WEARABLE CARDIOVERTER-DEFIBRILLATOR (WCD) THERAPY IN PRIMARY AND SECONDARY PREVENTION OF SUDDEN CARDIAC DEATH IN PATIENTS AT RISK

Project ID: WP4-ACB-CA-1

Project description and planning

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Contents:

A. VERSION LOG

Version number	Date	Name (Initials)	Modification	Reason for the modification
V1	15/06/16	SE	First version of draft project plan	
V2	29/06/16	SE, MS	Revised draft project plan	Comments received from co-authors
V3	12/07/16	SE, MS	Revised draft project plan	SABA e-meeting/discussions with co-authors, dedicated reviewers and external expert
V4	18/08/16	SE, MS	Revised draft project plan	Comments from dedicated reviewers, external experts and manufacturer

B. PROJECT PLAN

1.0 PARTICIPANTS

Table 1. Project participants

#	Agency	Country	Role in the project	Individual's expertise
1.	Ludwig Boltzmann Institute for Health Technology Assessment (LBI-HTA)	Austria	Authors	Public health, health technology assessment (HTA) of medical devices
2.	The Agency for Quality and Accreditation in Health Care and Social Welfare (AAZ)	Croatia	Co-Authors	Clinical (physician-specialist in clinical pharmacology and toxicology) and methodological expertise (evidence-based medicine and HTA)
3.	Institute for Quality and Efficiency in Health Care (IQWiG)	Germany	Reviewer	HTA, evidence-based medicine
4.	Galician Agency for HTA (Avalia-t)	Spain	Reviewer	Biology, pharmacy, methodological expertise in evidence-based medicine, systematic reviews, HTA reports and clinical practice guidelines development
5.	University hospital Sisters of Mercy, Zagreb	Croatia	External Expert	Cardiology
6.	Institute of Cardiology, Warsaw (on behalf of European Society of Cardiology)	Poland	External Expert	Cardiology
7.	Medical Advisory Service of the Statutory Health Insurance Funds North-Rhine	Germany	External Expert	Community medicine, evidence-based medicine, HTA
8.	TBD		Medical Editor	
9.	LBI-HTA	Austria	Project coordinator	Project management

1.1 PROJECT STAKEHOLDERS

Table 2. Project stakeholders[♣]

Organisation's name	Type of organisation
ZOLL Medical Corporation, Pittsburgh, PA, USA	Manufacturer

2.0 PROJECT INTRODUCTION/ RATIONALE

Project introduction/ rationale
The rationale for this assessment report is to produce joint assessments that are fit for purpose, of high quality, of timely availability, and cover the whole range of non-pharmaceutical health technologies. In addition, the implementation of the joint assessment in the national/regional practice will be facilitated.

3.0 PROJECT SCOPE AND OBJECTIVES

	List of project objectives	Indicator (and target)
1.	To produce joint 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 assessment according to the research question (see Table 3).
2.	To compile a rapid assessment of wearable cardioverter defibrillator (WCD).	Production of a rapid assessment of WCD. The WCD/LifeVest ® received CE mark for the WCD 4000 model in 2015 and is considered for inclusion in the list of reimbursed services of the Austrian Ministry of Health/ Association of Austrian Health Insurance Providers (HVB).
3.	To refine the production processes of joint assessment reports based on lessons learned and experiences from JA2 and to probe a stepped roll-out of additional collaborative assessments yielding timely information.	Development of sustainable production processes for joint assessments. Production of collaborative assessments probing a decentralized coordination process and facilitating to meet national timelines.
4.	To develop a process that facilitates the implementation of the joint assessment in the national/regional practice.	Production of >2 national/local reports based on the joint assessment.

♣ Here the term "stakeholder" has a generic meaning that goes beyond (yet may include) the identified EUnetHTA Stakeholder groups (as described in the EUnetHTA Stakeholder Policy).

This rapid assessment addresses the research question whether WCD/LifeVest ® is more effective and /or safer in primary and secondary prevention of sudden cardiac death (SCD) in patients at risk, in comparison with standard or usual care, according the most recent, evidence-based clinical guidelines.

Table 3. Project Scope: PICO

Description	Project scope
Population	Patients: adults (according to CE mark) – patients who are 18 years of age and above are considered as adults - and pediatric patients (outside of CE mark) with the following indications: 1. As a bridge to an implantable cardioverter-defibrillator (ICD) e.g. for: a) Patients immediately after explantation of an ICD, if an immediate reimplantation of an ICD is not possible [1]. b) Patients in whom an immediate implantation of an ICD is indicated, but not possible [1]: 1. due to temporary contraindications to an ICD, 2. due to being post ventricular tachycardia (VT)/ventricular fibrillation (VF) on the waiting list for an ICD, 2. Patients indicated for an ICD, who refuse implantation for personal or other reasons. 3. As a bridge to optimal pharmacological therapy when a heightened risk of SCD is present, but possibly resolvable over time or with treatment of left ventricular dysfunction [1] e.g. for: a) ischemic heart disease with envisaged or recent revascularization (90-day waiting period post

	revascularization with either CABG or PCI), b) newly diagnosed nonischemic dilated cardiomyopathy in patients starting guideline-directed medical therapy, c) secondary cardiomyopathy (tachycardia mediated, thyroid mediated, etc.) induced arrhythmias (secondary to hypothermia, electrolyte imbalance, iatrogenic prolongation of the QT interval, etc.) in which the underlying cause is potentially treatable, d) with certain forms of structural heart disease associated with risk of malignant arrhythmias or primary electric disease and in those with significantly impaired left ventricular systolic function. 4. "Watch and wait" strategy for patients at risk for SCA during diagnostics 5. Post myocardial infarct (MI) and LVEF of ≤ 35%, as a bridge therapy "in situations associated with increased risk of death in which ICDs have been shown to reduce SCD but not overall survival such as within 40 d of MI" [1, 2]. 6. As a bridge to a heart transplant [1, 2]. Rationale: According to guidelines (e.g. from the American Heart Association) [3], there is a recommended waiting time in some situations before an ICD is indicated. A recovery of structural abnormality and an improvement of ventricular dysfunction could occur so that an ICD therapy may not be indicated anymore. Furthermore, a patient could have some contraindications (e.g. an infection) and therefore should not receive an ICD for some time, or an ICD needs to be (temporary) explanted due to specific reasons. Thus a WCD could be used as a bridge to an ICD or to a heart transplant (in order to cover the waiting period). [4-7] ICD-10 codes: VT (I47.2), VF and flutter (I49.0), Cardiomyopathy (I42), Acute myocardial infarction (I21) MeSH-terms: sudden cardiac arrest, ventricular tachycardia,

	ventricular fibrillation, myocardial infarction, myocardial revascularization, heart transplantation Intended use of technology: treatment (prevention)
Intervention	WCD/LifeVest® (WCD 4000 which has CE mark), from ZOLL (Lifecor) Medical Corporation, Pittsburgh, PA, USA. The WCD device consists of 2 components: - an electrode belt that fits within a lightweight garment worn on the patient's chest - a monitor that the patient wears around the waist MeSH-terms: (cardioverter-) defibrillator (external), electric countershock
Comparison	In primary and secondary prevention: • ICD • Guideline directed pharmacological therapy • Guideline directed radiofrequency (catheter) ablation • External defibrillators to be used in 3 settings: home, public places and/or used by medical emergency staff during resuscitation Rationale: Comparators have been chosen based on information from relevant published clinical guidelines [2] and EUnetHTA guidelines [8].

Outcomes	**Effectiveness:**
	Primary endpoint:
	• Mortality (long term mortality)
	  ○ All-cause mortality
	  ○ Disease-specific mortality
	
	Secondary endpoints:
	• Incidence of VT/VF

	• Avoidance of ICD implantation • (Health-Related) Quality of Life • Hospitalisation rate • Satisfaction • Compliance **Safety:** • Adverse events (AEs), device related and patient related (frequency of AEs, what are these, frequency of discontinuation due to AEs, frequency of unexpected AEs), • Serious AEs (SAE), device related and patient related (frequency of SAEs, what are these, frequency of SAEs leading to death) **Organisational, ethical, patient and social, legal outcomes** Rationale: Outcomes have been selected based on the recommendations from relevant clinical guidelines [2, 4 or 8] and EUnetHTA Guidelines on Clinical and Surrogate Endpoints and Safety [9].
Study design	**Effectiveness**: Randomised controlled trials, prospective non-randomised controlled trials **Safety**: Randomised controlled trials, prospective non-randomised controlled trials, prospective studies without a control group e.g. observational studies, case series, registries (manufacturer database) **Organisational, ethical, patient and social, legal domains:** Qualitative studies (according to the EUnetHTA Core Model ® 3.0) [10]

4.0 PROJECT APPROACH AND METHOD

Table 4a. Project approach and method

Project approach and method
• The selection of assessment elements will be based on the EUnetHTA Core Model ® Application for Rapid Relative Effectiveness (REA) Assessments (4.2) [10]. The checklist for potential ethical, organisational, patient and social and legal aspects of the HTA Core Model ® for rapid REA will be filled in as well. Additionally, further assessment elements from the EUnetHTA Core Model ® (3.0) domains – "ethical analysis", "organisational aspects"," patients and social aspects", - and "legal aspects" - relevant for medical and surgical interventions - will be included if deemed relevant. The selected issues (generic questions) will be translated into actual research questions (answerable questions). • A systematic review of published clinical studies/documents regarding WCD will be performed. The following sources of information will be used: o Cochrane Library, Centre for Research and Dissemination (CRD), Embase, Medline o Clinical trial registries will be assessed for registered ongoing clinical trials or observational studies: ClinicalTrials.gov, International Clinical Trials Registry Platform (ICTRP) o Handsearch (in reference list of relevant studies), internet-search • All reporting of clinical effectiveness and safety data will be done according to the Preferred Reporting Items for Systematic Reviews and Meta-Analyses (PRISMA Statement 2012 [11]). • Literature selection: Two authors (from LBI-HTA) will include and exclude studies, independently from each other. These steps will be checked by co-authors. • Data extraction: One author will extract the data and the other second controls the extracted data (from LBI-HTA). Co-Authors will check this as well. • Cochrane risk of bias assessment approach will be used for RCTs and non-randomised controlled studies (ACROBAT-NRSI tool) [11])., according the EUnetHTA Guidelines on Therapeutic medical devices and EUnetHTA Guideline for internal validity of non-randomised studies [12]. "Quality appraisal tool for case series" document will be used for prospective studies without control group [13]. Assessment of the strength of evidence will be using "Grading of Recommendations, Assessment, Development and Evaluation" – GRADE approach [14]. These steps will be performed by two authors independently from each other (from LBI-HTA). Any disagreements will be resolved by consensus. Co-Authors will check this as well. • For TEC and CUR domains no quality assessment tool will be used, but multiple sources will be used in order to validate individual, possibly biased, sources. Descriptive analysis of different information sources will be performed. The completed EUnetHTA submission file from the manufacturer will be used as starting point. • For other domains (ETH, ORG, SOC, LEG) qualitative studies identified by the systematic literature search will be used. In addition handsearch of literature, internet-search, contacting manufacturer (EUnetHTA submission file from the manufacturer) will be performed. No

quality assessment tool will be used, but multiple sources will be used in order to validate individual, possibly biased, sources. Descriptive analysis of different information sources will be performed.

- Use of qualitative research methods: a focus group with 3-5 patients (which will be identified via cardiology-support groups or other channels) in order to include them in scoping (so that all relevant questions and endpoints will be included in the HTA-report) will be performed [15]. Extraction of patient-relevant endpoints (clustering) will be done by two authors (from LBI-HTA) independently. According to the Austrian ethics committee no ethical approval is needed. Patients will be asked to sign an informed consent form. With regard to identification of patient relevant endpoints, authors (from LBI-HTA) might as well look at e.g. patients blogs, if necessary.

Description of the distribution of responsibilities and the workload between authors and co-authors:
LBI-HTA:

- Develop first draft of EUnetHTA project plan
- Perform the literature search
- 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 reviewers comments
- Prepare final assessment and write a final summary of the assessment

AAZ:

- Review draft EUnetHTA project plan
- Check and approve all steps (e.g. literature selection, data extraction, assessment of risk of bias). Agree with author on conclusions made.
- Review draft assessment, propose amendments where necessary (perform additional hand search of literature if needed) and provide written feedback

Table 4b. Preliminary Evidence

Preliminary evidence table
Study characteristics
Author
Year of publication
Reference number
Study registration number (registry identifier)
Country/ies of recruitment
Sponsor
Comparator
Study design
Study duration (start and completion date)
Objectives
Model version of technology
Patient characteristics
Number of patients
Age
Sex
Inclusion criteria
Exclusion criteria
Follow-up (months)
Loss-to-follow-up, n (%)
Duration of therapy
Diagnosis
Previous treatments
Efficacy outcomes
Mortality (long term mortality)
- All-cause mortality
- Disease-specific mortality (prevention of SCD, prevention of sudden cardiac arrest)
Incidence of VT/VF
(Health-Related) Quality of Life (e.g. questionnaire, depression, anxiety….)
Hospitalisation rate
Satisfaction with technology
Compliance/patient adherence

Safety outcomes
Adverse device events (AE) in n (%) of patients
Description of AE in n (%) of patients
Frequency of discontinuation due to AEs in n (%) of patients
Frequency of unexpected AEs in n (%) of patients
Serious adverse device events (SAE) in n (%) of patients
Description of SAE in n (%) of patients
Frequency of SAEs leading to death in n (%) of patients
Organisational, ethical, patient and social, legal outcomes (please see assessment element questions below)

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 assessments 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. Assessment elements and translating research questions

ID	Topic	Topic Issue	Relevance in this assessment Yes/No	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)?	yes	What is the WCD and the comparator(s)?
A0020	Regulatory Status	For which indications has the technology received marketing authorisation or CE marking?	yes	For which indications has the WCD received CE marking?
B0002	Features of the technology and comparators	What is the claimed benefit of the technology in relation to the comparator(s)?	yes	What is the claimed benefit of the WCD in relation to the comparator(s)?

ID	Topic	Topic Issue	Relevance in this assessment Yes/No	Research question(s) or reason for non-relevance of 'mandatory' elements
B0003	Features of the technology	What is the phase of development and implementation of the technology and the comparator(s)?	yes	What is the phase of development and implementation of the WCD and the comparator(s)?
B0004	Features of the technology	Who administers the technology and the comparator(s) and in what context and level of care are they provided?	yes	Who administers the WCD and the comparator(s) and in what context and level of care are they 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	What kind of special premises are needed to use the WCD and the comparator(s)?
B0009	Investments and tools required to use the technology	What equipment and supplies are needed to use the technology and the comparator(s)?	yes	What equipment and supplies are needed to use the WCD and the comparator(s)?
A0021	Regulatory Status	What is the reimbursement status of the technology?	yes	What is the reimbursement status of the WCD?
Health problem and current use of technology				
A0002	Target Condition	What is the disease or health condition in the scope of this assessment?	yes	What is (risk of) SCD in the scope of this assessment?
A0003	Target Condition	What are the known risk factors for the disease or health condition?	yes	What are the known risk factors for SCD?
A0004	Target Condition	What is the natural course of the disease or health condition?	yes	What is the natural course of VT/VF and SCD?
A0005	Target Condition	What are the symptoms and the burden of disease or health condition for the patient?	yes	What are the symptoms and the burden of SCD?
A0006	Target Condition	What are the consequences of the disease or health condition for the society?	yes	What are the consequences of SCD 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?	yes	How is the risk of SCD currently diagnosed according to published guidelines and in practice?

ID	Topic	Topic Issue	Relevance in this assessment Yes/No	Research question(s) or reason for non-relevance of 'mandatory' elements
A0025	Current Management of the Condition	How is the disease or health condition currently managed according to published guidelines and in practice?	yes	How is the SCD currently prevented and managed according to published guidelines and in practice?
A0007	Target Population	What is the target population in this assessment?	yes	What is the target population in this assessment?
A0023	Target Population	How many people belong to the target population?	yes	How many people belong to the target population?
A0011	Utilisation	How much are the technologies utilised?	yes	How much are the WCDs utilised?
Clinical effectiveness				
D0001	Mortality	What is the expected beneficial effect of the intervention on mortality?	yes	What is the expected beneficial effect of the WCD on mortality (disease-specific and all-cause)?
D0005	Morbidity	How does the technology affect symptoms and findings (severity, frequency) of the disease or health condition?	yes	How does the WCD affect symptoms and findings (severity, frequency) of VT/VF?
D0006	Morbidity	How does the technology affect progression (or recurrence) of the disease or health condition?	yes	How does the WCD affect progression (or recurrence) of VT/VF?
D0011	Function	What is the effect of the technology on patients' body functions?	yes	What is the effect of the WCD on patients' body functions?
D0016	Function	How does the use of technology affect activities of daily living?	yes	How does the use of WCD 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?	yes	What is the effect of the WCD on generic health-related quality of life?
D0013	Health-related quality of life	What is the effect of the technology on disease-specific quality of life?	yes	What is the effect of the WCD on disease-specific quality of life?
D0017	Patient satisfaction	Were patients satisfied with the technology?	yes	Were patients satisfied with the WCD?

ID	Topic	Topic Issue	Relevance in this assessment Yes/No	Research question(s) or reason for non-relevance of 'mandatory' elements
Safety				
C0008	Patient safety	How safe is the technology in relation to the comparator(s)?	yes	How safe is the WCD in relation to the comparator(s)?
C0002	Patient safety	Are the harms related to dosage or frequency of applying the technology?	yes	Are the harms related to medical device-WCD?
C0004	Patient safety	How does the frequency or severity of harms change over time or in different settings?	yes	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	What are the susceptible patient groups that are more likely to be harmed through the use of the WCD?
C0007	Patient safety	Are the technology and comparator(s) associated with user-dependent harms?	yes	Are the WCD and comparator(s) 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	What kind of data/records and/or registry is needed to monitor the use of the WCD and the comparator(s)?
Additional assessment elements				
Ethical				
F0010	Benefit-harm balance	What are the known and estimated benefits and harms for patients when implementing or not implementing the technology?	yes	What are the known and estimated benefits and harms for patients when implementing or not implementing the WCD?
F0011	Benefit-harm balance	What are the benefits and harms of the technology for relatives, other patients, organisations, commercial entities, society, etc.?	yes	What are the benefits and harms of the WCD for relatives and care givers?
F0104	Benefit-harm balance	Are there any ethical obstacles for evidence generation regarding the benefits and harms of the intervention?	yes	Are there any ethical obstacles for evidence generation regarding the benefits and harms of the WCD?
F0005	Autonomy	Is the technology used for individuals that are especially vulnerable?	yes	Is the WCD used for individuals that are especially vulnerable?

ID	Topic	Topic Issue	Relevance in this assessment Yes/No	Research question(s) or reason for non-relevance of 'mandatory' elements
F0101	Respect for persons	Does the technology invade the sphere of privacy of the patient/user?	yes	Does the WCD invade the sphere of privacy of the patient?
F0012	Justice and Equity	How does implementation or withdrawal of the technology affect the distribution of health care resources?	yes	How does implementation or withdrawal of the WCD affect the distribution of health care resources?
F0017	Ethical consequences of the HTA	What are the ethical consequences of the choice of endpoints, cut-off values and comparators/controls in the assessment?	yes	What are the ethical consequences of the choice of endpoints, and comparators in the assessment?
Organisational				
G0002	Health delivery process	What kind of involvement has to be mobilised for patients/participants and important others and/or caregivers?	yes	What kind of involvement has to be mobilised for patients/doctors and/or caregivers?
G0003	Health delivery process	What kind of process ensures proper education and training of staff?	yes	What kind of process ensures proper education and training of staff?
G0004	Health delivery process	What kinds of co-operation and communication of activities have to be mobilised?	yes	What kinds of co-operation and communication of activities have to be mobilised?
G0012	Health delivery process	In What way is the quality assurance and monitoring system of the new technology organised?	yes	In what way is the quality assurance and monitoring system of the WCD organised?
G0101	Structure of health care system	What are the processes ensuring access to the new technology for patients/participants?	yes	What are the processes ensuring access to the WCD for patients/participants?
G0009	Management	Who decides which people are eligible for the technology and on what basis?	yes	Who decides which people are eligible for WCD and on what basis?
G0010	Culture	How is the technology accepted?	yes	How is the WCD accepted?
Social				
H0200	Patients' perspectives	What are the experiences of living with the condition?	yes	What are the experiences of living at risk of SCD?
H0100	Patients' perspectives	What expectations and wishes do patients have with regard to the technology and what do they expect to gain from the technology?	yes	What expectations and wishes do patients have with regard to the WCD; what do they expect to gain from the technology?

ID	Topic	Topic Issue	Relevance in this assessment Yes/No	Research question(s) or reason for non-relevance of 'mandatory' elements
H0006	Patients' perspectives	How do patients perceive the technology under assessment?	yes	How do patients perceive the WCD?
H0002	Patients' perspectives	What is the burden on care-givers?	yes	What is the burden on care-givers?
H0012	Social group aspects	Are there factors that could prevent a group or person from gaining access to the technology?	yes	Are there factors that could prevent a group or person from gaining access to the WCD?
H0203	Communication aspects	What specific issues may need to be communicated to patients to improve adherence?	yes	What specific issues may need to be communicated to patients to improve adherence?
Legal				
F0014	Ethical aspects	Does the implementation or use of the technology affect the realisation of basic human rights?	yes	Does the implementation or use of the WCD affect the realization of basic human rights?
I0026	Regulation of the market	What should be known about the legal issues in cases of new technologies where the current legislation is not directly applicable?	yes	What should be known about the legal issues in the case of WCD where the current legislation is not directly applicable?

Checklist for patient and social aspects

The following checklist should be considered in order to determine whether there are specific ethical, organisational, social and legal aspects which also need to be addressed. Since the assessment is comparative in nature, only new issues should be dealt with, which arise from a difference between the technology to be assessed and its major comparator(s). Already known problems/issues with regard to ethical, organisational, social and legal aspects which are common to the technology to be assessed and its comparator(s) will, as a rule, not be addressed, as it is not to be expected that the addition of a new technology will lead to changes.
If a question is answered with 'yes', further analysis of these issues may be warranted (please see above). If they are answered with no, the domains need not be dealt with further.

Table 6. 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?	Yes
The use of WCD gives rise to ethical issues with respect to principles of beneficence and justice. That is because of its wide base of indications that, due to its marginal benefit and cost-effective reasons, cannot be all covered in practice. Also, the WCD can only be used by patients who can (mentally and physically) operate it (i.e. push the "false alarm button" if necessary, who wear it appropriately), and hence it prefers those who are cognitively better-off to begin with.	
1.2. Does comparing the new technology to the defined, existing comparators point to any differences that may be ethically relevant?	Yes
Ethically relevant differences between WCD and its comparators depend on particular indications. Possible ethical issues may arise by comparing the standard medical therapy with WCD due to the increased number of serious adverse events caused by the medical therapy. Further issues may arise by comparing ICD to WCD due to the ICD's intrusion on bodily integrity that brings along more mortality related harms at the expense of the ICD's better protection.	
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
The introduction of the WCD requires training of doctors (i.e. briefing on how the WCD works, how the data can be monitored and evaluated etc.). Furthermore the doctors might need to dedicate more time to the patients (e.g. extra time for reviewing the data),	

patient/doctor communication is enhanced.	
2.2. Does comparing the new technology to the defined, existing comparator(s) point to any differences that may be organisationally relevant?	Yes
Depending on the comparator, free capacity of hospital beds can be generated, less emergency ambulance calls needed.	
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?	Yes
As the technology alters person's outlook, its use may lead to stigmatization particularly in women, as the technology makes the chest area look unnatural. By comparing WCD and best medical practice it may cause a possible harm to bystanders which may be considered as a new social issue.	
3.2. Does comparing the new technology to the defined, existing comparator(s) point to any differences that may be socially relevant?	Yes
Compared to alternative interventions, WCD allows patients to return to home and participate in their social life sooner.	
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
Introduction of the new technology gives rise to legal issue concerning person's rights and state's duties that will presumably vary upon particular indications. With respect to a progressively realizable human right to health, patients may claim their right to the best available treatment in their bridging periods even though their indication may not be included in the catalogue of covered interventions of particular countries. Further legal issues with respect to responsibility and insurance may arise in situations of false shocks when delivered in inappropriate moments such as when driving a car.	
4.2. Does comparing the new technology to the defined, existing comparator(s) point to any differences that may be legally relevant?	Yes

Comparing WCD to existing alternatives leads to legally relevant differences depending on particular indications. With reference to medical therapy, patients may claim their right to be treated by the WCD when faced with the option of medical therapy and its side effects. Patients may claim their right to be treated by the WCD when faced with the alternative of a surgical intervention that intrudes on their bodily integrity. Also, in particular settings with an elevated cultural perception of the notion of liability, patients may be themselves required to be legally responsible for wearing the WCD.

5.0 ORGANISATION OF THE WORK

5.1 MILESTONES AND DELIVERABLE(S)

Table 7. Milestones and Deliverables

Milestones/Deliverables	**Start date**	**End date**
Project duration	**01/05/2016**	**30/11/2016**
Scoping phase	**01/05/2016**	**05/07/2016 (delayed until 18/08/2016)**
Identification of manufacturers	01/05/2016	13/05/2016
Scoping and development of draft Project Plan	01/05/2016	22/06/2016
Send request for draft Submission file template to manufacturer(s)	06/06/2016	06/06/2016
Internal Scoping SABA e-meeting (including co-authors, dedicated reviewers, and external reviewers – if identified by then)		30/06/2016
Consultation of draft Project Plan with dedicated reviewers (external reviewers)	29/06/2016	05/07/2016 (5 days)
Amendment of draft Project Plan & final Project Plan available	29/06/2016	05/07/2016 (5 days) *DELAYED*
Completion of Submission file template by manufacturer(s)	06/06/2016	18/07/2016
Patient involvement (identification, interviewing)	01/05/2016	18/07/2016
Clarifying further questions concerning draft Submission file	19/07/2016	25/07/2016 (5 days)
Final submission file	26/07/2016	01/08/2016 (5 days)

Assessment phase	**06/07/2016**	**30/11/2016**
Writing first draft rapid assessment	06/07/2016	14/09/2016 (51 days)
Review by dedicated reviewer(s)	15/09/2016	28/09/2016 (10 days)
Writing second draft rapid assessment	29/09/2016	07/10/2016 (7 days)
Review by ≥ 2 external clinical experts (and by other potential stakeholders)	10/10/2016	21/10/2016 (10 days)
Writing third draft rapid assessment	24/10/2016	28/10/2016 (5 days)
Medical editing	31/10/2016	04/11/2016 (5 days)
Writing of final version of rapid assessment	07/11/2016	18/11/2016 (10 days)
Formatting	21/11/2016	25/11/2016 (5 days)
Final version of REA		from 28/11/2016 - to 30/11/2016
Local Reports (if applicable)		
Local (national or regional) REA N°1 [*Institution, country*]		
Local (national or regional) REA N°2 [*Institution, country*]		

5.2 MEETINGS

A SABA e-meeting is held with the pilot team during the Scoping phase (30/06/2016), a further one between authors and co-authors to discuss comments (11/07/2016). Whenever needed, further SABA e-meetings will be scheduled.

6.0 COMMUNICATION

Table 8. Communication

Communication Type	**Description**	**Date**	**Format**	**Participants/ Distribution**
Scoping				
	To discuss and reach the consensus on the scoping, as a preparation for the final Project Plan (optional).	30/06/2016	*e-meeting (SABA)*	*Authors, co-authors, dedicated reviewers, CT*
Feedback on draft submission file	*To formulate clarifying questions on draft submission file before sending it to the manufacturers*	25/07/2016	*E-mail*	*Authors, Co-authors, CT*

	To point out the requirements for the final submission file by manufacturers	25/07/2016	*E-mail*	*CT, manufacturer*
Draft Project Plan with timelines	Review of methods and assessment elements chosen, discussion of time-lines	17/06/2016	E-mail	*Authors, co-authors*, dedicated reviewer(s), CT
Final Project Plan	Review of methods and assessment elements chosen, discussion of time-lines.	05/07/2016 *DELAYED*	E-mail	*Authors, co-authors*, dedicated reviewers, CT (external experts)
First draft of the rapid assessment	To be reviewed by dedicated reviewer(s)	14/09/2016	E-mail	Dedicated reviewer(s)
	To discuss comments of dedicated reviewers (optional)	28/09/2016	E-Mail	*Authors, co-authors*, dedicated reviewers
Second draft of the rapid assessment	To be consulted with ≥2 clinical expert (other potential stakeholders)	21/10/2016	E-mail	≥2 clinical experts (other potential stakeholders)
Final rapid assessment	Medical editing by external editor	18/11/2016	E-Mail	Medical Editor

6.1 DISSEMINATION PLAN

The final rapid assessment will be distributed as laid-out in the Work Plan of WP4.

7.0 COLLABORATION WITH STAKEHOLDERS

The 2nd draft version of the assessment will be reviewed by external experts.
Manufacturer (ZOLL) will fill in the submission file and will be contacted with regard to questions if necessary.
Patients will be included in the scoping phase (i.e. will attend a focus group in order to identify patient-relevant endpoints).

8.0 COLLABORATION WITH EUnetHTA WPs

For the individual rapid assessment, no collaboration with other WPs is planned.

9.0 RESOURCE PLANNING

Please estimate the expected input in terms of human and financial resources necessary to achieve the project objectives.

9.1 HUMAN RESOURCES

Table 9. Human resources

Role	Total number of person days	Source	
		Staff of participating organisations	Subcontracting
Author	80 person days	80 person days	-
Co-Author	25 person days	25 person days	-
Reviewer	5 person days each	5 person days each	-
External reviewer	5 person days	-	5 person days
Medical Editor	5 person days	-	5 person days
Layout	5 person days	-	5 person days

10.0 CONFLICT OF INTEREST MANAGEMENT

Conflicts of interest will be handled according to EUnetHTA JA2 Conflict of Interest Policy. As conflict of interest may be topic dependent, conflict of interest declarations will be collected from authors and reviewers involved in a specific assessment via the Declaration of interest and confidentiality undertaking (DOICU) form. Authors and reviewers who declare a conflict of interest will be excluded from parts of, or the whole work under this specific topic. However, they may still be included in other assessments.
If external experts are involved in WP4 a conflict of interest declaration will be collected from them regarding the topic. External experts who declare a conflict of interest will be excluded from parts of, or the whole work under this specific topic. However, they may still be included in other assessments.

11.0 EXPECTED OUTCOME(S)

Project outcome(s)
Joint assessments that are fit for purpose, of high quality, of timely availability, and cover the whole range of non-pharmaceutical health technologies will have been produced. These assessments will have been used in the national/local context. Production processes for joint assessment reports will have been refined based on lessons learned and experiences from JA2. The decentralized approach for producing collaborative assessments will have been probed. The implementation of joint assessments in the national/local context will have been facilitated.

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