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Balloon Eustachian tuboplasty for the treatment of Eustachian tube dysfunction

Project ID: WP5-SB-13

Project description and planning

May 19th, 2014

Authors: THL, Co-authors: HIQA

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A. VERSION LOG

Version number	Date	Name (Initials)	Modification	Reason for the modification
V1	08/04/14	SS/TK	First version of the project plan	Sent to co-authors, deadline 15/04/14
V2	17/04/14	SS/TK	Second version of the project plan	Comments of co-authors have been incorporated. Sent to dedicated reviewers and external reviewers deadline 05/05/14
V3	06/05/14		Third version of the project plan	E-meeting
V4	16/05/14	SS/TK	Fourth version of the project plan for public consultation	Comments from dedicated reviewers and the e-meeting have been incorporated. Sent for public consultation on 19/05/2014.

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B. PROJECT PLAN

1.0 PARTICIPANTS

Table 1. Project participants

#	Agency	Role in the project	Individual's expertise	Country
1.	THL, National Institute for Health and Welfare, Finohta	Author(s)	public health, pharmacy, health services research medicine, pharmacology, neurology	Finland
2.	HIQA, Health Information and Quality Authority	Co-Author(s)	health economics health service research, pharmacy Surgery, medicine, ENT	Ireland
3.	HVB, Association of Austrian Social Insurance Institutions	Dedicated Reviewer	medicine, public health, nutrition/dietetics	Austria
4.	GYEMSZI, National Institute for Quality- and Organizational Development in Healthcare and Medicines	Dedicated Reviewer	medicine, health economics, medical device	Hungary
5.	AHTAPol, Agency for Health Technology Assessment in Poland	Dedicated Reviewer	pharmacy, health economics, systematic reviews	Poland
6.	HUS - The Hospital District of Helsinki and Uusimaa	External Reviewer 1	medicine, ENT	Finland Norway
	OUH - Oslo University Hospital	External Reviewer 2	medicine, ENT	
7.	TBD	Medical Editor		

1.1 PROJECT STAKEHOLDERS

Table 2. Project stakeholders

Organisation	Contact (name, e-mail, tel)	Comments
Spiggle & Theis Medizintechnik GmbH	Susanne Ferfers telephone: +49 (0) 2206 / 9081 - 53 e-mail: s.ferfers@spiggle-theis.de	Spiggle&Theis has a CE-marked balloon catheter for BET, the 'Bielefelder Ballonkatheter'
Acclarent Inc. (Johnson&Johnson)	Michael McCormack telephone: 901 341 3841 e-mail: mmccor@its.jnj.com	Acclarent Inc. has obtained CE mark for its Eustachian tube dilation technology on May 8 th , 2014

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 54 **2.0 PROJECT INTRODUCTION/ RATIONALE**
Project introduction/ rationale

The rationale for this pilot assessment report is to test the capacity of national HTA bodies to collaboratively produce structured rapid core HTA information on other medical technologies, such as medical devices, surgical interventions or diagnostics (strand B). In addition, the application (translation) of those collaboratively produced HTAs in the national contexts will be tested.

 55 **3.0 PROJECT SCOPE AND OBJECTIVES**

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	List of project objectives	Indicator (and target)
1.	To test the capacity of national HTA bodies to collaboratively produce structured rapid core HTA	Production of 1 pilot rapid assessment according to the research question (see Table 3)
2.	To test the application of these collaboratively produced rapid assessments into a national/local context	Production of ≥1 national/local report per pilot rapid assessment
3.	To test on-line tool for rapid assessment	Gain experience of the on-line tool and identify possible areas for improvement
4.	To compile a pilot rapid assessment on Balloon Eustachian tuboplasty (BET)	The treatment is increasingly being promoted and the potential patient group is large. The procedure is invasive and needs general anesthesia. There is a potential risk of life-threatening complications due to puncture of the carotid artery.

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59 This pilot rapid assessment addresses the research question whether Balloon Eustachian tuboplasty (BET) in adolescents and adults having
 60 Eustachian tube dysfunction is more effective and/or safer than standard care including tympanostomy or medication.

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63 Table 3. Project Scope: PICO

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Description	Project scope
Population	ICD-10: H65.3 chronic mucoid otitis media, otitis media with effusion (OME)(H65.2), H68.1 obstruction of Eustachian tube <ul style="list-style-type: none"> • MeSH terms: Ear Diseases, Eustachian Tube • Describe the target population: adolescents over 12 years and adults with otitis media with effusion (OME),

	<p>middle ear atelectasis or chronic/resistant Eustachian tube dysfunction (ETD) (muffled hearing, pain, feeling of fullness in the ear, tinnitus and dizziness)</p> <ul style="list-style-type: none"> • Mesh-terms: Humans, Adult, Adolescent, Ear, Middle Ear, Ear diseases • Describe the intended use of the technology: Treatment
<p>Intervention</p>	<p>In Balloon Eustachian Tuboplasty (BET) a balloon catheter is introduced in to the Eustachian tube via the nose under general anesthesia. Once the balloon is correctly positioned in the cartilaginous and bony position of the Eustachian tube, it is filled with saline up to a pressure of 10 bars. Pressure is maintained for approximately 2 minutes and then the liquid is aspirated and the catheter removed.</p> <p>MeSH term: Eustachian tuboplasty, Dilatation, Balloon dilatation, Ventilation</p>
<p>Comparison</p>	<ul style="list-style-type: none"> - Tympanostomy (ventilation tube, grommet) - Medication (to decrease oedema of the nasopharynx; nasal decongestants, antihistamines, leukotriene receptor antagonists, simethicone, oral or nasal corticosteroids, antibiotics) - Intraluminal catheter placement <p>MeSH-terms: Middle Ear Ventilation</p>
<p>Outcomes</p>	<p>Primary: Relief of ear symptoms measured by tympanometry</p> <p>Secondary: middle ear function, measured by Valsalva manoeuvre, or other test like Toynbee test, sono-tubo-manometria. audiometric evaluation of hearing function, pressure swallow test tube score, clearance of middle ear effusion, need for additional treatment quality of life</p> <p>For long term efficacy: frequency of hearing loss, otitis media, tympanic membrane perforations, cholesteatomas and complications of otitis media (eg. meningitis)</p> <p>Adverse effects (early complications, late adverse effects, treatment related adverse effects, serious adverse events)</p> <p>The outcomes were selected according to the earlier literature on the topic (1-9).</p>
<p>Study design</p>	<p>RCTs, non-randomised trials, prospective trials, controlled observational studies, case series with ≥ 10 patients</p>

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4.0 PROJECT APPROACH AND METHOD

Table 4a. Project approach and method

Project approach and method
<p>This rapid assessment is based on the assessment elements from the HTA Core Model for rapid REA of pharmaceuticals and on a systematic literature review from the following sources:</p> <ul style="list-style-type: none"> - Medline via OVID, EMBASE - Cochrane database, DARE and HTA databases via the Cochrane Library and CDR - WHO International Clinical trials Registry Platform (ICTRP) and ClinicalTrials.gov for the identification of registered clinical trials. - Information from the manufacturers. <p>Studies and other relevant data sources will be selected by the researchers at the agency who will answer research questions of the domain they are primarily responsible for. Inclusion and exclusion of the studies is based on PICO. Accepted study design for “Clinical effectiveness” include: randomised controlled trials, non-randomised trials, controlled observational studies, case series with ≥ 10 patients.</p> <p>Studies including adults and/or adolescents over 12 years are included. Exclusion by indication/population: children < 12 years, Exclusion by intervention: laser Eustachian tuboplasty, combined interventions</p> <p>For the “Safety” domain, also case studies and cadaver studies are accepted. For the “Health problem and current use of the technology” and “Description and technical characteristics”, no restrictions in terms of study design are applied. Additional searches and database information, such as databases for clinical guidelines, register data can be used on the “Health problem and current use of the technology” and “Description and technical characteristics” domains.</p> <p>Quality assessment for systematic reviews is based on: PRISMA (10). For the randomised controlled trials and non-randomised studies the EPOC risk of bias checklist (11) is used: For the case series appraisal a 18-criteria checklist by IHE is used (12).</p> <p>Distribution of work between author (THL) and co-author (HIQA):</p> <p>THL tasks are:</p> <ul style="list-style-type: none"> - responsible for the coordination of the work. - to develop the first draft of the project plan - to develop the scientific process plan with specific tasks to be carried out, time frames and deadlines of milestones and deliverables - perform the basic literature search

- involve clinical expert(s)
- carry out the assessment on the domains: “ Clinical effectiveness” and “Safety”
- perform the assessment of ethical and organizational aspects if needed
- review assessments of the co-author
- send the 2nd draft version to reviewers,
- compile feedback from reviewers and stakeholders make changes according to reviewers’ and stakeholders’ comments
- compile all domains into a final report and write the final summary of the assessment.

HIQA tasks are:

- review the draft project plan
- carry out the assessment on the domains: ”Health problem and Current use of the technology” and “Description and technical characteristics of technology”
- carry out a search in EMBASE based on a given literature search protocol by Finohtha
- review other domain assessments made by THL
- review the final version of the assessment/review

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Table 4b. Preliminary Evidence

Preliminary evidence table

Author, year, reference, country

Sponsor

Intervention

Comparator

Study design

Number of patients/ears

Patient characteristics: age, diagnosis

Diagnostic methods used

Previous treatments

Follow up (mean+SD, weeks, months)

Author disclosure (conflict- of –interest)

Efficacy outcomes

Change in severity and or frequency of symptoms (symptoms scores, resolution of symptoms %)

Hearing improvement (air-bone gap, measurement of hearing dB)

Middle ear functioning (tympanometry, Valsalva manoeuvre, pressure swallow test)

Need for additional treatment (medication, grommets, repeated dilatation, other procedures)

Quality of life

Safety

Any complication/adverse event, n, %

Serious adverse events, n, %

Description of adverse events

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Selected assessment elements

Table 5. Assessment elements and translating research questions

ID	Domain	Topic	Issue	Relevance in this assessment Yes/No	Reason for non-relevance/ Preliminary research question(s)	Source of assessment element
Health problem and current use of technology						
A0002	Health Problem and Current Use of the Technology	Target Condition	What is the disease or health condition in the scope of this assessment?	Yes	What is the definition of Eustachian tube dysfunction (ETD), glue ear according to ICD-10?	HTA Core Model for rapid REA of Pharmaceuticals in all
A0003	Health Problem and Current Use of the Technology	Target Condition	What are the known risk factors for the condition?	Yes	What factors causes Eustachian tube dysfunction or glue ear?	
A0004	Health Problem and Current Use of the Technology	Target Condition	What is the natural course of the condition?	Yes	What is the natural course of Eustachian tube dysfunction and glue ear?	
A0005	Health Problem and Current Use of the Technology	Target Condition	What is the burden of disease for the patient?	Yes	What is burden of Eustachian tube dysfunction and glue ear for the patient? How does Eustachian tube dysfunction, glue ear affect the daily life of the patient?	
A0006	Health Problem and Current Use of the Technology	Target Condition	What is the burden of the disease for society?	Yes	Not a serious condition which causes early retirement etc.	
A0007	Health	Target	What is the target	Yes	What is the target population in this	

	Problem and Current Use of the Technology	Population	population in this assessment?		assessment?	
A0023	Health Problem and Current Use of the Technology	Target Population	How many people belong to the target population?	Yes	What is the prevalence of the condition?	
A0001	Health Problem and Current Use of the Technology	Utilisation	For which health conditions and populations, and for what purposes is the technology used?	Yes	For which indications or symptoms is balloon Eustachian tuboplasty used and in which patient groups?	
A0011	Health Problem and Current Use of the Technology	Utilisation	How much are the technologies utilised?	Yes	How widely is balloon Eustachian tuboplasty being used in Europe?	
A0024	Health Problem and Current Use of the Technology	Current Management of the Condition	How is the health condition currently diagnosed according to published guidelines and in practice?	Yes	How are Eustachian tube dysfunction and glue ear diagnosed according to clinical practice guidelines and in practice?	
A0025	Health Problem and Current Use of the Technology	Current Management of the Condition	How is the health condition currently managed according to published guidelines and in practice?	Yes	How are Eustachian tube dysfunction and glue ear managed according to clinical practice guidelines and in practice?	
A0020	Health Problem and Current Use of the Technology	Regulatory Status	What is the marketing authorisation status of the technology?	Yes	What is the marketing authorisation status of balloon Eustachian tuboplasty catheters in Europe?	
A0021	Health Problem and	Regulatory Status	What is the reimbursement status of the technology?	Yes	What is the reimbursement status of balloon Eustachian tuboplasty catheters in Europe?	
Description and technical characteristics of technology						
B0001	Description and technical characteristics of technology	Features of the technology	What is the technology and the comparator(s)?	Yes	What is balloon Eustachian tuboplasty (BET) and what are the treatment alternatives?	
B0002	Description and technical characteristics of technology	Features of the technology	What is the approved indication and claimed benefit of the technology and the comparator(s)?	Yes	What are the approved indications and claimed benefits of BET and the treatment alternatives?	

B0003	Description and technical characteristics of technology	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 BET and the treatment alternatives)?	
B0004	Description and technical characteristics of technology	Features of the technology	Who performs or administers the technology and the comparator(s)?	Yes	Who performs or administers BET and the treatment alternatives?	
B0005	Description and technical characteristics of technology	Features of the technology	In what context and level of care are the technology and the comparator used?	Yes	In what context and level of care are BET and the treatment alternatives used?	
B0008	Description and technical characteristics of technology	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 BET and the treatment alternatives?	
B0009	Description and technical characteristics of technology	Investments and tools required to use the technology	What supplies are needed to use the technology and the comparator?	Yes	What supplies are needed to use BET and the alternative treatments?	
B0010	Description and technical characteristics of technology	Investments and tools required to use the technology	What kind of data and records are needed to monitor the use of the technology and the comparator?	Yes	What kind of data and records are needed to monitor the use of BET and the other treatment alternatives?	
B0011	Description and technical characteristics of technology	Investments and tools required to use the technology	What kind of registry is needed to monitor the use of the technology and comparator?	Yes	What kind of registry is needed to monitor the use of BET and treatment alternatives?	
Safety						
C0001	Safety	Patient safety	What kind of harms can use of the technology cause to the patient?	Yes	What kind of harms can use of balloon Eustachian tuboplasty cause to the patient?	
C0002	Safety	Patient safety	What is the dose relationship of the harms?	No	No dose-relationship here. (including intensity or length or treatment)	
C0004	Safety	Patient safety	How does the frequency or severity of harms change over time or in different settings?	Yes	Are there differences in the frequency and severity of adverse events (harms) over time or according to treatment setting?	
C0005	Safety	Patient safety	What are the susceptible patient groups that are more likely to be	Yes	Are there any patient sub-groups that are more likely to be harmed?	

			harmed?			
C0007	Safety	Patient safety	What are the user-dependent harms?	Yes	Are there user-dependent harms caused by providers (surgeons)	
C0008	Safety	Patient safety	How safe is the technology in relation to the comparator?	Yes	What is the safety of the balloon Eustachian tuboplasty compared to standard of care (tympanostomy or medication)?	
C0040	Safety	Environmental safety	What kind of harms are there for public and environment?	No	None	
Clinical effectiveness						
D0001	Clinical effectiveness	Mortality	What is the expected beneficial effect of the intervention on overall mortality?	No	Balloon Eustachian tuboplasty does not have beneficial effect on mortality	
D0002	Clinical effectiveness	Mortality	What is the expected beneficial effect on the disease-specific mortality?	No	Balloon Eustachian tuboplasty does not have beneficial effect on mortality	
D0005	Clinical effectiveness	Morbidity	How does the technology affect symptoms and findings?	Yes	How does balloon Eustachian tuboplasty affect symptoms and findings?	
D0006	Clinical effectiveness	Morbidity	How does the technology affect progression of disease?	Yes	How does BET affect progression of Eustachian tube dysfunction?(more questions of yes/no symptoms, not progression?)	
D0011	Clinical effectiveness	Function	What is the effect of the technology on patients' body functions?	Yes	What is the effect of BET on patients' body functions (e.g. hearing)	
D0016	Clinical effectiveness	Function	How does the use of technology affect activities of daily living?	Yes	How does the use of BET affect activities of daily living?	
D0012	Clinical effectiveness	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 BET on generic health-related quality of life?	
D0013	Clinical effectiveness	Health-related quality of life	What is the effect of the technology on disease-specific quality of life?	Yes	What is the effect of BET on disease-specific quality of life?	
D0017	Clinical effectiveness	Patient satisfaction	Was the use of the technology worthwhile?	Yes	Were patients satisfied with the BET outcomes?	
D0023	Clinical effectiveness	Change in management	How does the technology modify the need for other technologies and use of resources?	Yes	How does balloon Eustachian tuboplasty modify need for other technologies and use of resources?	HTA Core Model for Diagnostic Technologies

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Checklist for potential ethical, organisational, social and legal aspects

Table 6. Checklist for potential ethical, organisational, social and legal aspects.

1. Ethical	
1.1. Does the introduction of the new technology and its potential use/nonuse 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 which may be ethically relevant?	No
2. Organisational	
2.1. Does the introduction of the new technology and its potential use/nonuse instead of the defined, existing comparators require organisational changes?	No
2.2. Does comparing the new technology to the defined, existing comparators point to any differences which may be organisationally relevant?	No
3. Social:	
3.1. Does the introduction of the new technology and its potential use/nonuse 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 comparators point to any differences which may be socially relevant?	No
4. Legal:	
4.1. Does the introduction of the new technology and its potential use/nonuse 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 comparators point to any differences which may be legally relevant?	No

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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	01/04/2014	12/12/2014
Pilot's team building	07/02/2014	28/02/2014
Scoping phase	01/04/2014	19/06/2014
Consultation of draft project plan with co-authors	10/04/2014	18/04/2014
Consultation of draft project plan with dedicated reviewers	28/04/2014	14/05/2014
Consultation of draft Project Plan (public consultation including WP5 SAG, SF and manufacturer(s))	19/05/2014	06/06/2014
Final Project Plan	06/06/2014	19/06/2014
Assessment phase	19/06/2014	12/12/2014
First draft available	19/06/2014	25/08/2014
Review by dedicated reviewers	25/08/2014	08/09/2014
Second draft available	08/09/2014	29/09/2014
Review by ≥ 1 external clinical expert, manufacturer(s), by Strand B members and other potential stakeholders	29/09/2014	20/10/2014
Third draft available	20/10/2014	11/11/2014
Medical Editing	17/11/2014	28/11/2014
Fourth draft available	01/12/2014	05/12/2014
Formatting	08/12/2014	12/12/2014
Final pilot assessment		week from 15/12/2014
Local Reports (if applicable)		
Local (national or regional) REA N°1 [THL, Finland]		
Local (national or regional) REA N°2 [HBV, Austria]		
Local (national or regional) REA N°2 [GYEMSZI, Hungary]		

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5.2 MEETINGS

Besides face-to-face meetings mentioned in the Work Plan of WP5, no further face-to-face meetings are planned for this specific project. Up to 4 e-meetings may be scheduled for this pilot rapid assessment (see section 6.0), if considered necessary.

6.0 COMMUNICATION

Table 8. Communication

Communication Type	Description	Date	Format	Participants/ Distribution
Draft Project Plan with timelines	Review of methods and assessment elements chosen, discussion of time-lines	[06/05/2014]	E-mail	Author(s), Co-author(s), dedicated reviewers, Coordinating Team
Final Project Plan	Review of methods and assessment elements chosen, discussion of time-lines considering comments from Stakeholder Advisory Group, public, manufacturer	[13/06/2014]	E-mail	Author(s), Co-author(s), dedicated reviewers, Coordinating Team
First draft of the pilot assessment	To be reviewed by dedicated reviewers	[25/08/2014]	E-mail (e-meetings to be planned here -optional)	Dedicated reviewers
	To discuss comments of dedicated reviewers (optional)	[10/09/2014YY]	E-Mail (e-meetings to be planned here -optional)	Author(s), co-author(s), dedicated reviewers
Second draft of the pilot assessment	To be consulted with ≥1 clinical expert, WP5 members, manufacturer(s), other potential stakeholders	[29/09/2014]	E-mail	≥1 clinical expert, WP5 members, manufacturer, other potential stakeholders
Final pilot rapid assessment	Medical editing by external editor	[17/11/2014]	E-Mail	Medical Editor

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111 **6.1 DISSEMINATION PLAN**

112 The final pilot rapid assessment will be distributed as laid-out in the Work Plan of WP5.

 113 **7.0 COLLABORATION WITH STAKEHOLDERS**

 114 A public consultation of the draft Project Plan will be conducted. The draft Project Plan will be made publicly available on the EUnetHTA website
 115 for a period of 15 days. The WP5 SAG, the Stakeholder Forum as well as the manufacturer(s) will be invited to comment on the draft Project Plan
 116 for this pilot rapid assessment.

117 In addition, the manufacturer will be asked for further information (e.g. C/E mark, on-going studies, available evidence, reimbursement status).

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 119 **8.0 COLLABORATION WITH EUnetHTA WPs**

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

 121 **9.0 RESOURCE PLANNING**

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 123 **9.1 HUMAN RESOURCES**

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125 Table 9. Human resources

Role	Total number of person days	Source	
		Staff of participating organisations	Subcontracting
Author	60 person days	60 person days	-
Co-Author	30 person days	30 person days	-
Reviewer	3 person days each	3 person days each	-
External reviewer	8 person days	-	8 person days
Medical Editor	5 person days	-	5 person days
Layout	4 person days	-	4 person days

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 129 **10.0 CONFLICT OF INTEREST MANAGEMENT**

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 131 Conflicts of interest will be handled according to EUnetHTA JA2 Conflict of Interest Policy. As conflict of interest may be topic dependent, conflict
 132 of interest declarations will be collected from authors and reviewers involved in a specific pilot assessments. Authors and reviewers who declare a
 133 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 pilots.

 134 If external experts are involved in WP5 a conflict of interest declarations will be collected from them regarding the topic. External experts who
 135 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
 136 pilots.

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138 **11.0 EXPECTED OUTCOME(S)**

Project outcome(s)

The capacity of national HTA bodies to collaboratively produce structured rapid core HTA.
 Translation into local reports immediately and later. Redundancies is reduced and efficiency gains achieved.
 Applicability of the HTA Core Model for rapid REAs to other technologies is elicited and the Model accordingly adapted.
 On-line tool will be tested in the rapid assessment for the first time.

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140 **C. REFERENCES**

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