/interpreting/maintaining) the technology that may increase the risk of harmful events?	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?	3	2	Research articles, manufacturers' product data sheets, safety monitoring databases		Description and technical characteristics and Organisational domains	Yes

ID	Topic	Issue	Clarification	Im.	Tr.	Information sources	Reference	Relations	Core
C0008	Patient safety	What is the safety of the technology in comparison to alternative technologies used for the same purpose?		3	2	Research articles, manufacturers' product data sheets, safety monitoring databases		Current use, Clinical Effectiveness and Ethical domains	Yes
C0020	Occupational safety	What kind of occupational harms can occur when using the technology?		2	3	Research articles, manufacturers' product data sheets, safety monitoring databases		Ethical and Social domains	Yes
C0040	Environmental safety	What kind of risks for public and environment may occur when using the technology?		2	2	Research articles, manufacturers' product data sheets, safety monitoring databases		Ethical and Social domains	Yes
C0060	Safety risk management	How does the safety profile of the technology vary between different generations, approved 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	2	Accuracy and effectiveness research, epidemiological risk research		Current use, Effectiveness, Organisational	Yes
C0062	Safety risk management	How can one reduce safety risks for patients (including technology-, user-, and patient-dependent aspects)?	Technical means, protective equipment, education etc. Including information on what kind of risk communication is needed for patients, citizens and decision makers	3	3	Research articles, manufacturers' product data sheets, safety monitoring databases		Ethical F0006, Description and technical characteristics B0012, B0014, B0015	Yes
C0063	Safety risk management	How can one reduce safety risks for professionals (including technology-, user-, and patient-dependent aspects)?	Technical means, protective equipment, education etc. Including information on what kind of risk communication is needed for patients, citizens and decision makers	2	2	Research in occupational health and safety		Organisational and Social Domains	Yes
C0064	Safety risk management	How can one reduce safety risks for environment (including technology-, user-, and patient-dependent aspects)?	Technical means, protective equipment, education etc. Including information on what kind of risk communication is needed for patients, citizens and decision makers	2	2	Research articles, manufacturers' product data sheets.		Social Domain	Yes

5 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?	In screening the technology is seen as the combination of screening test, subsequent diagnostic work-up and treatment.	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. Modelling studies.			Yes
D0002	Mortality	What is the effect of the intervention on the mortality caused by the target disease?	A screening test can lead to an earlier diagnosis, thus earlier treatment which might reduce the mortality.	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. Modelling studies.			Yes
D0003	Mortality	What is the effect of the intervention on the mortality due to other causes than the target disease?	This may be due to e.g. side effects, accidents, or consequences of interventions after false positive or incidental findings.	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. Modelling studies.		C0001, C0006	Yes
D0004	Mortality	What is the mortality related to the diagnostic test?	In diagnostic and screening technologies it is worthwhile distinguishing the possible mortality risk of the test itself from the mortality outcomes of the whole diagnostic or screening process (D0001-D0003). Inappropriate use of the technology or errors may contribute to this issue.	3	2	Observational research, RCTs, safety monitoring databases, registers, statistics		C0001	Yes
D0005	Morbidity	How does the use of the technology modify the symptoms and findings of the target condition?	Severity, frequency and recurrence of symptoms and findings.	3	2	Trials, observational studies		Social domain	Yes

ID	Topic	Issue	Clarification	Im.	Tr.	Information sources	Reference	Relations	Core
D0006	Morbidity	How does the technology modify the progression of the target condition?	E.g. complete cure, alleviation, delay of the onset of the next stage of the disease.	3	2	Trials, prognostic studies			Yes
D0026	Morbidity	How does the technology modify the effectiveness of subsequent interventions?	Different tests may detect slightly different subpopulations as test positive. Results from further diagnostic testing and the effectiveness of subsequent interventions can be different in test A positive compared to test B positive. E.g. treatment may work differently in screening-identified cases than in cases that are diagnosed at regular physician's appointment.	2	2	Trials, observational studies, accuracy studies			Yes
D0008	Morbidity	What is the morbidity directly related to the technology?	In diagnostic and screening technologies it is worthwhile distinguishing the possible morbidity caused by the test itself from the morbidity outcomes of the whole diagnostic or screening process (D0005-D0006). Inappropriate use of the technology or errors may contribute to this issue.	3	2	Trials reporting adverse events.. Observational studies. Registries		C0003 to C0005	Yes
D0020	Change-in management	Does use of the test lead to improved detection of the condition?	Although the test is reliable, the information it provides does not necessarily affect clinical decision making. If it does not change sufficiently the pre-test probability the added value of the information may be low. E.g there may be routine preoperative lab tests that nobody uses in decision making. Moreover, users´ ability to make a correct diagnosis may depend on their knowledge and ability to interpret the results.	2	2	RCT, CT, accuracy studies, before-after studies, interrupted time series, change-in management studies		Organisational domain	Yes
D0021	Change-in management	How does the use of the test change physicians' management decisions?	There may be technology-related or non-related factors that might influence the physicians' perceptions, ability and attitude to decision making. Management decisions mean both testing and treatment decisions.	2	2	Change-in-management studies, qualitative research		Organisational domain	Yes
D0024	Change-in management	Is there an effective treatment for the condition the test is detecting?		3	2			Ethical domain	Yes
D0022	Change-in management	Does the test detect other potential health conditions that can impact the subsequent management decisions?	Management decisions mean both testing and treatment decisions.	2	2	Trials, Descriptive literature		B0006	Yes
D0023	Change-in management	How does the technology modify the need for other technologies and use of resources?	Some treatments require ongoing monitoring and healthcare visits including hospitalisation. Screening tests may cause further diagnostic testing and different treatment due to detection of disease at an earlier stage.	2	2	RCT, CT, observational studies, statistics		Costs, organisational aspects domain	Yes

ID	Topic	Issue	Clarification	Im.	Tr.	Information sources	Reference	Relations	Core
D0011	Function	What is the effect of the intervention on global function?		3	2	RCT, CT, observational studies		Social domain	Yes
D0014	Function	What is the effect of the technology on return to work?	Sick leave, retirement and various outcomes describing working ability are relevant outcomes to this issue.	3	2	Trials and other studies with return-to-work or work ability outcomes reported.		Social and costs domain	Yes
D0015	Function	What is the effect of the technology on return to previous living conditions?	Testing may affect the ability to return to previous living conditions. It may have implications for family members / carers too.	3	2	RCT, CT, observational studies		Social domain	Yes
D0016	Function	How does use of the technology affect activities of daily living?		3	2	RCT, CT, observational studies		Social domain	Yes
D0012	Quality of life	What is the effect of the technology on generic health-related quality of life?		3	2	RCT, CT, observational studies		Costs, social domain	Yes
D0013	Quality of life	What is the effect of the technology on disease specific quality of life?		3	2	RCT, CT, observational studies		Costs domain	Yes
D0030	Quality of life	Does the knowledge of the test result affect the patient's non-health-related quality of life?	It can improve or worsen the quality of life. Test result may alleviate symptoms although there is no effectiveness to the primary outcome. It can also trigger or worsen symptoms.	2	2	Qualitative research, observational studies, trials		Social and ethical domain	Yes
D0017	Patient satisfaction	Was the use of the technology worthwhile?	Patients overall assessment of the worthiness of the intervention.	3	2	Qualitative research, observational studies, trials		Social domain	Yes
D0018	Patient satisfaction	Is the patient willing to use the technology?	Differences in acceptability may predict the overall uptake of the technology and would impact on the overall effectiveness.	2	2	Qualitative research, observational studies, trials		Social domain	Yes
D1001	Test accuracy	What is the accuracy of the test against reference standard?	Accuracy in terms of sensitivity and specificity, and other measures such as likelihood ratios, pre-test probabilities, SDORs, AUC or Q*? In screening programmes one should consider separately the accuracy of the screening test and the accuracy of subsequent diagnostic tests.	2	2	Accuracy studies			Yes

ID	Topic	Issue	Clarification	Im.	Tr.	Information sources	Reference	Relations	Core
D1003	Test accuracy	What is the reference standard and how likely does it classify the target condition correctly?		2	2	Accuracy studies			Yes
D1004	Test accuracy	What are the requirements for accuracy in the context the technology will be used?	Acceptable number of false negative and false positive test results is different e.g. in replacement/ triage/ add-on situations, and in life threatening / harmless conditions. In screening programs one should consider separately the screening test and the subsequent diagnostic tests.	2	2	Descriptive literature, expert advice, prevalence data, modelling studies, calculations		Ethical aspects domain	Yes
D1005	Test accuracy	What is the optimal threshold value in this context?	Sensitivity and specificity vary according to the threshold value. Optimal combination of sensitivity and specificity defines optimal threshold value. The optimum depends on the consequences of the test results. E.g. whether it does more harm to overlook a case or to treat someone unnecessarily. In screening programs one should consider separately the screening test and the subsequent diagnostic tests.	2	2	Screening studies with varying thresholds, accuracy studies with varying thresholds, modelling studies			Yes
D1006	Test accuracy	Does the test reliably rule in or rule out the target condition?	When assessing screening programs one should consider here the combination of the screening test and the subsequent diagnostic tests.	2	2	Accuracy studies, modelling studies		Safety, social, ethical domains	Yes
D1007	Test accuracy	How does test accuracy vary in different settings?	How do patient spectrum, disease prevalence, disease severity, and properties of the technology itself affect the accuracy of the test? This may have implications on how frequently a test needs to be repeated, optimal age range for a screening programme and adjustments in different populations.	2	2	Accuracy studies in different settings, descriptive literature, expert advice		B0004, B0016, B0005, Organisational domain	Yes
D1002	Test accuracy	How does the test compare to other optional tests in terms of accuracy measures?	Or, how does the technology compare to other development stages of the same technology?	2	2	Accuracy studies			Yes
D1008	Test accuracy	What is known about the intra- and inter-observer variation in test interpretation?	This is especially relevant in tests with subjective assessments, such as most imaging tests.	2	2	Accuracy studies, trials, observational studies			Yes
D1019	Test accuracy	Is there evidence that the replacing test is more specific or safer than the old one?	If there is effective treatment for a condition, then a new diagnostic technology with similar sensitivity but greater safety or specificity may be seen as improved effectiveness. In screening programs one should consider separately the screening test and the subsequent diagnostic test.	2	2	Accuracy studies, trials, observational studies		Safety domain	Yes

ID	Topic	Issue	Clarification	Im.	Tr.	Information sources	Reference	Relations	Core
D0027	Test accuracy	What are the negative consequences of further testing and delayed treatment in patients with false negative test result?	In screening programmes one should consider separately the false negative screening test results and the subsequent false negative diagnostic test results.	2	2	Observational studies, trials, qualitative research		Safety domain	Yes
D0028	Test accuracy	What are the negative consequences of further testing and treatments in patients with false positive test result?	In screening programs one should consider separately the false positive screening test results and the subsequent false positive diagnostic test results.	2	2	Observational studies, trials, qualitative research		C0006, Organizational, costs and ethical domains	Yes
D0029	Benefit-harm balance	What are the overall benefits and harms of the technology in health outcomes?	This question integrates all benefits and harms concerning mortality, morbidity, QoL and further patient relevant outcomes, also considering the amount of false positive and false negative test results. It is the central question about clinical effectiveness. There is no common quantitative summary measure, and even qualitatively a balanced and meaningful presentation is difficult to reach. In diagnostic technologies one should consider also the benefits and harms of subsequent diagnostic testing and treatments in patients with true positive test result in a prior diagnostic or screening test. For true positive cases there is a benefit-harm balance, because diagnostics and treatment can harm. Consequences for true negative cases are identical with the possible harms of the screening test (see D0004, D0008).The integration of some assessment elements of other domains into the benefit-harm-balance is essential and differs between the core model applications. For screening the frequency of disease and coverage of screening are essential AES	3	2	RCT, CT, observational studies, modelling studies		A0007, A0011, C0001, C0003, C0004, C0005, C0006, C0007, C0061, Ethical Domain	Yes

6 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 or whether the costs are born inside or outside the health care sector. If a health care provider perspective is applied, then resource utilization paid for by the patient is not relevant and if a health care payer perspective is applied, non-health care costs should not be taken into account. In identifying the resource use of a screening programme, the screening test, further examinations and treatments, as well as administration and organisation of the screening programme need to be taken into account.	3	2	Health care registers and databases, 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	A0011, A0013, A0014, A0015, A0016, A0017, A0018) G0001, G0003, G0004, G0005, G0006, G0007, G0010, B0007, B0008, B0009	Yes
E0002	Resource utilization	What amounts of resources are used when delivering the assessed technology and its comparators (resource use measurement)?	After identifying the types of resources used, also the quantities of resources must be measured, for all types of resource utilization of implementing the technology and its comparators. Resource use data may be collected prospectively (e.g. alongside a clinical trial) or estimated retrospectively by reviewing patient registries, hospital or reimbursement databases, or other routine data collection.	3	2	Health care registers and databases, 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	Organisational, Health Problem and Current Use, B0007, B0008, B0009	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 value of 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 or shadow prices (e.g. for voluntary work) are often used as proxies for opportunity costs. Also costs caused by a false negative or false positive screening test result should be included.	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 examinations, treatments, or illness; reduced working capacity due to illness and disablement; or lost production due to an early death. Depending on the	2	2	The data are available from different registers e.g. register on sick leave, sickness allowance, patient administration systems/	Kristensen 2007	D0014, Social	Yes

ID	Topic	Issue	Clarification	Im.	Tr.	Information sources	Reference	Relations	Core
			perspective of analysis, also indirect costs related to patients and relatives (e.g. income loss, transportation costs) should be examined.			clinical databases, earlier studies, cost diaries.			
E0005	Outcomes	What are the incremental effects of the technology relative to its comparator(s)?	The calculation of an incremental cost-effectiveness ratio (ICER) requires the estimation of the incremental effectiveness/utility/benefit of an intervention relative to its comparator(s). Estimation of utility related to screening differs from many curative interventions, since the target population of screening is healthy or at least asymptomatic, who might become patients due to the screening. Benefits of screening include improved diagnosis, timely and appropriate treatment and reduction in mortality and morbidity. Also the number of detected positives and false positives (specificity and sensitivity) are important aspects in evaluation of effects of the assessed screening programme.	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 incremental effectiveness may result from an economic model, where inputs from the effectiveness domain are used.	Guidelines for economic evaluation of Health Technologies: Canada, 3rd edition, 2006, Guidelines for Pharmacoeconomic Evaluations in Belgium, 2008	A0004, A0005, A0006, A0009, A0023) D0001, D0002, D0003, D0004, D0005, D0006, D0008, D0011, D0012, D0013, D0023, D0030, C0001, C0002, C0003, C0004, C0006, C0008	Yes
E0008	Cost-effectiveness	What is the method of analysis?	Clinical trials usually compare a limited number of screening options over a relatively short time horizon and it is unlikely that trial data will inform all relevant aspects of a screening programme. Decision analytic models provide a structure for synthesizing information from various sources as well as analysing how the uncertainty affects the results.	3	2		Guidelines for economic evaluation of Health Technologies: Canada, 3rd edition, 2006, Guidelines for Pharmacoeconomic Evaluations in Belgium, 2008		Yes
E0007	Cost-effectiveness	What is the appropriate time horizon?	Both costs and effects should be modelled over an appropriate time horizon. In most curative interventions both costs and effects occur in a relatively short time period, while in screening the effects occur later in the future. Effectiveness data is rarely available for the whole appropriate time horizon and economic evaluation needs to link intermediate endpoints to final endpoints and/or extrapolate the effectiveness. Thus it is often argued that the effects are penalized by discounting and there is controversy on this issue. One needs to take into account any relevant official guidance when choosing specific discount rate for analysis. After that it is important to decide whether to discount both costs and effects, and whether to use uniform discount rate.	3	2		Guidelines for economic evaluation of Health Technologies: Canada, 3rd edition, 2006, Guidelines for Pharmacoeconomic Evaluations in Belgium, 2008	Effectiveness domain (effectiveness data may need extrapolation)	Yes

ID	Topic	Issue	Clarification	Im.	Tr.	Information sources	Reference	Relations	Core
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 an intervention 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 type 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.	Guidelines for economic evaluation of Health Technologies: Canada, 3rd edition, 2006, Guidelines for Pharmacoeconomic Evaluations in Belgium, 2008	Safety, Effectiveness	Yes

7 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 screening programmes are likely to be more difficult to predict than the consequences of changing methods within an existing screening programme (breast screening and digital imaging), for individual values, attitudes and expectations as well as for health care systems. Novel screening programmes (screening for rare metabolic disorders in newborn), improved specificity of screening methods (ultrasound for fetal abormalities), or totally new screening tests (screening for maternal drug and alcohol abuse from hair or meconium) - may have far-reaching consequences on health care. They may require more emphasis on ethical analysis than replacing a test already in use with another testing the same diagnostic marker, although the literature and research base on the topic may be narrow.	3	2	Literature search. Expert opinion		DTC, Organisational.	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. Finding other acceptable possibilities for 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. screening for fetal abnormalities and on the other hand the concept of “design babys” through development of preimplantation diagnostics).	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.	The technology may be used for other purposes and have side-effects in addition to those following from the intended use. E.g. screening for fetal abnormalities may give information on gender. Unintended consequences may be difficult to predict (eg abortion due to unwished gender), but the intended purpose and uses of the technology should be evaluated against the likely uses and consequences of the technology. New technologies give rise to new ethical questions (e.g. screening for metabolic disorders in newborn with non-existing early treatment options). As pre-symptomatic screening tests have become available, the health care system has to be prepared to handle moral issues raised by true positive and false negative findings. Screening positive and being diagnosed with the disease may have effects on relatives as a all diagnoses of hereditary disorders, also provide knowledge of relatives. Screening	3	2	Literature search. Expert opinion. Stakeholder	Ogletree 2004, Hofmann 2005b, Hofmann 2002b		Yes

ID	Topic	Issue	Clarification	Im.	Tr.	Information sources	Reference	Relations	Core
			positive may also affect social relations. In screening programmes by definition diagnostic information necessitates further action, so all screening programmes may have large impact on the health care processes and systems and on individuals. They may even change the concepts of disease if the definition of whom to treat as a patient is unclear (eg screening for aorta aneurysm).						
F0004	Autonomy	Does the implementation or use of the technology challenge patient autonomy?	Patients have in most cases a right to autonomy. This means both the right to decide, but also right to relevant information. The information should enable understanding the issues, enable considering it in relation to personal values, and deciding accordingly. Screening programmes represent complex technologies that may be difficult to be understandably explained to the patient (e.g.meaning of screening positive or negative and the possible risks associated with diagnostic tests and/or treatment) , as are screening programmes that require patients to behave in a certain way (e.g.dietary restrictions for fecal blood test). The practical challenge with screening programmes is that in order to be fully autonomous, the participating person should understand all alternatives following different test results and be able to make informed consent at every step.	3	2	Literature search. Expert opinion. Stakeholder hearing	Miller 2004		Yes
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 cannot 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 technology with patients enough, or is special care needed with this technology? Should the patient be explicitly informed, for example, that false positive results may lead unnecessary further investigations and treatments with serious harms? Screening programmes to be used for early identification of life-threatening situations may have life-threatening side effects (e.g. treatment is invasive surgery with risk of death). Technology used to get exact diagnostic information for those screening positive may have unexpected severe side-effects (e.g. miscarriage due to amniocentesis).	3	3	Literature search. Expert opinion. Registers	Miller 2004	Safety	Yes

ID	Topic	Issue	Clarification	Im.	Tr.	Information sources	Reference	Relations	Core
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 (eg. screening for drug abuse when use is denied). Technologies that align with professional ethics are more likely to be implemented successfully. For example, people may require a test or intervention for many reasons, even if the professionals think them unnecessary and potentially harmful (eg whole body MRI scans).	3	2	Expert opinion	Hofmann 2005b. Medical Professionalism Project 2002	DTC, Organisational.	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 means to others ends. Labelling people may also threaten their dignity (eg. screening children for fetal alcohol spectrum disorders). Some screening tests may label healthy people as sick (eg PSA for prostate cancer) or otherwise less worthy (screening for a non-dominant gene defect in fertile aged, screening for STD in school aged girls). Handicapped people may be labelled by prenatal screening programmes which imply that their handicap is an indication for abortion.	3	2	Literature search. Expert opinion. Stakeholder hearing	Kilner 2004		Yes
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. Institutions that discourage honesty or ethical conduct are detrimental to integrity; for example, systems where lying about one's health state might lead to better treatment than being honest. Prenatal screening programmes might challenge the integrity of people who value new life as gift; screening for cervical cancer and/or HPV may be problematic for some religious groups.	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	The decision to implement a technology requires careful decision on the balance between benefit and harm, cost-effectiveness, reallocation of resources etc. When this decision has been made on	3	2	Literature search. Expert opinion.	Autti-Rämö 2007	Safety.and Effectiveness	Yes

ID	Topic	Issue	Clarification	Im.	Tr.	Information sources	Reference	Relations	Core
		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 system level, the decision on individual patient level rests on both the professional who offers the technology and the patient who autonomously accepts to participate at every possible step. 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.			Stakeholder hearing			
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, 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 prenatal screening and screening for metabolic disorders in newborn may negatively interfere with the family planning and social life of not only the individual being tested but also of his or her relatives. Changes in the availability of treatment facilities may significantly alter the requirements placed on the health care system.	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 implementing the technology on justice in the health care system? Are principles of fairness, justness and solidarity respected?	A new intervention may require reallocation of human resources, funding and training. A large reallocation of resources may seriously jeopardize other patient groups. 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 and who would equally benefit for the programme? 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. Screening technologies sometimes acquire significant symbolic value (e.g. fetal ultrasound, PSA) that may create demands for tests that are not justified on health grounds.	3	2	Literature search. Expert opinion. Stakeholder hearing	Sterba 2004 Daniels 2001	Cost-effectiveness. Organisational. Social	Yes
F0013	Justice and Equity	How are technologies presenting with relevantly similar (ethical) problems treated in health care	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	3	2	Littrature search. Expert opinion	Hofmann 2005b		Yes

ID	Topic	Issue	Clarification	Im.	Tr.	Information sources	Reference	Relations	Core
		system?	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.						
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. For screening programmes, issues of access to screening and diagnostic tests and treatments as well as labelling and potential discrimination of diagnosed persons may be relevant issues.	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. Screening and diagnostic technologies are commonly differently regulated than treatments, especially medications. 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 assessment of the adequacy of the legislation based on all available information. For example, who has a right to get the results and for what purposes? Is legislation needed to ensure equal access? What kind of rules and regulations are needed to ensure good quality of high risk diagnostic tests and treatments.	2	1	Law, rules and regulations. Stakeholder hearing. Expert opinion	Capron 2004	Legal	No
F0017	Questions about effectiveness and accuracy	What are the proper end-points for assessment and how should they be investigated?	The acceptable and feasible endpoints must be carefully considered early in the analysis. The context must be especially considered; some technologies require extensive interpretative skills, and sometimes the consequences will depend on the target population. This is especially true in disorders related to life style. The importance	3	2	Other domains of analysis: accuracy, safety, effectiveness.			Yes

ID	Topic	Issue	Clarification	Im.	Tr.	Information sources	Reference	Relations	Core
			of context relates to what kinds of studies are deemed acceptable. For diagnostic technologies and screening programmes, clinical effectiveness – improved health outcome -should ideally be directly investigated. This is not always possible so other endpoints may have to be used. In addition, screening programmes may have several aims (e.g. screening for hearing disorder in newborn - early institution of therapy and possibility for cochelar implant).			Expert opinion			
F0018	Questions about effectiveness and accuracy	Are the accuracy measures decided and balanced on a transparent and acceptable way?	Are the accuracy measures (sensitivity and specificity) chosen so that they accord with the purpose of the HTA? How and by whom are cut-off values decided? How and by whom has balancing sensitivity and specificity been done? This should be done considering the moral value of different results – for example, high specificity is required if false positives have serious consequences.	3	3	Other domains of analysis: accuracy, safety, effectiveness. Expert opinion			Yes

8 Organisational aspects

ID	Topic	Issue	Clarification	Im.	Tr.	Information sources	Reference	Relations	Core
G0001	Process	What kind of work flow, participant flow and other processes are needed?	Current tasks and work processes and participant path should be described. Preparations participants need to do before and after the intervention (e.g. diet before bariatric surgery) must be taken into account, as well as need for self/home monitoring. There are many actors at different levels (intra-organisational, inter-organisational and health care system level) in the process. Continuity should be ensured so that there will be no gaps between the steps of the process. It has to be described how the screening process has been organised, e.g.: 1) how the target population is chosen, 2) how and by whom the invitation is carried out (open/fixed invitation, announcement/personal invitation letter), 3) how and by whom the information for consent is given, 4) how, where and by whom the test is executed, 5) how, where and by whom the further investigations and treatment are carried out, 6) how, when, and by whom the follow up services are carried out (e.g notifying results, recalls, reminders).	3	2	Literature search, guidelines, annual reports and statistics, reports and own study (e.g. questionnaires and interviews of different actors)	Kristensen 2001, Kristensen 2007	Mandatory: A0007, A0023, A0011, A0013, A0014, A0015, A0016, A0017. Other: B0004, B0005, B0016. Order of doing: to be answered prior to E0001	Yes
G0012	Process	What kind of quality assurance is needed and how should it be organised?	A new technology usually have an effect on current quality assurance not only inside the organization but also outside in different health care levels. To assure the quality, a monitoring system with standards and indicators are needed. Screening involves asymptomatic participants and therefore quality control is crucial. There are national, regional and/or (cross)organisational (screening unit) demands for quality assurance. Quality control needs to be systematic at every step of the screening process steps and throughout the screening programme. Acceptable delay from screening test to test positive result and finally to treatment must be specify. Special attention has to be paid to the control when the programme is provided by several providers (e.g. a combination of private and public health care organisations) when test and further investigations are separated.	3	2	Literature search, annual reports and statistics reports of hospitals and own study: questionnaires and interviews of different actors of the process (monitoring authorities, hospitals, hospital districts, laboratories). Information from manufacturers. .		B0012, C0007	Yes
G0002	Process	What kind of involvement has to be mobilized for participants and important others?	A new technology may require distribution of tasks among the people involved in the treatment and care. Participants 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. The screening has to be organised in the way that the test and the further investigations are easily attainable e.g. mobile mammography.	3	1	Literature search, annual reports and statistics reports, hospital documents and own study: questionnaires and interviews of different actors of the process (monitoring authorities, hospitals, hospital districts, laboratory, participants).	Kristensen 2007	A0006, A0007, A0023, B0014, B0015, H0002, H0003	Yes

ID	Topic	Issue	Clarification	Im.	Tr.	Information sources	Reference	Relations	Core
G0003	Process	What kind of staff, training and other human resources are required?	How much staff is needed and what kind? How much trained resources are needed to ensure proper functioning? Different health care levels (e.g. primary and secondary care) should be taken into account. What are the needs for training and expert advice? Are there national, regional or in-house registries and criteria for personnel and training? Implementing a technology can change the job and have thus influence on job satisfaction.	3	2	Literature search, guidelines, reports and documents of the hospital or hospital districts and own study: interview or questionnaires of different actors of the process.	Busse 2002, Kristensen 2001, Kristensen 2007	B0013, C0063, E0001	Yes
G0004	Process	What kind of co-operation and communication of activities have to be mobilised?	Implementing a technology can demand new co-operation and communication in- and outside the organization, e.g. other hospitals, pharmacies. Also interaction and communication with patients/participants and their important others will change. Adaptation of self/home monitoring needs close co-operation and fluent communication. Screening needs close co-operation and fluent communication between all actors of the screening process in all steps (e.g. screening unit, laboratory, hospital, registry, participants). There are actors at different levels which make the communication and co-operation challenging, especially when making up a new screening. The information must be fluent and electronic communication (software) is crucial. Adequate communication with participants and their important others must be taken into account. Different kinds of "patient information" could be defined for screening. For example: 1. "promotional/educational information" with the aim to involve target population and to promote participation 2. "screening related information" to communicate with participant the "phase related information" in the different phases of the process (e.g. sending invitation; communicating the test results etc.). Information strategies should be tailored to the specific subgroup of the target population (depending on socio-economic status, cultural background, epidemiological features, etc.). Risk families need special information.	3	2	Literature search, guidelines, reports and documents of hospital and hospital districts, guidelines, own study: questionnaires and interviews of different actors of the process (monitoring authorities, hospitals, hospital districts, laboratory, participants).	Kristensen 2001, Kristensen 2007, Senter för Medisinsk metodevurdering (SMM) 2003	B0015, C0063, H0007, H0008	Yes
G0005	Structure	How does de-centralisation or centralization requirements influence the implementation of the technology?	The setting (primary - secondary - tertiary care) can vary between different countries depending on the health care system. (De)centralisation could have some economical and qualitative benefits. Centralisation could make the technology more difficult to access. Sometimes screening test (for example maternal ultrasound) needs special experience from personnel which is possible after education and sufficient amount of patients. Centralisation could make screening or further investigation more difficult to access. For example timing is important in foetal screening. Decentralisation makes screening more attainable but the quality can weaken.	3	1	Literature search, guidelines, reports and documents of hospital and hospital districts, health information databases (DRG etc.), own study: questionnaires and interviews of different actors of the process (monitoring authorities, hospitals, hospital districts, laboratory,	Busse 2002, Kristensen 2001, Kristensen 2007, Senter för Medisinsk metodevurdering (SMM) 2003	B0005	Yes

ID	Topic	Issue	Clarification	Im.	Tr.	Information sources	Reference	Relations	Core
						participants).			
G0006	Structure	What kinds of investments are needed (material or premises) and who are responsible for those?	Implementing the required changes in e.g. premises may be costly for the organisation. High costs can influence the decision of purchasing the new technology. There may be division of costs so that some organisation(s) take the acquisition costs and others the running costs. Investments of all steps and actors of the process must be perceived. When building up a new screening programme, there's need for many investments (e.g. equipments, education and implementation support, training).	3	2	Literature search, guidelines, reports and documents of hospitals and hospital districts and manufacturers (e.g. producer handbook), own study: questionnaires and interviews of different actors of the screening process (monitoring authorities, hospitals, hospital districts, laboratory)	Kristensen 2007	A0011, A0012, A0019, B0008,, D0023, E0001. Order of doing: to be answered prior to E0001.	Yes
G0007	Structure	What is the likely budget impact of the implementation of the technology for the payers (e.g. government)?	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 the technology on financial outlays from the perspective of the payers (e.g. government). Different payers include: government, region, municipalities, employer, insurance company or participant. Payer can change during the management process. Incentives are connected to this issue: What kind of incentives the budget impact imposes on different actors? How this potentially impact on the organization? Payer could change during the screening process (e.g. municipality pays screening test but hospital district pays further investigations). Screening is usually free of charge for people, but sometimes participants have to pay e.g. hospital fee for further investigations. It must be noticed that when building up a new screening, initial costs are needed.	3	1	Literature search, reports questionnaires and interviews of different actors of the screening process (monitoring authorities, hospitals, hospital districts, laboratory), information from manufacturers.	Mauskopf et al. 2007 Principles of Good Practice for Budget Impact Analysis, Kristensen 2007	A0011, E0001	Yes
G0008	Management	What management problems and opportunities are attached to the technology?	The issue concerns the administrative / managerial questions of technology: management of resources (e.g. investments), co-ordination (in relation to different levels and different steps of the process), establishment of objectives, monitoring and control, evaluation and sanctioning. Data/information management systems connected to each of these points have to take account.	3	2	Literature search, guidelines, reports and documents of hospitals, own study: questionnaires and interviews of different actors of the process (monitoring authorities, hospitals, hospital districts, laboratory).	Report of the ISPOR Task Force on Good Research Practices	A0011, A0012, A0015, A0016, A0017, H0009	Yes
G0013	Management	What kind of monitoring requirements and opportunities are	There may be different monitoring systems for different phases of the process where the technology is used (e.g. personnel registry or quality control system) These registries are part of quality assurance. It is necessary to define validated/recommended indicators (guidelines for QA, or other documents). A	3	2	Literature search, reports and documents of hospitals and hospital districts, guidelines, own		A0013, A0014,	Yes

ID	Topic	Issue	Clarification	Im.	Tr.	Information sources	Reference	Relations	Core
		there for the technology?	core data set is needed to monitor the phases and to produce the recommended indicators. The information flow should be analysed.			study: questionnaires and interviews of different actors of the process (monitoring authorities, hospitals, hospital districts, laboratory).			
G0009	Management	Who decides which people are eligible for the technology and on what basis?	Information about the possible variations in the decision level and criteria has ethical implications. Decisions about the people eligible for screening is done in the beginning of the screening. Usually, it has been made nationally or regionally (in municipalities) but also locally (by employers). In systematic screening, the screening unit does not make decisions about who is eligible for screening. The management of positive test result needs systems to guarantee proper follow up and sometimes case specific evaluation. In this topic responsibilities should be identified.	2	2	Literature search, guidelines, documents of hospitals, own study: questionnaires and interviews of different actors of the process (monitoring authorities, hospitals, hospital districts, laboratory).	Kristensen 2007	F0012, I0012	Yes
G0010	Culture	How is the technology accepted?	Acceptance should be looked at by different perspectives: by organisation, by personnel and by participants. Organisational view can be separated out intra-organisational (primary care), inter-organisational (secondary care) and health care system level. In all these actors/views acceptance could vary. Alternative ways to introduce a new technology into the organisation could influence problems e.g. resistance among staff and dysfunction of processes. Acceptance could vary in the same screening process for example in foetal screening someone accepts ultrasound but not chromosomal (serum) test. Example of organisational acceptance: Sometimes screening could consist of elements which are not suitable for the image of the organisation. Screening is voluntary and for persons eligible for screening both decisions are right decisions: to participate or not. Giving understandable information on pros and cons of screening is important. Communicational skills of personnel may have an influence on acceptance of screening.	3	2	Literature search, own study: questionnaires and interviews of different actors of the screening process (monitoring authorities, hospitals, hospital districts, screening units, laboratory, staff, participants).	Finohta's EUnetHTA workshop 2006, Kristensen 2007	F0007, H0006	Yes
G0011	Culture	How are the other interest groups taken into account in the planning / implementation of the technology?	It may be useful to know who are the possible stakeholders, as well as what kind of co-operation exists and what kind of interaction is needed. The stakeholders could be e.g. the pharmaceutical industry and companies offering technologies for screening, authorities (national / regional), registry, administrative parties, municipalities, policy makers / decision makers, staff groups, GPs/primary care physicians and patient organisation. One can also ask: Has the patient organisation taken part into the evaluation process? Has it been involved from the beginning (in the planning) or in the later stages for example as commentator?	2	1	Literature search, reports and documents of hospitals, own study: questionnaires and interviews of different actors of the screening process (monitoring authorities, hospitals, hospital districts, screening units, laboratory, manufacturers, registry,	Kristensen 2001, Kristensen 2007, Senter för Medisinsk metodevurdering (SMM) 2003	F0003, F0011	No

ID	Topic	Issue	Clarification	Im.	Tr.	Information sources	Reference	Relations	Core
						participants).			

9 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 patients or citizens using the technology, and their important others. Major life areas include family life, day care, school, work, leisure time, lifestyle, or other daily activities. The use of the technology can affect the final decision of the individual about participating.	3	2	Search for existing literature review, or collect primary studies and if possible conduct a litterateur 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, patients, citizens, or important others can be consulted.	Hansen 2007		Yes
H0002	Major life areas	Who are the important others that may be affected, in addition to the individual using the technology?	E.g. the results of screening or genetic and prenatal testing, may affect relatives.	3	2	Search for existing literature review, or collect primary studies and if possible conduct a litterateur 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, patients, citizens, or important others can be consulted.		Ethical and Legal domains	Yes
H0004	Major life areas	What kind of changes may the use of the technology generate in the individual'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 (associated by the social norms and values defining the role) manner in major life areas.	3	2	Search for existing literature review, or collect primary studies and if possible conduct a litterateur 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, patients, citizens, or important others can be consulted	ICF 2001: activities and participation, interpersonal interactions and relationships (chapter 7, d710-779), community, social and civic life (chapter 9:d910-d999). Douglas 1996, Goffman 1990, Hoffman 2005, Becker 1997	Ethical, Effectiveness, Safety and Legal domains	Yes
H0005	Individual	What kind of physical and psychological changes does the implementation and use of the technology bring about and what kind of changes do patients or citizens expect?	This issue covers whether, from a patient perspective, the technology leads to improvements or harms, or generates any other unexpected effects on functioning.	3	2	Search for existing literature review, or collect primary studies and if possible conduct a litterateur 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, patients, citizens, or important others can be consulted.	ICF 2001, Good 1994	Effectiveness and Safety Domains	Yes
H0006	Individual	How do patients, citizens and the important others using the technology react	Micro sociological aspect: This issue is about the attitudes, perceptions, preferences, and satisfaction of the patients, citizens using the technology and their important other in relation to	3	2	Search for existing literature review, or collect primary studies and if possible conduct a litterateur review, or, if relevant data is not available, conduct a primary	ICF 2001: body functions: mental functions (chapter 1:b110-b199), environmental	Effectiveness and Ethical Domains	Yes

ID	Topic	Issue	Clarification	Im.	Tr.	Information sources	Reference	Relations	Core
		and act upon the technology?	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.			study; if there's no time for primary study, the opinion of health care professionals, patients, citizens, or important others can be consulted.	factors: attitudes (chapter 4:, e410-499), Whyte 1997		
H0007	Communication	What is the knowledge and understanding of the technology in patients and citizens?	This issue explores the 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) is needed before, during and after the use of the technology.	3	2	Search for existing literature review, or collect primary studies and if possible conduct a litterateur 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, patients, citizens, or important others can be consulted.		Health problem and current use, Safety, and Organisational Domains	Yes
H0008	Communication	How do patients and citizens perceive the information they receive or require about the technology?	This issue is about the exchange of information from the patients' and important others' perspectives. What are their questions? How do they receive answers?	3	2	Search for existing literature review, or collect primary studies and if possible conduct a litterateur 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, patients, citizens, or important others can be consulted.		Organisational Domain, B0014, B0015	Yes
H0013	Communication	What are the social obstacles or prospects in the communication about the technology?	E.g. limitations to decision making in participating or using the technology (dependent, passive user), and possibilities (empowered, active user)..	3	2	Search for existing literature review, or collect primary studies and if possible conduct a litterateur 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, patients, citizens, or important others can be consulted.		Organisational and Ethical Domains	Yes
H0009	Communication	What influences patients' or citizens' decisions to use the technology?	What kind of societal influences lead patients to decide to participate? How do the provisional perceptions about the outcome influence the use of the technology?	3	2	Search for existing literature review, or collect primary studies and if possible conduct a litterateur review, about what works and what does not.		Ethical and Effectiveness Domains	Yes
H0003	Major life areas	What kind of support and resources are needed for the patient	This issue is about any kind of support and resources (practical, physical, emotional, information, personal, social, nurturing, financial	3	2	Search for existing literature review, or collect primary studies and if possible conduct a litterateur review, or, if relevant	ICF 2001: environmental factors: support and relationships (chapter 3:	Organisational and Costs domains	Yes

ID	Topic	Issue	Clarification	Im.	Tr.	Information sources	Reference	Relations	Core
		or citizen as the technology is introduced?	etc.) to ensure the access and 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, attitudes, reasons for (non)-participation.			data is not available, conduct a primary study; if there's no time for primary study, the opinion of health care professionals, patients, citizens, or important others can be consulted.	e310-399); " activities and participation, chapter 6: d698, structural arrangements of patient's environment. Dreier 2000, Rapp 1999, Kaufert 2000		
H0010	Major life areas	What kind of social support and resources are needed for the providers as the technology is introduced?	This issue is about any kind of support and resources (attitude of providers, social gap between providers and patients, number of providers, time, documentation, flow for additional diagnostic or treatment, financial etc.) that need to be mobilized, and organized - or might be released to use the technology with satisfactory results.	3	2	Search for existing literature review, or collect primary studies and if possible conduct a litterateur 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, patients, citizens, or important others can be consulted.		Organisational domain	Yes
H0011	Major life areas	What kinds of reactions and consequences can the introduction of the technology cause at the overall societal level?	Macro sociological aspect: This issue is about the broader society. What social reactions can be expected for example from religious groups, specific patients and citizens organisations and associations and from any other stakeholder groups (social burden with accepted versus stigmatising diseases)? Are special (social) risk groups defined (ethnic, age etc.) and their possible reactions assessed?	3	2	Search for existing literature review, or collect primary studies and if possible conduct a litterateur review, or, if relevant data is not available, conduct a stakeholder analysis and a qualitative/quantitative primary study; if there's no time the systematic collection of opinion of some of the involved stakeholders and interest groups can be done. Patients, citizens and important others can be consulted.		Ethical, organizational and Legal domains	Yes
H0012	Individual	Are there factors that could prevent a group or persons to participate?	Do providers select? Are special groups discriminated? It should reflect how the legal regulation takes place in practice. Ethical and social issues have often been considered in academic articles and discussions in the HTA field, but they have rarely been translated into practice.	3	1	Implement the best available evidence about social restrictions, social pressure, social attitudes		Legal domain	Yes

10 Legal aspects

ID	Topic	Issue	Clarification	Im.	Tr.	Information sources	Reference	Relations	Core
I0002	Autonomy of the patient	Is the voluntary participation of patients guaranteed properly?	What kind of informed consent procedure is required by the law/binding rules? The use of screening programs is for symptom free (and probably healthy) people, therefore it must not compromise patient safety. Patients should not be pressured into such programs.	3	1	National, international, databases, legal binding guidelines, published laws, related or affected laws	EU Charter of fundamental rights (2000/C 364/01) Art 3;	Organisational domain	Yes
I0034	Autonomy of the patient	Who is allowed to give consent for minors and incompetent persons?		3	2	National law	Convention on Human Rights and Biomedicine, Art 6 and 7		Yes
I0036	Autonomy of the patient	Do laws/ binding rules require appropriate counseling and information to be given to the user or patient?	It is important to provide information on the consequences of using the technology in such a manner that the patient can truly understand it.	2	2		Convention on Human Rights and Biomedicine, Art 5; Art 12	B0004	Yes
I0008	Privacy of the patient	Do laws/ binding rules require informing relatives about the results?	The results of a test, or the incidental findings related to use any technology, may indicate that the relatives of a patient may have a medical condition that would need to be addressed. Do the laws/binding rules require breaking the privacy of the original patient in order to inform the relatives of their situation.	2	2		Directive 95/46/EC; Convention on Human Rights and Biomedicine Art 10. ECHR Case Law: Z. v. Finland Appl. 22009/93.	Ethical aspects, B0004	Yes
I0009	Privacy of the patient	Do laws/ binding rules require appropriate measures for securing patient data?	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. Data security has to be provided within a national legal framework when processing claims data or therapeutic information.	2	1		Directive 95/46/EC; Convention on Human Rights and Biomedicine Art 10,	Organisational aspects	No
I0011	Equality in health care	Do laws/ binding rules require appropriate processes or resources to guarantee equal access to the technology?	Is equitable access prescribed in the law or in practice, both at national and international level? The technology can be part of a public program or opportunistic. In many Constitutions equality of citizens covers also access to health care.	3	1		European Social Charter, 1996, ETS No. 163, Art 11 (1., 3.); Convention on Human Rights and Biomedicine Art 3; UN Covenant on Economic, Social and Cultural Rights (1966), Art 12. (Universal declaration Bioethics UNESCO (2005).)	Social, Ethical and Organisational Domains	Yes
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. Does subsidization enhance equal access?	2	1		Charter of Fundamental Rights of the European Union (2000/C 364/01). Art 35	Organisational and Costs Domains	No

ID	Topic	Issue	Clarification	Im.	Tr.	Information sources	Reference	Relations	Core
I0035	Equality in health care	Do laws/ binding rules require appropriate preventive or treatment measures available for all?	A screening program without the infrastructure to treat the detected diseases appropriately (and with equal access) would be unethical and senseless.	2	1		Additional protocol to the Convention on human rights and biomedicine on Genetic testing, Art 19 Genetic screening for public health purposes. CETS No 203 (2008).	In screening model only	No
I0015	Authorisation and safety	Has the technology national/EU level authorisation (marketing authorisation, registration, certification of safety, monitoring, qualification control, quality control)?	Does the technology require approval and evaluation of a certain committee? Which? How are professional competences and quality of laboratories being governed? A European database of medical devices (EUDAMED) is under construction.	3	2		In vitro diagnostic directive (98/79/EC); EUDAMED;	Safety domain, B0004, B0011	Yes
I0019	Ownership and liability	Does the technology infringe some intellectual property right?	Infringement of intellectual property rights can reduce the use of the 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; C-317/05 (ECJ), C-283/03 (ECJ).	2004/18/EC on public contracts.		Yes