EUnetHTA Joint Action 3 2016-2020

Clinical utility of point-of care tests: D-Dimer and Troponin

Project ID: ***OTCA22***

Project description and planning

Ludwig Boltzmann Institute for Health Technology Assessment (LBI-HTA), Austria

National School of Public Health, Management and Professional Development Bucharest (SNSPMPDSB), Romania

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Version Log

Version number	Date	Modification	Reason for the modification
V1	14/05/19	First draft	
V2	10/07/19	Developed draft	Comments from co-authors and dedicated reviewers included
V3	09/08/19	Further developed draft	Comments from external experts included
V4	12/08/19	Final draft	Formatted and edited version

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1 Project organisation

1.1 Participants

Table 1-1: Project participants

	Agency	Role in the project	Country	Distribution of work
Assessment team				
1.	LBI-HTA	Author	AT	Develop first draft of EUnetHTA project plan, amend the draft if necessary. Perform the literature search (systematic and by hand), literature selection, data extraction and risk of bias assessment (in agreement with co-author). Perform interviews with stakeholders in AT to ascertain context factors. Carry out the assessment: answer assessment elements, fill in checklist regarding potential "ethical, organisational, patient and social and legal aspects" of the HTA Core Model for rapid REA (see table 6). Send "draft versions" to reviewers, compile feedback from reviewers and perform changes according to reviewer's comments. Prepare final assessment and write a final summary of the assessment
2.	NSPHMPDB	Co-Author	RO	Review the project plan draft. Support the production of all domains and quality check the steps of their production (data, information, sources). Contribute in answering questions related to potential ethical, organisational, patient, social, and legal aspects if needed. Perform interviews with stakeholders in RO to ascertain context factors. Approve/endorse conclusions drawn as well as all draft versions and the final assessment including the executive summary.
3.	SNHTA	Dedicated Reviewer	CH	Guarantee quality assurance by thoroughly reviewing the project plan and the assessment drafts. Review methods, results, and conclusions based on the original studies included. Provide constructive comments in all the project phases
4.	HVB	Dedicated Reviewer	AT	Guarantee quality assurance by thoroughly reviewing the project plan and the assessment drafts. Review methods, results, and conclusions based on the original studies included. Provide constructive comments in all the project phases

Contributors				
5.	Dr.Susanne Rabady	External expert	AT	• Guarantee quality assurance by thoroughly reviewing the project plan and the assessment drafts. • Review methods, results, and conclusions based on the original studies included. Provide constructive comments in all project phases.
6.	Dr.Prof. Andreas Sönnichsen	External expert	AT	• Guarantee quality assurance by thoroughly reviewing the project plan and the assessment drafts. • Review methods, results, and conclusions based on the original studies included. Provide constructive comments in all project phases.
7.	TBD	Medical Editor		Medical editing
8.	LBI-HTA	Project Manager	AT	Project management

1.2 Project stakeholders

Table 1-2: Project stakeholders

Organisation	Role in the project
troponin test manufacturers: Roche, Siemens, Abbott, Samsung Healthcare, Eurolyser, Micropoint Bioscience, NowDiagnostics, Philips, Radiometer, Quidel, Pathfast, PBM, Response Biomedical	Manufacturers
d-dimer test manufacturers[1]: Agen Biomedical, Sekisui, Alere, Abbott, Roche, Siemens, SYCOmed, Micropoint Bioscience, Pathfast	Manufacturers

1.3 Milestones and Deliverables

Table 1-3: Milestones and Deliverables

Milestones/Deliverables	Start date	End date
Project duration	**15/04/2019**	**31/10/2019**
Scoping phase	15/04/2019	17/06/2019
Identification of manufacturer(s) and external experts	10/05/2019	21/05/2019
Scoping and development of draft Project Plan incl. preliminary PICO	10/05/2019	27/05/2019
Share the preliminary PICO with external experts for comments	27/05/2019	03/06/2019
Internal Scoping e-meeting with the assessment team	20/05/2019	20/05/2019
Consultation of draft Project Plan with dedicated reviewers	05/06/2019	12/06/2019
Consultation of draft Project Plan with external experts	10/07/2019	24/07/2019
Amendment of draft Project Plan & final Project Plan available	24/07/2019	12/08/2019
Assessment phase	19/06/2019	31/10/2019
Writing first draft rapid assessment POCT	19/06/2019	07/08/2019
Review by dedicated reviewer(s)	24/09/2019	07/10/02019
Writing second draft rapid assessment	08/10/2019	22/10/2019
Review by ≥ 2 external clinical experts and fact check by manufacturers	23/10/2019	06/11/2019
Writing third draft rapid assessment	07/11/2019	14/11/2019
Medical editing	14/11/2019	21/11/2019
Writing of fourth version of rapid assessment	21/11/2019	22/11/2019
Formatting	22/11/2019	28/11/2019
Publish final version of rapid assessment		**29/11/2019**

[1] Riley et al, Widely used types and clinical applications of D-Dimer assay, 2016. Laboratory Medicine 47; 2:90-102

2 Project Outline

2.1 Project Objectives

The rationale of this assessment is to collaboratively produce structured (rapid) core HTA information on other technologies. In addition, the aim is to apply those collaboratively produced assessments in the national or regional context.

Table 2-1: Project objectives

	List of project objectives	Indicator (and target)
1.	To jointly produce health technology assessments that are fit for purpose, of high quality, of timely availability, and cover the whole range of health technologies.	Production of 1 (rapid) relative effectiveness assessment.
2.	To apply this collaboratively produced assessment into local (e.g. regional or national) context.	Production of ≥2 local (e.g. national or regional) reports based on the jointly produced assessment.

This rapid assessment addresses the research question whether using the point of care technologies (POCT) D-dimer and troponin in symptomatic populations presenting at ambulatory [general (primary) or specialist medicine at outpatient or community care settings)] or emergency care settings is more effective and/or safer than current diagnostic practice. This topic was chosen based on a request from the representatives of the federal states in Austria who commissioned our agency to do an HTA on two POCTs, D-dimer and cardiac troponin (or cTn), in symptomatic patients [such as those reporting chest pain, breathlessness or swelling of the leg for the former and symptoms of acute coronary syndrome (ACS) such as chest pain or breathlessness that are potentially indicative of acute myocardial infarction for the latter] presenting at outpatient or general practice settings. The relevance of the topic lies in the fact that POCT enables testing during a consultation, potentially enabling triage to operate more effectively, through for instance preventing unnecessary further tests or hospital admissions.

2.2 Project Method and Scope

2.2.1 Approach and Method

Table 2-2: Project approach and method

Project approach and method
The HTA core model® for Rapid Relative Effectiveness (REA) will be used, focusing on the effectiveness (EFF), safety (SAF) and organisational (ORG) modules. Manufacturers will be asked to submit non-confidential evidence, focusing on the technical characteristics and current use of the technology. The evidence provided will be used in addition to the literature identified by the literature search. Study and outcomes validity and level of evidence will be assessed according to the EUnetHTA guidelines. AMSTAR will be used to assess the quality of systematic reviews. Should the inclusion of studies at the individual study level prove necessary, QUADAS-2 will be applied to assess the quality of the study. The quality of guidelines will be assessed using the Appraisal of Guidelines for Research & Evaluation (AGREE) instrument. The quality of the body of evidence will be assessed using GRADE (Grading of Recommendations, Assessment, Development and Evaluation). Evidence tables will be presented. Relevant subgroup analyses will be assessed especially for the most important outcomes.

To address country-specific context factors, semi-structured interviews will be conducted with representatives of the health care sector at different service provision levels (primary care, office-based specialists, emergency medicine) in Austria and in Romania.

All assessments and data extraction will be carried out by the main author; the co-author will act as the second independent reviewer for all stages.

Table 2-3: Planned literature search strategy

Literature search strategy
Sources for locating EFF and SAF domain specific information: databases including Embase, Medline, CRD database, Cochrane Library, Guideline International Network (GIN) database, AWMF and Trip will be used. Search terms: The main search concepts used are POC, point of care tests, troponin, d-dimer, “fibrin fibrinogen degradation products” Inclusion criteria: • English or German language • According to PICO criteria (see below) Exclusion criteria: • Population: • Animals, models and cadavers •Hospital in-patient settings Types of studies: HTA-reports, systematic reviews and meta-analyses, evidence-based guidelines. Where these types of publications cannot be identified, or require updating, a systematic search and review of primary studies will be conducted. Types of publications: Published articles, reports. Relevant ongoing RCTs will be identified by searching the following information sources: Clinicaltrials.gov, international clinical trials registry platform (ICTRP), EU Clinical Trials Register. Other written sources/grey literature For guidelines and HTA reports, the websites of relevant agencies (i.e., NICE, SIGN, ASERNIP-S, AWMF, DGK, New Zealand Guidelines Group, Australian Clinical Practice Guidelines, KCE) will be screened for relevant publications. This search will be supplemented by reviewing the bibliographies of key papers and through contacts with appropriate experts and industry. Interviews To address country-specific context factors, semi-structured interviews will be conducted with representatives of the health care sector at different service provision levels (primary care, office-based specialists, emergency medicine) in Austria and Romania. These interviews will remain confidential and transcripts will not be published.

Table 2-4: Plan for data extraction

Planned data extraction
Data will be extracted regarding: • Information about the systematic review/HTA/guideline study (e.g., authors, year of publication, setting, study design, inclusion and exclusion criteria, funding source, comparator) • Participant/patient characteristics of the included studies (e.g., number of participants in the trial, age, etc.) • Intervention and control characteristics (e.g., description of procedure, frequency of intervention per patient, dosage etc.) • Outcomes (e.g., diagnostic accuracy, number of patients in whom patient management

changed such as fewer subsequent tests or an avoidance of hospital admissions)
- For guidelines: recommendations regarding the use of the POCT tests in the diagnostic pathway, recommended cut-off levels and relevance of test results in different populations, settings and sub-groups.

2.2.2 Project Scope

The EUnetHTA Guidelines, available at https://www.eunethta.eu/methodology-guidelines/ **need to be consulted** throughout the assessment process.

Table 2-5(a): Project Scope: PICO for D-dimer (please see HTA Core Model® for rapid REA)

Description	Project Scope
Population	Adult patients ≥18 years with symptoms such as leg swelling, chest pain or trouble breathing that are potentially indicative of deep vein thrombosis or pulmonary embolism. Specific high-risk groups of patients (e.g. those with a previous VTE or those with cancer) will be excluded. Pulmonary embolism ICD 10: 0882, I269, I260; Deep vein thrombosis ICD 10: I801, I828, I829, O223, I822, I820, I802, I81, O082, I823, O871; Thrombophlebitis ICD 10: I809, I821, I808, I803.[2] The intended use of the technology is for use as a diagnostic tool to rule out the presence of venous thromboembolism often in conjunction with use of a clinical prediction rule (such as Wells or Geneva). MeSH-terms: Pulmonary Embolism, venous thrombosis, thromboembolism, “fibrin fibrinogen degradation products”
Intervention	The following point of care D-dimer products are available on the market: SimpliRED D-dimer (Agen Biomedical), NycoCard™ D-Dimer Single Test (Abbott), AxSYM D-dimer (Abbott), Triage D-dimer (Alere), Clearview Simplify D-dimer (Sekisui), DIMERTEST Latex (Sekisui), Roche Cardiac D-Dimer (Roche), Dade Dimertest Stratus CS Acute Care D-Dimer (Siemens), mLabs D-Dimer (Micropoint Bioscience), PATHFAST D-Dimer (Pathfast), i-CHROMA D-Dimer (SYCOmed)
Comparison	All comparators will be included. In the diagnostic performance testing, reference standard tests are likely to include computerized tomography pulmonary angiography (CTPA), ultrasound, venography/angiography and laboratory testing (as opposed to the near-patient testing devices). For the impact of POC diagnostics on patient management, usual care (incl. central laboratory methods) will be used.
Outcomes	➢ Evidence-based **clinical recommendations** regarding the use of POCT D-dimer (time interval between repeated tests, cut-off, etc.) ➢ **Diagnostic test accuracy outcomes** (sensitivity, specificity, positive predictive value, negative predictive value, positive likelihood ratio, negative likelihood ratio, rate of false positives and false negatives) of the test ➢ **Clinical utility**: benefit of near patient testing on patient management e.g. change in diagnostic thinking/further testing; change in hospital admission rate; change in time to start of treatment

[2] https://bmjopen.bmj.com/content/suppl/2015/11/11/bmjopen-2015-008864.DC1/bmjopen-2015-008864supp_tables.pdf

	➢ **Patient outcomes**: change in patient outcomes like morbidity and mortality ➢ **Harms** i.e. safety outcomes: harm from false positive and false negative tests, harm of imaging procedures, harms from delayed treatment ➢ **Behaviour/treatment patterns** of health care professionals ➢ **Availability** of the test, acceptability of and interest in the test for patients
Study design	At the first stage, systematic reviews and meta-analyses as well as HTA reports and evidence-based guidelines will be included. In a second stage, single studies (controlled trials ≥ 10 participants) may be included in order to update the results of available systematic reviews or expand the scope of available systematic reviews, where necessary. Yet, only primary studies on the clinical utility will be included for the update assessment. Studies published from 2009 onwards will be included.

Table 2-6(b): Project Scope: PICO for troponin (please see HTA Core Model® for rapid REA)

Population	Adult patients ≥18 years with signs and or symptoms of acute coronary syndrome (ACS) such as chest pain or breathlessness that are potentially indicative of acute myocardial infarction which is suspected but has not been ruled out. Specific high-risk groups of patients will be excluded. The intended use of the biomarker cardiac troponin is for use in patients who present with chest pain or suspected myocardial infarction (MI). MeSH-terms: acute coronary syndrome, myocardial infarction, unstable angina pectoris, cardiac troponin. ICD-10: I20-I24
Intervention	Point of care cardiac troponin products that are available on the market are as follows: i-STAT CtnI CARTRIDGE (Abbott Diagnostics), CARDIAC POC Troponin T (Roche), Stratus® CS Analyzer (Siemens), Minicare Troponin-I (cTnI) assay and Minicare I-20 (Philips), LABGEO^{IB}10 analyzer and LABGEO^{IB} TnI (Samsung), ADEXUSDx® Troponin I Test (NowDiagnostics), RAMP® Cardiac Troponin I test (Response Biomedical), Troponin I Test (Eurolyser), mLabs Troponin I (Micropoint), PATHFAST^{TM} (LSI Medience Corporation; former Mitsubishi), Quidel Cardio3 (cTnI), Cardio2, Triage Troponin I (Quidel), AQT90 FLEX cTnI and AQT90 FLEX cTnT (Radiometer), troponin I test (PBM), i-CHROMA Diagnostics (Sycomed)
Comparison	All comparators will be included. In the diagnostic performance testing, gold standards are likely to include echocardiography, angiography and laboratory testing (as opposed to the near-patient testing devices). For the impact of POC diagnostics on patient management, usual care (incl. central laboratory methods) will be used.
Outcomes	➢ Evidence-based **clinical recommendations** regarding the use of POCT cardiac troponin as opposed to high sensitive cardiac troponin (time interval between repeated tests, cut-off, etc.) ➢ **Diagnostic test accuracy outcomes** (sensitivity, specificity, positive predictive value, negative predictive value, positive likelihood ratio, negative likelihood ratio, rate of false positives and false negatives) of the test ➢ **Clinical utility**: benefit of near patient testing on turnaround time (as opposed to laboratory testing), time to clinical decision-making, impact on

	patient management e.g. change in diagnostic thinking/further testing; impact on hospital admissions; change in time to start of treatment ➢ **Patient outcomes**: change in patient outcomes like morbidity and mortality ➢ **Harms** i.e. safety outcomes: harm from false positive and false negative tests, harm of imaging procedures, harms from delayed treatment ➢ **Behaviour/treatment patterns** of health care professionals ➢ **Availability** of the test, acceptability of and interest in the test for patients
Study design	At the first stage, systematic reviews and meta-analyses as well as HTA reports and evidence-based guidelines will be included. In a second stage, single studies may be included in order to update the results of available systematic reviews or expand the scope of available systematic reviews. Yet, only primary studies on the clinical utility will be included for the update assessment. Studies published from 2009 onwards will be included.

3 Communication and collaboration

Table 3-1: Communication

Communication Type	Description	Date	Format	Participants/ Distribution
Scoping	To internally discuss and reach consensus on the scoping.	20-21/05/2019	E-meeting	Author(s), co-author(s), dedicated reviewers, observers, project manager (external experts, patients)
		[DD/MM/YYYY]	*Additional e-meetings may be planned whenever needed*	*Author(s), Co-author(s), dedicated reviewer(s), project manager*
First draft of the rapid assessment	*To discuss comments of dedicated reviewers*	*[DD/MM/YYYY]*	*E-meetings may be planned*	*Author(s), co-author(s), dedicated reviewers*
Second draft of the rapid assessment	*To discuss comments from ≥ 2 external clinical experts and manufacturers*	*[DD/MM/YYYY]*	*E-meetings may be planned*	*Author(s), co-author(s), dedicated reviewers; external experts, manufacturers*

3.3 Dissemination plan

The final rapid assessment will be published on the EUnetHTA website:
https://www.eunethta.eu/rapid-reas/
All stakeholders and contributors are informed about the publication of the final assessment by the project manager.

3.4 Collaboration with stakeholders

Collaboration with manufacturer(s)

There will be a review of the preliminary PICO and a fact check of the 2nd draft project plan and the 2nd draft assessment by the manufacturer(s). In addition, manufacturers will be requested to complete a submission file.

Collaboration with other stakeholders

There will be collaborations (via interviews) with stakeholders or physicians in different settings in Austria to provide information on context factors.

3.5 Collaboration with EUnetHTA WPs

For the individual rapid assessment, some collaboration with other WPs is planned: WP7 [Implementation] will be informed of the project, in order to prepare activities to improve national uptake of the final assessment. Feedback on the WP4 REA process will be asked from the involved parties by WP6 [Quality Management], and this information will be processed by WP6 to improve the quality of the process and output.

3.6 Conflict of interest and confidentiality management

Conflicts of interest will be handled according to the EUnetHTA Conflict of Interest Policy. All individuals participating in this project will sign the standardised “Declaration of Interest and Confidentiality Undertaking” (DOICU) statement.

Author, co-author(s) and dedicated reviewers who declare a specific conflict of interest will be excluded from the whole work under this specific topic. However, they still may be included in other assessments.

For external experts, patients or other stakeholders involved, conflict of interest declarations are collected. External experts or patients who declare a specific conflict of interest will be excluded from parts of or the whole work under this specific topic. However, they still may be included in other assessments.

Manufacturer(s) will sign a Confidentiality Undertaking (CU) form regarding the specific project.

4 References

CADTH Rapid Response Report: Summary with Critical Appraisal Point-Of-Care Testing: A Review of Diagnostic Accuracy, Clinical Utility and Safety. November 14, 2017

CADTH Optimal Use Report : Point-of-Care Troponin Testing in Patients with Symtoms Suggestive of Acute Coronary Syndrome: A Health Technology Assesment. March 2016.

Crawford F, Andras A et al. D-dimer test for excluding the diagnosis of pulmonary embolism (Review). Cochrane Database of Systematic Reviews 2016, Issue 8.

Geersing, G., et al., Excluding venous thromboembolism using point of care D-dimer tests in outpatients: a diagnostic meta-analysis. BMJ, 2009 Aug 14(339): p. b2990.

Larsson A., Greig-Pylpczuk R., Huisman A. The state of point-of-care testing: a European perspective. Ups J Med Sci, 2015. 120(1): p. 1-10.

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NHS National Instutute for Health Researh. Westwood M., van Asselt T. et al. High-sensitivity troponin assays for the early rule-out or diagnosis of acute myocardial infarction in people with acute chest pain: a systematic review and cost-effectiveness analysis. Health Technology Assessment vol. 19, Issue 44. June 2015

Pecoraro, V., L. Germagnoli, and G. Banfi, Point-of-care testing: where is the evidence? A systematic survey. Clin Chem Lab Med, 2014. Mar;52(3): p. 313-24.

5 Appendix A

5.1 Selected Assessment Elements

The table shows the assessment elements and the translated research questions that will be addressed in the assessment. They are based on the assessment elements contained in the 'Model for Rapid Relative Effectiveness Assessment'. Additionally, assessment elements from other HTA Core Model Applications (for medical and surgical interventions, for diagnostic technologies or for screening) have been screened and included/ merged with the existing questions if deemed relevant.

Table 5-1: Selected Assessment Elements

ID	Topic	Topic Issue	Relevance in this assessment	Mandatory (M) or non-mandatory (NM)	Research question(s) or reason for non-relevance of 'mandatory' elements
Description and technical characteristics of technology					
B0001	Features of the technology and comparators	What is the technology and the comparator(s)?	Y	M	
A0020	Regulatory Status	For which indications has the technology received marketing authorisation or CE marking? [This assessment element can be placed either in the TEC OR in the CUR domain]	Y	M	
B0002	Features of the technology and comparators	What is the claimed benefit of the technology in relation to the comparator(s)?	Y	M	
B0003	Features of the technology	What is the phase of development and implementation of the technology and the comparator(s)?	Y	NM	
B0004	Features of the technology	Who administers the technology and the comparator(s) and in what context and level of care are they provided?	Y	M	
B0008	Investments and tools required to use the technology	What kind of special premises are needed to use the technology and the comparator(s)?	N	NM	
B0009	Investments and tools required to use the technology	What equipment and supplies are needed to use the technology and the comparator(s)?	Y	NM	
A0021	Regulatory Status	What is the reimbursement status of the technology? [This assessment element can be placed either in the TEC OR in the CUR domain]	*Y*	NM	
Health problem and current use of technology					
A0002	Target Condition	What is the disease or health condition in the scope of this	Y	M	

ID	Topic	Topic Issue	Relevance in this assessment	Mandatory (M) or non-mandatory (NM)	Research question(s) or reason for non-relevance of 'mandatory' elements
		assessment?			
A0003	Target Condition	What are the known risk factors for the disease or health condition?	Y	NM	
A0004	Target Condition	What is the natural course of the disease or health condition?	Y	M	
A0005	Target Condition	What are the symptoms and the burden of disease or health condition for the patient?	Y	M	
A0006	Target Condition	What are the consequences of the disease or health condition for the society?	Y	NM	
A0024	Current Management of the Condition	How is the disease or health condition currently diagnosed according to published guidelines and in practice?	Y	M	
A0025	Current Management of the Condition	How is the disease or health condition currently managed according to published guidelines and in practice?	Y	M	
A0007	Target Population	What is the target population in this assessment?	Y	M	
A0023	Target Population	How many people belong to the target population?	Y	M	
A0011	Utilisation	How much are the technologies utilised?	Y	M (NM for diagnostics)	
Clinical effectiveness					
D0001	Mortality	What is the expected beneficial effect of the intervention on mortality?	Y	M	
D0005	Morbidity	How does the technology affect symptoms and findings (severity, frequency) of the disease or health condition?	Y	M	
D0006	Morbidity	How does the technology affect progression (or recurrence) of the disease or health condition?	Y	M	
D0011	Function	What is the effect of the technology on patients' body functions?	N	M	
D0016	Function	How does the use of technology affect activities of daily living?	N	NM	
D0012	Health-related quality of life	What is the effect of the technology on generic health-related quality of life?	N	M	
D0013	Health-related	What is the effect of the technology on	N	M	

ID	Topic	Topic Issue	Relevance in this assessment	Mandatory (M) or non-mandatory (NM)	Research question(s) or reason for non-relevance of 'mandatory' elements
	quality of life	disease-specific quality of life?			
D0017	Patient satisfaction	Were patients satisfied with the technology?	N	NM	
Safety					
C0008	Patient safety	How safe is the technology in relation to the comparator(s)?	Y	M	
C0002	Patient safety	Are the harms related to dosage or frequency of applying the technology?	N	NM	
C0004	Patient safety	How does the frequency or severity of harms change over time or in different settings?	Y	M	
C0005	Patient safety	What are the susceptible patient groups that are more likely to be harmed through the use of the technology?	Y	M	
C0007	Patient safety	Are the technology and comparator(s) associated with user-dependent harms?	N	NM	
B0010	Safety risk management	What kind of data/records and/or registry is needed to monitor the use of the technology and the comparator(s)?	N	M for medical devices NM for screening and diagnostics	

5.2 Checklist for potential ethical, organisational, patient and social and legal aspects

The following checklist will be completed during the assessment.

1. Ethical	
1.1. Does the introduction of the new technology and its potential use/non-use instead of the defined, existing comparator(s) give rise to any new ethical issues?	No
1.2. Does comparing the new technology to the defined, existing comparators point to any differences that may be ethically relevant?	No
2. Organisational	
2.1. Does the introduction of the new technology and its potential use/non-use instead of the defined, existing comparator(s) require organisational changes?	Yes
Should the tests show benefits in terms of clinical utility or patient outcomes, it may be necessary to effect organisational changes to be able to realise the potential of the tests.	
2.2. Does comparing the new technology to the defined, existing comparator(s) point to any differences that may be organisationally relevant?	Yes

Yes there may be organisationally relevant, contextual factors e.g. in referring practises.	
3. Social	
3.1. Does the introduction of the new technology and its potential use/non-use instead of the defined, existing comparator(s) give rise to any new social issues?	No
3.2. Does comparing the new technology to the defined, existing comparator(s) point to any differences that may be socially relevant?	No
4. Legal	
4.1. Does the introduction of the new technology and its potential use/non-use instead of the defined, existing comparator(s) give rise to any legal issues?	No
4.2. Does comparing the new technology to the defined, existing comparator(s) point to any differences that may be legally relevant?	No