EUnetHTA Joint Action 3 2016-2020

Robot-assisted surgery in thoracic and visceral surgery

Project ID: ***OTCA14***

Project description and planning

Ludwig Boltzmann Institute for
Health Technology Assessment

Azienda Zero
Regione del Veneto

Version Log

Version number	Date	Modification	Reason for the modification
V1	22/05/2018	First draft	-
V2	19/06/2018	Developed draft	Comments from co-authors, dedicated reviewers and external experts included
V3	24/06/2018	Further developed draft	Comments from manufacturers included
V4	10/07/2018	Final draft	Final comments from co-authors and dedicated reviewers included

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1 Azienda ZeroProject organisation

1.1 Participants

Table 1-1: Project participants

	Agency	Role in the project	Country	Distribution of work
Assessment team				
1.	Ludwig Boltzmann Institute for Health Technology Assessment (LBI-HTA)	Author	Austria	• 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). • 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.	Azienda Zero Regione del Veneto	Co-Author	Italy	• Review draft EUnetHTA project plan.
				• Check and approve all steps (e.g. literature selection, data extraction, assessment of risk of bias).
				• Review draft assessment, propose amendments where necessary and provide (written) feedback on:
				  • Information retrieval: sources and search terms for locating domain specific information, inclusion/exclusion criteria for studies or other information, in terms of content, methods and quality.
				  • Handling the published data: do a systematic review, cite recent reviews, "screen until saturated" etc.
				  • Finding information when there is no published data: From web sites of organisations, discussion forums, registers: Other type of own research (analysis of primary data, modelling etc).
				  • Quality assessment tools or criteria planned to be used.
				  • Synthesis: evidence table, plan for meta-analysis, if applicable.

3.	Health Information and Quality Authority (HIQA)	Dedicated Reviewer	Ireland	• 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.
4.	DEFACTUM, Social & Health Services and Labour Market	Dedicated Reviewer	Denmark	• 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.
Contributors				
5.		External experts		• 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.	Compuscript Ltd.	Medical Editor		Medical editing.
7.	Ludwig Boltzmann Institute for Health Technology Assessment, LBI-HTA	Project Manager	Austria	Project management.

1.2 Project stakeholders

Table 1-2: Project stakeholders

Organisation	Role in the project
Intuitive Surgical	Manufacturer
TransEnterix	Manufacturer (no response in time received)
Surgica Robotica	Manufacturer (no response received)

1.1 Project Method and Scope

1.3 Milestones and Deliverables

Table 1-3: Milestones and Deliverables

Milestones/Deliverables	Start date	End date
Project duration	**02/05/2018**	**30/11/2018**
Scoping phase	02/05/2018	06/07/2018
Identification of manufacturer(s) and external experts	02/05/2018	22/05/2018
Scoping and development of draft Project Plan incl. preliminary PICO	02/05/2018	22/05/2018
Internal Scoping e-meeting with the assessment team	28/05/2018	28/05/2018
Share the preliminary PICO with external experts for comments	30/05/2018	07/06/2018
Send the preliminary PICO for comments *and the request for the completion of the Submission file template to manufacturer(s)*	*29/05/2018*	*20/06/2018*
Consultation of draft Project Plan with dedicated reviewers	25/06/2018	29/06/2018
Consultation of draft Project Plan with external experts and fact	03/07/2018	09/07/2018

check by manufacturers		
Amendment of draft Project Plan & final Project Plan available	09/07/2018	13/07/2018
Completion of Submission file template by manufacturer(s) + Clarifying further questions concerning draft Submission file	*06/06/2018*	*06/07/2018*
Assessment phase	16/07/2018	30/11/2018
Writing first draft rapid assessment	16/07/2018	31/08/2018
Review by dedicated reviewer(s)	03/09/2018	14/09/2018
Writing second draft rapid assessment	17/09/2018	28/09/2018
Review by ≥ 2 external clinical experts and fact check by manufacturers	01/10/2018	19/10/2018
Writing third draft rapid assessment	22/10/2018	25/10/2018
Medical editing	29/10/2018	09/11/2018
Writing of fourth version of rapid assessment	12/11/2018	16/11/2018
Formatting	19/11/2018	23/11/2018
Final version of rapid assessment		**week** from 26/11/2018 - to 30/11/2018

2 Project OutlineProject 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 robot-assisted surgery in patients with an indication for operations in the area of the thorax and viscera (abdomen) is more effective and safer (or at least as safe) than laparoscopic or open surgery (or thoracoscopic approach for thoracic surgery). This topic was chosen based on a request from the representatives of the Austrian federal states who commissioned our agency (LBI-HTA) to do an HTA on robot-assisted surgery in patients with an indication for operations in the area of the thorax and viscera. The relevance of the topic lies in the fact that the areas of indications for robot-assisted surgery are increasing, but robot-assisted surgery is associated with high costs for acquisition.

2.1.1 Approach and Method

Table 2-2: Project approach and method

Project approach and method
The HTA Core Model Application for rapid Relative Effectiveness Assessment (REA) (4.2) will be the primary source for selecting assessment elements. The selected assessment element with generic questions, will be translated into research questions. TEC and CUR domains Answers to these domains will be based on • Input from manufacturers, particularly related to questions on CE mark, marketing, availability and current use. The Medical Devices Evidence Submission template will be sent to all relevant manufacturers of the technology under assessment. 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. • Input from clinical experts, particularly related to description of disease, current treatment, current use and best available epidemiological data. The clinical experts will be asked to verify the relevance and accuracy of the information and citations. • Clinical guidelines. A search for the clinical guidelines will be performed by the author using G-I-N as a source, supplemented by a hand search (e.g. via Google). EFF and SAF domains A systematic search of the literature will be performed, supplemented by a hand search. The author and co-author will independently screen the titles and abstracts and select studies according to the pre-defined inclusion and exclusion criteria. The full-text publications will be retrieved by the author and the full-text examination will be performed by the author and the co-author independently. The author will provide a list of included and excluded studies. Disagreement will be solved by discussion or by the involvement of third parties (dedicated reviewers, external experts). Study and outcomes validity and level of evidence will be assessed according to the EUnetHTA guidelines.

The Cochrane Risk of bias tool will be used on study and outcome level. The quality of the body of evidence will be assessed using GRADE (Grading of Recommendations, Assessment, Development and Evaluation). Relevant subgroup analyses will be assessed especially for the most important outcomes.

Evidence will be synthesised in evidence tables and by GRADE (see above). If feasible, data will be also synthesised in meta-analyses, using "OpenMeta[Analyst]".

Table 2-3: Planned literature search strategy

Literature search strategy

• Sources for locating EFF and SAF domain specific information: Embase, Medline, CRD database, Cochrane Library.
• Search terms: TBA
• Inclusion criteria:
  • English or German language
  • According to PICO criteria (see below)
• Exclusion criteria:
  • Population:
  • Animals, models and cadavers
  • Patients with indication for:
  o Pneumonectomy (exclusion recommended by manufacturer)
  o Pleurectomy (exclusion recommended by external experts and manufacturer)
  o Pleural / pulmonary decortication (exclusion recommended by external experts and manufacturer)
  o Appendectomy (exclusion recommended by external experts and manufacturer)
  o Splenectomy (exclusion recommended by external experts and manufacturer)
  o Pancreatectomy (exclusion recommended by external experts and manufacturer)
  o Cardiothoracic surgeries
  o Mediastinoscopy, Pleuroscopy and Thorascopy (e.g. for diagnosis)
  o Thoracotomy (without any further intervention, e.g. lung resection)
  o Relaparotomy (without any further intervention)
  • Surgical robots used for stereotactic, single incision laparoscopic surgery, robotic instrument positioners (without concurrent use of other robotic instruments)
  • Technologies that are generally not considered robotic (e.g. pure computer navigation system)
  • Types of studies:
  • controlled studies with less than 10 patients
  • retrospective controlled studies
  • uncontrolled studies (like case reports, case series, single-arm studies, etc.)
  • HTA-reports and systematic reviews (these documents will partly be considered as background literature)
  • Types of publications:
  • unpublished documents
  • abstracts, posters, letters
  • editorials, letters to the editor, comments, other correspondence etc.
  • books
  • retrospective study design, uncontrolled studies, controlled studies with less than 10 patients, HTA-reports, systematic reviews (HTA-reports and systematic reviews will be considered as background literature)
• Relevant ongoing RCTs will be identified by searching the following information sources: Clinicaltrials.gov, international clinical trials registry platform (ICTRP), EU Clinical Trials Register

Table 2-4: Plan for data extraction

Planned data extraction
Data to be extracted from the studies included: • Information about the study (authors, year of publication, setting/country, funding, study design, clinical trial identification number/ registry identifier and funding source) • Participant/patient characteristics (diagnosis, number of participants in the trial, age, clinical stage, risk category,) • Intervention and control characteristics (description of procedure, comparator, name/type of the device, frequency of intervention per patient, length of follow up and loss to follow up) • Outcomes (see section 2.2.2). For missing data trial authors will be contacted by the author (via e-mail). If possible, dichotomous outcome results will be expressed as risk ratio (RR). Where continuous scales of measurement are used to assess the effects of treatment, the mean difference (MD) will be used; if different scales are used the standardised mean difference (SMD) will be used.

2.1.2 Project Scope

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

Description	Project Scope
Population	Patients with indication for thoracic surgery: • Pulmonary (sleeve) lobectomy [non-small cell lung cancer] o International classification of diseases **(ICD)-10-CM code**: e.g. Z90.2 Acquired absence of lung [part of], C34.1/C34.2/C34.3 Malignant neoplasm of upper/middle/lower lobe, bronchus or lung **MeSH Terms**: e.g. Lung Neoplasms [C04.588.894.797.520, C08.381.540, C08.785.520], Pulmonary Surgical Procedures [E04.928.600] • Lung segmentectomy / wedge resection [non-small cell lung cancer] o **ICD-10-CM code**: e.g. Z90.2 Acquired absence of lung [part of], C34.1/C34.2/C34.3 Malignant neoplasm of upper/middle/lower lobe, bronchus or lung o **MeSH Terms**: e.g. Lung Neoplasms [C04.588.894.797.520, C08.381.540, C08.785.520], Pulmonary Surgical Procedures [E04.928.600] • Mediastinal surgery: e.g. Thymectomy [Myasthenia gravis (pseudoparalytica); thymoma]; (posterior) mediastinal lesion resection [(posterior) mediastinal mass / tumour, neurogenic tumour]; other mediastinal pathology [e.g.mediastinal bronchogenic cyst, lipoma, teratoma or fibrous tumour of the mediastinum] o **ICD-10-CM code**: e.g. G70.0 Myasthenia gravis, D15.0 Benign neoplasms of thymus, C37 Malignant neoplasms of the thymus, D15.2 Benign neoplasm of mediastinum, D21.3 Benign neoplasm of connective and other soft tissue of thorax, C38.1 Malignant neoplasm of anterior mediastinum, C38.2 Malignant neoplasm of posterior mediastinum, C38.3 Malignant neoplasm of mediastinum, part unspecified, J85.3 Abscess of mediastinum, J98.5 Diseases of mediastinum, not elsewhere classified, Q33.0 Congenital cystic lung, Q33.2 Sequestration of lung, Q33.5 Ectopic tissue in lung o **MeSH Terms**: e.g. Myasthenia Gravis [C10.114.656, C10.668.758.725, C20.111.258.500], Thymoma [C04.557.435.850, C04.588.894.949.500, C15.604.861.800], Mediastinum [A01.923.761.800.500], Thymectomy [E04.928.770] Patients with indication for visceral (abdominal) surgery: • Oesophagus: o Anti-reflux surgery / fundoplication [gastroesophageal reflux disease (GERD), hiatal hernia] o **ICD-10-CM code**: e.g. K21 Gastro-esophageal reflux disease, K44 Diaphragmatic hernia o **MeSH Terms**: e.g. Gastroesophageal Reflux [C06.405.117.119.500.484], Hernia, Hiatal [C23.300.707.500.467] o Oesophagectomy (total or partial) / transhiatal oesophagectomy [benign or malignant oesophageal tumours, oesophageal leimyoma, oesophageal diverticula] o **ICD-10-CM code**: e.g. C15 Malignant neoplasm of esophagus, D13.0 Benign neoplasm of esophagus, K22.1 Ulcer of esophagus, K22.8 Other specified diseases of esophagus. K22.9 Disease of esophagus, unspecified, K22.5 Diverticulum of esophagus, acquired o **MeSH Terms**: e.g. Esophageal Diseases [C06.405.117], Esophageal Neoplasms [C04.588.274.476.205, C04.588.443.353, C06.301.371.205,

	C06.405.117.430, C06.405.249.205], Diverticulosis, Esophageal [C06.405.117.136, C06.405.205.282.500.438], Esophagus [A03.556.875.500], Esophagectomy [E04.210.346] o Oesophageal repair[1] [oesophageal perforation] o **ICD-10-CM code**: e.g. K22.3 Perforation of esophagus o **MeSH Terms**: e.g Esophageal Perforation [C06.405.117.468, C26.348], Esophagus [A03.556.875.500] o (Heller) Myotomy [swallowing disorder / achalasia] o **ICD-10-CM code**: e.g. K22.0 Achalasia of cardia o **MeSH Terms**: e.g. Esophageal Achalasia [C06.405.117.119.500.432], Myotomy [E04.515] • Stomach: o Gastrectomy [subtotal for gastric cancer <stage IB, radical for IB-III] o **ICD-10-CM code**: e.g. C16 Malignant neoplasm of stomach o **MeSH Terms**: e.g. Stomach Neoplasms [C04.588.274.476.767, C06.301.371.767, C06.405.249.767, C06.405.748.789], Gastrectomy [E04.210.419] o Bariatric surgery[2]: e.g. (ROUX-en-Y) gastric bypass, sleeve gastrectomy, gastric banding, implantable gastric stimulator, band revision; [obesity] o **ICD-10-CM code**: e.g. E66 Overweight and obesity o **MeSH Terms**: e.g. Obesity [C18.654.726.500, C23.888.144.699.500, E01.370.600.115.100.160.120.699.500, G07.100.100.160.120.699.500], Bariatric Surgery [E02.570.500.062, E04.062] • Bowel: o Small bowel resection[1] [bleeding, infection, ulcers, blockage, benign tumours, precancerous polyps, cancer, injuries, Meckel's diverticulum] o **ICD-10-CM code**: e.g. K26 Duodenal ulcer, C17 Malignant neoplasm of small intestine, D13.2 Benign neoplasm of duodenum, C17.3 Meckel's diverticulum, malignant o **MeSH Terms**: e.g. Intestine, Small [A03.556.124.684], Meckel Diverticulum [A03.556.124.684.249.612, A03.556.249.124.612, C01.539.463.199.750.750, C06.198.859, C06.405.205.282.750.750, C16.131.314.556, C23.300.415.750], Duodenal Diseases [C06.405.469.275], Duodenal Neoplasms [C04.588.274.476.411.445, C06.301.371.411.445, C06.405.249.411.445, C06.405.469.275.270, C06.405.469.491.445], Jejunal Neoplasms [C04.588.274.476.411.523, C06.301.371.411.523, C06.405.249.411.523, C06.405.469.491.523, C06.405.469.600.523], Ileal Neoplasms [C04.588.274.476.411.501, C06.301.371.411.501, C06.405.249.411.501, C06.405.469.420.501, C06.405.469.491.501] o Colectomy (total, partial) / hemicolectomy (left, right) / abdominal colectomy / proctocolectomy / sigmoid colectomy / transverse colectomy [bleeding, bowel obstruction, cancer, Crohn's disease, ulcerative colitis, diverticulitis, cancer prevention] o ICD-10-CM code: e.g. C18 Malignant neoplasm of colon, D12 Benign neoplasm of colon, rectum, anus and anal canal, K51 Ulcerative colitis, K50 Crohn's disease [regional enteritis], K56 Paralytic ileus and intestinal obstruction without hernia, K57 Diverticular disease of intestine o **MeSH Terms**: e.g. Diverticulitis [C01.539.463.199.375,

[1] Intervention was recommended to be excluded from PICO by one external expert, but not by the manufacturers. Thus, the intervention was kept.
[2] Intervention was recommended to be excluded from PICO by one manufacturer (studies are currently underway). However, TransEnterix claims that the Senhance™ Surgical System is intended for use in bariatric surgery.

	C06.405.205.282.500], Colorectal Neoplasms [C04.588.274.476.411.307, C06.301.371.411.307, C06.405.249.411.307, C06.405.469.158.356, C06.405.469.491.307, C06.405.469.860.180], Crohn Disease [C06.405.205.731.500, C06.405.469.432.500], Colitis [C06.405.205.265, C06.405.469.158.188], Colectomy [E04.210.219] o Rectal resection (anterior, low anterior, inter sphincteric, total) / colorectal resection / polyectomy / proctectomy / rectopexy / total mesorectal excision [e.g. rectal cancer, rectal prolapse] o **ICD-10-CM code**: e.g. C20 Malignant neoplasm of rectal ampulla, D12.8 benign neoplasm of rectum, K62.3 Rectal prolapse o **MeSH Terms**: e.g. Rectal Neoplasms [C04.588.274.476.411.307.790, C06.301.371.411.307.790, C06.405.249.411.307.790, C06.405.469.491.307.790, C06.405.469.860.180.500], Rectal Prolapse [C06.405.469.860.800, C23.300.842.624.500] • Gallbladder / Liver / Spleen: o Cholecystectomy[3] [biliary colic, acute cholecystitis, cholangitits (e.g. caused by symptomatic gallstones), gallbladder cancer] o **ICD-10-CM code**: e.g. R10.83 Colic, K81 Cholecystitis, K83.0 Cholangitis, C23 Malignant neoplasm of gallbladder o **MeSH Terms**: e.g. Colic [C16.614.166], Cholecystitis [C06.130.564.263], Cholangitis [C06.130.120.200], Gallbladder Neoplasms [C04.588.274.120.401, C06.130.320.401, C06.130.564.401, C06.301.120.401], Cholecystectomy [E04.210.120.172] o Liver resection (partial, total) / hepatectomy[4] [liver cell carcinoma, hepatocellular carcinoma / adenoma, hepatic hemangioma, focal nodular hyperplasia] o **ICD-10-CM code**: e.g. C22 Malignant neoplasm of liver and intrahepatic bile ducts, C22.0 Liver cell carcinoma, D13.4 Benign neoplasm of liver, D18.09 Hemangioma of other sites o **MeSH Terms**: e.g. Liver Neoplasms [C04.557.470.200.025.255, C04.588.274.623.160, C06.301.623.160, C06.552.697.160], Carcinoma, Hepatocellular [C04.557.470.200.025.255, C04.588.274.623.160, C06.301.623.160, C06.552.697.160], Adenoma, Liver Cell [C04.557.470.035.120, C04.588.274.623.040, C06.301.623.040 C06.552.697.040], Hepatectomy [E04.210.556] o Hernia repair[3] o **ICD-10-CM code**: e.g. K40-K46 Hernia, K40 inguinal hernia o **MeSH Terms**: e.g. Hernia [C23.300.707], Hernia, Abdominal [C23.300.707.374], Hernia, Inguinal [C23.300.707.374.875], Herniorrhaphy [E04.680.325] **Rationale:** The population has been defined based on the suggested interventions for robot-assisted surgery in recent systematic reviews or studies [1-4], and informed by external experts and manufacturers. Moreover, since the interventions are in the focus of the assessment, the individual indications are examples, which the assessment is not limited to.
Intervention	• Robot-assisted surgery (several products)

[3] Intervention was recommended to be excluded from PICO by external experts and one manufacturer. However, TransEnterix claims that the Senhance™ Surgical System is intended for this intervention (cholecystectomy and inguinal hernia repair). Thus, the intervention was kept.
[4] Intervention was recommended to be excluded from PICO by one manufacturer (studies are currently underway). However, TransEnterix claims that the Senhance™ Surgical System is intended for use in bariatric surgery.

Comparison	• Laparoscopic surgery (or thoracoscopic approach for thoracic surgery) • Open surgery **Rationale**: Appropriate comparators have been informed by selected guidelines [5, 6] and systematic reviews [7].
Outcomes[5]	Effectiveness (*critical* outcomes are highlighted in **bold**): • **Survival (overall and disease-specific or disease-free)** • Positive (surgical) margins • **Recurrence (local, regional or distant)** • **Quality of life (e.g. measured by EQ-5D or SF-36)** • Other disease-specific effectiveness-related outcomes (e.g. time to nutrition for gastrointestinal surgery) • Conversion to laparoscopic/thoracoscopic/open surgery • Length of hospital stay • Time to resume work / daily activities • Patient satisfaction Safety (*critical* outcomes are highlighted in **bold**): • **Intraoperative complications (e.g. bleeding, procedure-related mortality)** • **Postoperative complications (e.g. 30-day overall complications, pain, infections)** • Re-operations / additional surgeries Perioperative outcomes: • Blood loss • Operation time • Transfusions **Rationale**: Appropriate clinical outcomes have been informed by systematic reviews [8] and the EUnetHTA guidelines [9, 10].
Study design	Effectiveness: • Randomised controlled studies (RCTs) with ≥ 10 patients (for effectiveness and safety) • Prospective non-randomised controlled studies with ≥ 10 patients in the absence of RCTs (in case no RCTs will be identified) Safety: • Randomised controlled studies (RCTs) with ≥ 10 patients (for effectiveness and safety), • Prospective non-randomised controlled studies with ≥ 10 patients in the absence of RCTs (in case no RCTs will be identified) • Prospective studies with ≥100 patients and without a control group in the absence of comparative evidence (in case no controlled trials will be identified)

[5] Not all outcomes apply for every single population/ indication.

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.	28/05/2018	E-meeting	Author(s), co-author(s), dedicated reviewers, project manager (external experts)
		TBD	Additional e-meetings may be planned whenever needed	Author(s), Co-author(s), dedicated reviewer(s), project manager
Feedback on draft submission file (optional)	To point out the requirements for the final submission file by manufacturers	TBD	E-mail	Author(s), project manager, manufacturers
First draft of the rapid assessment	To discuss comments of dedicated reviewers	31/08/2018	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	28/09/2018	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: http://www.eunethta.eu/joint-assessments.

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). Furthermore authors will ask the manufacturers to complete the submission file.

Collaboration with other stakeholders

None is planned.

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.

Authors, co-authors and dedicated reviewers who declare a specific conflict of interest will be excluded from the whole work under this specific topic.

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.

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

4 References

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[2] Kuo S-W, Huang P-M, Lin M-W, Chen K-C, Lee J-M. Robot-assisted thoracic surgery for complex procedures. Journal of Thoracic Disease. 2017;9(9):3105-13.

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[8] Ballini L, Minozzi S, Negro A, Pirini G, Grilli R. A method for addressing research gaps in HTA, developed whilst evaluating robotic-assisted surgery: a proposal. Health Research Policy and Systems. 2010;8(28).

[9] uropean Network for Health Technology Assessment. Endpoints used for Relative Effectiveness Assessment: Clinical endpoints. EUnetHTA; 2015 [28-02-2018]; Available from: http://www.eunethta.eu/sites/default/files/WP7-SG3-GL-clin_endpoints_amend2015.pdf.

[10] European Network for Health Technology Assessment. Endpoints used in Relative Effectiveness Assessment: SAFETY. EUnetHTA; 2015 [18-12-2017]; Available from: http://www.eunethta.eu/sites/default/files/sites/5026.fedimbo.belgium.be/files/WP7-SG3-GL-safety_amend2015.pdf.

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)?	Critical	M	What is robot-assisted surgery? What is open surgery (OS)? What is laparoscopic/video-assisted) thoracoscopic surgery (LS/(VA)TS)?
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]	Critical	M	For which indications/interventions has robot-assisted surgery received marketing authorisation or CE marking?
B0002	Features of the technology and comparators	What is the claimed benefit of the technology in relation to the comparator(s)?	Critical	M	What is the claimed benefit of robot-assisted surgery in relation to OS and LS/(VA)TS?
B0003	Features of the technology	What is the phase of development and implementation of the technology and the comparator(s)?	Yes	NM	What is the phase of development and implementation of robot-assisted surgery?
B0004	Features of the technology	Who administers the technology and the comparator(s) and in what context and level of care are they provided?	Critical	M	Who administers robot-assisted surgery? In what context and level of care is robot-assisted surgery provided?
B0008	Investments and tools required to use the technology	What kind of special premises are needed to use the technology and the comparator(s)?	Yes	NM	What kind of special premises are needed to use robot-assisted surgery?
B0009	Investments and tools required to use the technology	What equipment and supplies are needed to use the technology and the comparator(s)?	Yes	NM	What equipment and supplies are needed to use robot-assisted surgery?
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]	Yes	NM	What is the reimbursement status of robot-assisted surgery?
Health problem and current use of technology					
A0002	Target Condition	What is the disease or health condition in the	Critical	M	What is the disease or health condition in the scope of this

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

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?			life?
D0017	Patient satisfaction	Were patients satisfied with the technology?	Yes	NM	Were patients satisfied with the robot-assisted surgery?
Safety					
C0008	Patient safety	How safe is the technology in relation to the comparator(s)?	Critical	M	How safe is robot-assisted surgery in relation to OS and LS/(VA)TS?
C0002	Patient safety	Are the harms related to dosage or frequency of applying the technology?	Yes	NM	Are the harms related to dosage or frequency of applying robot-assisted surgery?
C0004	Patient safety	How does the frequency or severity of harms change over time or in different settings?	Yes	M	How does the frequency or severity of harms change over time or in different settings?
C0005	Patient safety	What are the susceptible patient groups that are more likely to be harmed through the use of the technology?	Yes	M	What are the susceptible patient groups that are more likely to be harmed through the use of robot-assisted surgery?
C0007	Patient safety	Are the technology and comparator(s) associated with user-dependent harms?	Yes	NM	Is robot-assisted surgery associated with user-dependent harms?
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)?	Yes	M for medical devices	What kind of data/records and/or registry is needed to monitor the use of robot-assisted surgery?

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

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
Introduction of robot-assisted surgery requires the device and training for the staff. If a hospital plans to purchase a robot, an adequate infrastructure is also required (e.g. room/space for robots).	
2.2. Does comparing the new technology to the defined, existing comparator(s) point to any differences that may be organisationally relevant?	Yes

Robot-assisted surgeries will probably take longer than open or laparoscopic/thoracoscopic surgeries.	
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?	Yes
In case of any malfunction of the robotic system the question of liability could arise.	
4.2. Does comparing the new technology to the defined, existing comparator(s) point to any differences that may be legally relevant?	No
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