WP4

Appendix 1

Minutes of WP4 meeting in March 2010

EUnetHTA Joint Action

Work package 4

Minutes of

WP4 Workshop 1
Online Tool and Service Workshop 1
HTA Core Model Application for Screening Technologies Workshop 1

March 18-19, 2010
Scandic Continental Hotel, Helsinki, Finland

Organized by
The Finnish Office for Health Technology assessment
within the National Institute for Health and Welfare (FINOHTA/THL, Finland)
in collaboration with the Agency for Regional Healthcare (Age.na.s, Italy),

This document contains minutes of three WP4 meetings organized in Helsinki in March 2010. WP4 Workshop 1, organized on March 18th, was a joint meeting for all WP4 member agencies (both Strands A and B). On March 19th, two parallel meetings were organized for members of WP4 Strand A, one for the Online Tool and Service and another for the Screening application of the HTA Core Model. Due to the early phase of the project and several overlapping topics, these meetings took place to a large extent as a joint meeting. Participants, however, were divided into discussion groups based on the main focus of their agency within Strand A (Online tool & service vs. Screening application).

All presentations are available online at the EUnetHTA web site, Members Only section, WP4 Workroom.

Contents

WP4 Workshop 1, Thursday March 18th

Chairs: Kristian Lampe (FINOHTA/THL) and Marina Cerbo (AGENAS)
Meeting room: Consul I-II

Participants:
Akiola Linda (THL, Finland), Antoine Sunya-Lee (DIMDI, Germany), Ballini Luciana (ASSR, Italy), Becla Lidia (AHTAPol, Poland), Burnand Bernard (SNHTA, Switzerland), Børlum Kristensen Finn (NBoH, Denmark), Cerbo Marina (AGE.NA.S, Italy), Cleemput Irina (KCE, Belgium), Corbacho Belén (AETSA, Spain), Crabb Nick (NICE, UK), Dahlgren Helena (SBU, Sweden), Endel Gottfried (HVB, Austria), Frønsdal Katrine B (NOKC, Norway), Gasparetto Teresa (Regione del Veneto, Italy), Giorgi Rossi Paolo (Laziosanità, Italy), Groth Jensen Lotte (Dept of Health Services Research and HTA, Denmark), Hovi Sirpa-Liisa (THL, Finland), Imaz Iñaki (ISCIII, Spain), Kleijnen Sarah (CVZ, Netherlands), Lampe Kristian (THL, Finland), Lee Anne (SDU, Denmark), Lo Scalzo Alessandra (AGE.NA.S, Italy), Mathis Stefan (LBI-HTA, Austria), Mäklin Suvi (THL, Finland), Pace Asciak Renzo (SSD/MSOC, Malta), Pasternack Iris (THL, Finland), Perrini Maria Rosaria (AGE.NA.S, Italy), Pertl Daniela (GÖG, Austria), Raustia Leena (THL, Finland), Saarekas Oskari (THL, Finland), Saluse Janek (UTA, Estonia), Schnell-Inderst Petra (University of Health Sciences, Austria), Sihvo Sinikka (THL, Finland), Stich Anne (IQWIG, Germany), Waldron Caroline (HIQA, Ireland), Werkö Sophie (SBU, Sweden), Vieira Isaura (INFARMED, Portugal), Zagórska Aleksandra (AHTAPol, Poland).

9:00 – 9:20 Kristian Lampe and Marina Cerbo welcomed the participants.

9:20 – 9:30 Welcome addressed by research professor Markku Pekurinen, director of Service System Department of THL.

9:30 – 10:10 Introduction of WP4 Strand A and Strand B (FINOHTA & AGENAS)
Kristian Lampe and Alessandra Lo Scalzo presented the overview of the WP4 for years 2010-2012.. Kristian introduced strand A, and Alessandra presented plans for strand B.

10:10 – 10:30 previous work from WP4 2006–2008 (FINOHTA)
FINOHTA lead the WP4 of earlier EUnetHTA project in 2006-2008. Iris Pasternack introduced thedeliverables from the previous project.

Questions:

- Question 1: Is there one core model or several different core models?

Answer: In the earlier project the HTA Core Model was delivered as two documents, "HTA Core Model for medical and surgical interventions" and "HTA Core Model for diagnostic technologies". The terminology and concepts were further clarified at the very end of the project (and after the preparation of the two aforementioned documents). In that context it was decided that there is only one HTA Core Model and the two "models" developed during the project are actually *applications* of the HTA Core Model. Hence the same common structure can be used in several applications that are developed for assessing various kinds of technologies. The online tool allows the user to select

which application is used in each assessment project. Now we are building an application for screening technologies.

- Question 2: Are the online tool and the screening model developed in a parallel process, are they inter-related?

Answer: Yes, they are very much related to each other, as the online tool needs to allow users easy access to the screening application. We work on them separately because of practical reasons, so that each agency can focus their person-days on something in a more substantial manner. The screening application will be developed mostly "on paper", but in such a format that it can be afterwards easily fed into the online system.

10:45 – 11:30 Kristian Lampe introduced the HTA Core Model.

Questions:

- Question 1: Who are the primary recipients of summary of findings?
Answer: Summary will be primarily written for HTA experts. We will take this into further policy consideration within this project.

- Question 2: It was claimed that HTA Core Model enables greater variability of topics within HTA reports, but will the structure actually limit the information available?
Answer: Our basic assumption is that if agencies can jointly identify topics that are of interest to them and their health systems, it is a good idea to produce jointly a core HTA that can be then adjusted in local settings. This is an alternative to the more traditional approach in which agencies in several countries may work on the same topic and e.g. repeat the same literature reviews multiple times. Resources that are freed from unnecessary duplication of work may be used to look at more technologies than before and hence there would be greater variability in information available. Part of this process is the identification of most important topics, which will be looked at within WP4 Strand B and several other WPs of EUnetHTA.

- Question 3: Have you had any discussion about the language? Will we have to write reports in English?
Answer: A tentative decision was made during the previous project that core HTA's will be written in English. HTA units will write their own (local) reports in their own language. As this is an important policy decision, we can discuss this within the current project as well.

- Question 4: Lifecycle, versioning of Core Model, how is it and applications updated?
Answer: Not known yet, will be discussed and the matter is part of the policy discussions.

11:30 – 12:00 Introduction to group discussions (FINOHTA & AGENAS)

Participants were divided into four discussion groups, each of which was assigned one of the following topics as their main discussion topic. Another, secondary topic was assigned to each group as well. Hence each of the four topics was discussed in two (or more) groups.

Each group was chaired by one of the participants. Notes were taken and results reported in each group by another group member. Groups were asked to write down summary notes on a flip chart paper and more detailed notes on computer.

- HTA Core Model
- Topic selection and priority setting of Core HTA's
- How to collaborate in Core HTA preparation
- Stakeholder involvement

13:00 – 14:00 Group discussions
Meeting rooms Consul I-II, Senator I and III.

14:30 – 15:30 Reports from group discussions

Each group presented their results and summary points were collected to flip chart papers, which are available as Attachment A of this document.

15:30 – 16:00 Conclusions

Finn Børlum Kristensen emphasized that after the previous EUnetHTA project ended, there was a one year break in WP4 activities, and that now many new people have started to work in the project. Influence should go also from here to the agencies. EUnetHTA members only website has lots of new facilities. This is a key work package for EUnetHTA.

Kristian Lampe ended the meeting by thanking the participants and encouraging everyone to send feedback on the WP4 plans and products in order to maximize international usability of our efforts.

17:00 - Dinner at the hotel

WP4 Strand A meeting, Friday March 19th

The minutes below are common for the two parallel and to a large extent merged meetings: Online Tool and Service Workshop 1, HTA Core Model Application for Screening Technologies Workshop 1

Chairs Kristian Lampe and Iris Pasternack
Meeting room: Consul I-II

Participants:
Akiola Linda (THL, Finland), Antoine Sunya-Lee (DIMDI, Germany), Ballini Luciana (ASSR, Italy), Becla Lidia (AHTAPol, Poland), Burnand Bernard (SNHTA, Switzerland), Børlum Kristensen Finn (NBoH, Denmark), Cerbo Marina (AGE.NA.S, Italy), Cleemput Irina (KCE, Belgium), Corbacho Belén (AETSA, Spain), Crabb Nick (NICE, UK), Dahlgren Helena (SBU, Sweden), Endel Gottfried (HVB, Austria), Frønsdal Katrine B (NOKC, Norway), Gasparetto Teresa (Regione del Veneto, Italy), Giorgi Rossi Paolo (Laziosanità, Italy), Groth Jensen Lotte (Dept of Health Services Research and HTA, Denmark), Imaz Iñaki (ISCIII, Spain), Kleijnen Sarah (CVZ, Netherlands), Lampe Kristian (THL, Finland), Lo Scalzo Alessandra (AGE.NA.S, Italy), Mäklin Suvi (THL, Finland), Palmhøj Nielsen Camilla (NBoH, Denmark), Pasternack Iris (THL, Finland), Perrini Maria Rosaria (AGE.NA.S, Italy), Saalasti-Koskinen Ulla (THL, Finland), Saarekas Oskari (THL, Finland), Saluse Janek (UTA, Estonia), Schnell-Inderst Petra (University of Health Sciences, Austria), Sihvo Sinikka (THL, Finland), Stich Anne (IQWIG, Germany), Waldron Caroline (HIQA, Ireland), Werkö Sophie (SBU, Sweden), Vieira Isaura (INFARMED, Portugal), Zagórska Aleksandra (AHTAPol, Poland).

9:00 – 9:10 Welcome

Participants were welcomed to the second day of the meeting. Most participants were the same as during the first day.

As many participants are involved in WP4 strands, Alessandra Lo Scalzo first presented Strand B's action points. AGENAS will send the WP4 Stakeholder Issue Standard Operating Procedure, and SI and TS/PS questionnaires to everyone for comments in the near future.

9:10 – 10:30 Online Tool & Service and policies

Oskari Saarekas and Kristian Lampe presented the online tool and service. It can be found at **http://www.corehta.info**.

The process through which a core HTA is produced is currently suggested to take place in the following five phases:

1. **Project definition**, participants and their roles (project manager, primary investigator, reviewer etc.). The collaborative model will be taken into account while developing this phase.
2. **Protocol design** This phase results in a *Core HTA protocol, which is not* a full research protocol or research plan in traditional terms. Instead it is a protocol of what will be studied within an

assessment, i.e. which questions will be answered. It also contains methodological guidance on finding answers to the questions. A research group has freedom to define the protocol and the framing of research may vary across domains, as long as the scoping stays the same. When the project group is happy with the protocol, the project manager can *lock* it. After locking, only the project manager can change it.
3. **Research**. During this phase a more detailed research plan, containing methodological details e.g. on literature review will be developed and consequently the questions defined by the core HTA protocol will be answered. The tool provides limited support for this phase, as it is not meant to interfere too much with various research practices. It will have links to relevant guidelines within the HTA Core Model and elsewhere.
4. **Results** acquired during the previous phase are uploaded to the system. This phase may overlap the previous phase, i.e. the research group can share preliminary results to the research group using the tool.
5. **Review and publishing**. After the research group has finalized their work, the material can be submitted to a review and publication procedure. As this phase requires definition of several policies, it will be implemented later.

EUnetHTA agencies can start using the online tool with the test user names and passwords (sent to them earlier) and send feedback to developers. Agencies should test the system using a topic that they are actually going to assess within the near future. Currently the testing can be done freely and a more rigorous exercise will be performed in May.

Questions:

- Question 1: Can you copy/paste text for example from a Word-file?
Answer: Yes.
- Question 2: Do the tables that are included have a maximum size?
Answer: Not sure, will check.
- Question 3: Can images be posted?
Answer: Yes.
- Question 4: Is it possible to add an upload function of files (Excel or graphic files)?
Answer: Currently not, but we will try to make it happen.
- Question/Comment 5: Can the possibility to use a free selection of elements (e.g. in a short project) be implemented also soon?
Answer: We are currently focusing on the core hta protocol, as that is needed for Strand B to start their work in M15. On the other hand, the free selection is not a huge task to implement, so we will try to do that as soon as possible too.
- Question 6: Who can make changes?
Answer: Roles of each participant of a core HTA project translate to different user rights. After the protocol has been locked, only the project manager can unlock it, and then again changes can be made by a larger group.
- Question 7: How to refine the research questions?
Answer: Good question, which was not discussed much during the 2006-2008 project. Will be discussed within policies.
- Question 8: Can reviewers enter feedback directly using the tool?
Answer: Currently not, but it would probably be a good feature, will try implement.

10:45 – 11:30 Adaptation of Core HTA information into local settings

Bernand Burnand from SNHTA presented experience from the WP5 of the earlier EUnetHTA project. The Adaptation toolkit was developed by WP5. We will have to investigate how we can integrate the toolkit with the HTA Core Model so that the combination supports the process in which core HTAs are adjusted to local reports. Although this work will primarily take place in 2011 and 2012, we need start the thinking process. Current WP4 members should read the documentation of former WP5 Adaptation Toolkit. It has been a very important piece of work. One key challenge in the integration is that the toolkit considers the relevance and reliability of information within domains as a whole, whereas the HTA Core Model splits the domains into topics and even smaller issues. Despite some differences in the approach, there are many similarities that make integration and interesting and useful effort.

11:30 – 12:00 Introduction to group discussions

Participants were divided into four groups depending on the focus of their agency. Group 1 discussed the Online Tool and Service and Groups 2-4 the application for screening technologies. Participants were divided into groups 2-4 based on their interest in various domains of HTA.

– Kristian Lampe introduced the online tool and service discussion questions for Group 1:

  - Is the current division to phases feasible at face value (i.e. as starting point without rigorous testing)?
  - Current pilot does not contain search function. What kind of searches should one be able to do?
  - How should we handle references to literature? Integration to reference databases (Endnote, Refworks, etc)?
  - What kind of metadata do we need (authorship, descriptors, classifications) and on what/which level(s) (core hta, domain, assessment element)?

– Iris Pasternack introduced screening application of the HTA Core Model discussion questions for Groups 2-4:

- How to ensure sufficient expertise in the Domain teams?
- How to communicate: email, MO workroom, e-meetings?
- What do we expect from the general design team?
- What are the specificities of a screening technology compared to an intervention or diagnostic technology in your domain? Both substance and methodology issues.

Each group selected a chairman and rapporteur from members of the group. Summary notes were requested on flip chart papers and more detailed notes on a computer.

13:00 – 14:00 Group discussions

Meeting rooms Consul I-II, Senator I and III

14:30 – 15:00 Group discussions continue

15:00 – 15.45 Reports from discussions, conclusions and future plans

Findings from the groups discussions were collected on flip charts and discussed.

Kristian Lampe thanked participants for productive and useful discussions that outline further developments within WP4.

The EUnetHTA team within FINOHTA includes 5 persons, Kristian Lampe, Iris Pasternack, Leena Raustia, Oskari Saarekas and Linda Akiola. Other FINOHTA personnel, such as Ulla Saalasti-Koskinen, Suvi Mäklin, Sinikka Sihvo participate in the work of one or more domains when developing the screening application and conducting core HTAs. You can contact the EUnetHTA team of FINOHTA by email: eunethta@thl.fi. Screening application is coordinated by Iris Pasternack. Kristian focuses more on online tool and policies.

Development of the screening application is big task; currently it seems to be that we need particularly legal experts, even as reviewers. Member agencies are urged to try to identify such experts.

Attachment A: Notes on Group discussions on Thursday 18 March

Group 1: HTA Core Model

What remained unclear, what needs further clarification/elaboration?

- Limited practical experience on use
- Learning curve ahead
- Target group of the tool
    - Daily work in HTA?
    - Focus on the doers of HTAs
    - All involved in doing HTA vs. project leader/manager/creator of the protocol?
    - Different user rights (project manager in key role)
- Rights management

What is needed of a Tool & Service that provides an easy-to-use interface to the HTA Core model and information produced through it?

- Clear process required
- Idea: core model content in English, local aspects in local language
- Policy part
    - E.g. policy on publicity of internal communication
    - Stakeholder involvement
    - Public review process
- Help, FAQ

How would the Model best serve local HTA production?
How can we promote the adoption of the Model and the new Tool & Service by national agencies?

- Support for local reports and success in promoting the tool highly related to each other
- Shared information on topics that is worked on between the HTA agencies
- Many young researchers – support by the Core model at performing the first HTA?
- Core HTA will not answer local questions ->no answers to policy questions, but provides evidence/information base for local use
- Carrot: collaboration, speed, project management

Other

- Transfer of knowledge - project management capability (4 people during strand A to support project managers of each core HTA (WP4/B and WP5)
- Search function, description
- Promote what? Use/production? => both

- How to identify different Core HTA reports when there are many of them? Is name sufficient?

Group 2: Topic selection and priority setting

1. Proposals
We started the discussion reviewing the **TS/PS** procedure conducted during **EUnetHTA 2006-2008** in order to elucidate the validity of the method. The aim was trying to decide possible ways to improve the method and in case of necessity, learn from past experiences. Notes on earlier method:

2 step web based voting procedure
Intervention technology: 20 proposals, at last DES selected
Diagnostic technology: 14 proposals, MSCT selected
5 criteria: European scope, transferability, relevance for several domains, feasibility of carrying out assessment and voters preferences.

Planned and ongoing projects (WP7) – POP- database should be checked.
Group the technologies that are "planned" and make a range from the most planned by the various countries, to the less. POP is a Eunethta tool and this should assure that the most planned technologies are the ones of common interest for European countries.

2. Filtering
Exclusion criteria: recently assessed in the European level

3. Prioritising
How risky to be when deciding a topic?
Level of complexity: simple vs complex topics
Not restricting to interventions or diagnostic

4. Draft questionnaire

Further general notes on the discussion:

Initial brainstorming focused on the following issues:

- Before deciding potential topics it should be clear if we have lo limit it to Interventions and Diagnostic.
- Filtering: we have to find topics that are common to all of us. This implies thinking in what are the criteria that will permit to filter technologies that are common to all partners.
- Is there any document to assist scoring the topics in terms of the European common interest?
- POP database is fine but as there are new partners maybe it should be complemented with input from new partners (Claudia sent a file to be filled out, can we use this update or do we ask all again?)
- Have we got to be risky or not when deciding?
- New proposals on which they have no reports done or technologies that represent a real problem when you´ve got to disseminate later (to take into account for the draft questionnaire) and so avoiding duplication.
- Define criteria for selection or topics that are universally valid or only for the definition of the 2 interventions that we have to validate?

- How ambitious to be when selecting the topics of relevance for the policy makers in our countries?
- Think about accuracy: Pool of experts created? Validation rounds? Consultation?

Taking into consideration the concerns above the following proposals were made:

- Use the POP database from WP7 as source to detect potential subjects. It was proposed to group the interventions, make a range from the more planned, detect uncovered topics and use "the recently assessed in the European area" as exclusion criteria.
- It was proposed not restricting to INTERVENTIONS AND DIGNOSTICS, in the sense that if SCREENING technologies are on top of the list they should be taken into account.
- Evaluate the level of complexity in terms of scope (specific vs complex) and number of domains assessed.
- Regarding PS and the criteria use to score the topics, it was discussed that ones the topic is considered of European common interest the classical criteria for PS (ex. sufficient scientific data, epidemiologic impact, economical impact, ethical/controversial) were in a way implicit to this.

REGARDING STAKEHOLDER INVOLVEMENT

- Are the scientific societies considered in the definition that EUnetHTA SOP manual as stakeholders?
- When talking about screening or preventing interventions, where the population covered is really high, the involvement of the local authorities and decision makers should be taken into account.
- Public consultation is focused on the guidance and HTA reports are to inform guidance, is there much need for public consultation?

Group 3: Collaboration in doing core htas

1. **How to maximize expertise in domain teams?**
   - Agencies should not specialize
   - Pool of specialists needed: tools and skills matrix
   - Criteria for working in collaboration needed to ensure quality
   - The use of English speaking experts outside accepted: e.g. medicinal societies like UEMS
2. **How to ensure good coordination?**
   - Pool of project managers
   - Project management procedural system
   - Use of web
   - Extra tasks: scoping, finding expertise, consultation for concerns
3. **How to ensure good quality and acceptability of Core HTAs?**
   - Use of guidelines

- Description of methodology
- Peer review is needed, "call for reviewers"
- Review of different stages

4. How to ensure proper reporting?

- One editor with expertise
- One summary writer with experience
- Writing instructions and style guide

Group 4: Stakeholder involvement

1. How to involve

- Specific questions - specific experts
- SI is problematic in some contexts
- Role of public consultation?
- Feedback on feedback, transparency

2. On what to involve stakeholders?

- Deliverables
- Topic selection (in the future)
- Protocol

3. If stakeholders are asked "specific questions" (i.e. ?) are they playing as Experts? Can this substitute systematic collection of primary data end information from e.g. samples of subjects?

- Expert opinion is complementary to systematic review
- Scientific societies as stakeholders?
- Local policymakers /actors as stakeholders?

4. Questionnaire discussion

- Some comments made

Attachment B: Notes on discussions on Friday 19 March

Group 1: Online tool and service

1. Is the current division to phases feasible at face value (i.e. as starting point without rigorous testing)?

Division of phases:
phase 1: project definition
phase 2: protocol design
phase 3: research
phase 4: results
phase 5: review and publishing

After discussion of the items below, the group concludes that these phases should be feasible at face value.

The following items were discussed:

- Phase 3 consists of finding answers to the questions of phase 2. During this phase you forget the tool. You just do the work. Phase name may be reconsidered to make it clearer.
- There may be need to put a status to an element, so the author can give an indication of the status. E.g. completed/ work in progress or preliminary. Progress report should be available easily.
- They may be different ways to use the tool. We should have an overview of the most important options. Now we should focus on doing an core HTA. Other options might be extraction of data form an existing report. Maybe do update of previous core HTA's.
- The essence of the tool is that multiple persons/organisations can work on 1 model.

2. Current pilot does not contain search function. What kind of searches should one be able to do?

- The idea behind this question is that if there will be many reports than it might be beneficial to be able to search though these reports.
- All domains should have metadata such as ICD-10, Mesh, ATC, But then there can specific extra meta-data for domains or elements.
- You should be able to define if you van to search Core-HTA's or domains/elements. So a limitation to content type.
- One should be able to find "my items", i.e. easy access to own work.
- One should be able to search based on technologies and patients.
- One should be able to limit searches by content type (e.g. core htas, elements)

3. How should we handle references to literature? Integration to reference databases (Endnote, Refworks, etc)?

- In the previous core HTA's there were domain specific literature list. Do we want this again? Do we want to use a specific program?
- It is desirable to see the online tool as a dynamic thing that can be improved in the future.
- An online reference system may be an option (refworks?!). A license is used to enter. Maybe we can take a look at the tool at home after receiving more information.

- There will be some research, asking all countries to list which reference system they use to see if it is possible to introduce 1 system. WP4/Stream A will conduct a small survey.

4. What kind of metadata do we need (authorship, descriptors, classifications) and on what/which level(s) (core hta, domain, assessment element)?

- The following meta-data may be included as well: ICD-10, Mesh, ATC.
- It should be possible to assign metadata on all the following levels: core hta – domain – assessment element
- We should have rules to who is author and contributor etc. Maybe everyone should be a contributor. However, people may be strict on what is the intellectual property right. We may need a distinction between writing (editor) rights and intellectual property management.
- It was discussed that there a valid reasons for having authorship specified as specific as possible. For one it is a reward for doing the work. But also for future updating purposes of specific elements it is handy if only the authorship for these elements can be changed. Specific names are preferred above agency names.
- If a specific person develops a cost-effectiveness model, this person should have the exclusive right for publishing this model.
- It might be worthwhile to think about setting up a EUnetHTA journal because if you have guarantee for publications authors might be easier inclined to participate.
- Creative commons: this is kind of a license for data on the internet. You can restrict the use of data for specific purposes. For example, if you use the data you have to feed the results back into the public domain.

More on this topic from other groups:

- Topic selection very important when doing applications of Core Model
- Clarity regarding promotion of use of Core Model for local HTAs
- Call for HTA procedure
- Acceptability – quality of EUnetHTA HTAs very important for promotion and uptake

Groups 2-4: Screening application of the HTA Core Model

1. **How to ensure sufficient expertise in the Domain teams?**

– We need both screening and methodology experts, e.g. health economists. Double expertise?

– We need to exchange expertise across domain teams.

– More people needed in legal, social and ethical domains

2. **How to communicate: email, MO workroom, e-meetings?**

– All three. Add face-to-face meetings.

– We need a communication protocol that everyone adheres. If a domain team decides to use the workroom for document drafting, everyone should use it.

– Workroom can be used for both storing the documents and drafting them.

– Email alerts are needed when adding document to the workroom

3. **What do we expect from the general design team?**

- Definition of screening
- Glossary
- Overall coordination of the work, enabling interaction with domain teams
- Identify overlaps
- Ensuring that there is the possibility to test the draft Model and commenting it during the preparation phase.
- Style and editorial guidance
- "Umbrella" methodology issues
- Should consist of one member of each domain team

4. What are the specificities of a screening technology compared to an intervention or diagnostic technology in your domain? Both substance and methodology issues.

Effectiveness:

- Healthy people: consequences in test selection, low prevalence causes false positive results
- Different study types need to be linked: RCT. observational, registries, accuracy studies, modeling

Costs:

- Time horizon - discounting
- Costs alongside the intervention
- Extra costs (FP) or less costs (prevention)
- Outcomes: final (QoL, LYS), intermediate
- What to compare: no screening, other type of screening?

Organizational, ethical, social, legal:

- Prevention
- Healthy population
- Multidisciplinarity
- Multisequence: disease-test(s)-treatment -organisation
- Quality assurance
- Coverage

EUnetHTA WP4 meeting in Helsinki 18.3.2010 participants
Venue: Hotel Scandic Continental, Helsinki, Finland

	Name	Organization	Signature
1	Akiola Linda	THL, Finland	
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7	Cerbo Marina	AGE.NA.S, Italy	
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23	Mathis Stefan	LBI-HTA, Austria	
24	Mäklin Suvi	THL, Finland	
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27	Perrini Maria Rosaria	AGE.NA.S, Italy	
28	Pertl Daniela	GÖG, Austria	
29	Raustia Leena	THL, Finland	
30	Saarekas Oskari	THL, Finland	
31	Saluse Janek	UTA, Estonia	
32	Schnell-Inderst Petra	University of Health Sciences, Austria	
33	Sihvo Sinikka	THL, Finland	
34	Stich Anne	IQWIG, Germany	
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EUnetHTA WP4 meeting in Helsinki 19.3.2010 participants

Venue: Hotel Scandic Continental, Helsinki, Finland

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4	Ballini Luciana	ASSR, Italy	
5	Becla Lidia	AHTAPol, Poland	
6	Burnand Bernard	SNHTA, Switzerland	
7	Børlum Kristensen Finn	NBoH, Denmark	
8	Cerbo Marina	AGE.NA.S, Italy	
9	Cleemput Irina	KCE, Belgium	
10	Corbacho Belén	AETSA, Spain	
11	Crabb Nick	NICE, UK	
12	Dahlgren Helena	SBU, Sweden	
13	Endel Gottfried	HVB, Austria	
14	Frønsdal Katrine B	NOKC, Norway	
15	Gasparetto Teresa	Regione del Veneto, Italy	
16	Giorgi Rossi Paolo	Laziosanità, Italy	
17	Groth Jensen Lotte	Dept of Health Services Research and HTA, Denmark	
18	Imaz Iñaki	ISCIII, Spain	
19	Kleijnen Sarah	CVZ, Netherlands	
20	Lampe Kristian	THL, Finland	
21	Lo Scalzo Alessandra	AGE.NA.S, Italy	
22	Mäklin Suvi	THL, Finland	
23	Pace Asciak Renzo	SSD/MSOC, Malta	
24	Palmhøj Nielsen Camilla	NBoH, Denmark	
25	Pasternack Iris	THL, Finland	
26	Perrini Maria Rosaria	AGE.NA.S, Italy	

27	Raustia Leena	THL, Finland	
28	Saalasti-Koskinen Ulla	THL, Finland	
29	Saarekas Oskari	THL, Finland	
30	Saluse Janek	UTA, Estonia	
31	Schnell-Inderst Petra	University of Health Sciences, Austria	
32	Sihvo Sinikka	THL, Finland	
33	Stich Anne	IQWIG, Germany	
34	Waldron Caroline	HIQA, Ireland	
35	Werkö Sophie	SBU, Sweden	
36	Vieira Isaura	INFARMED, Portugal	
37	Zagórska Aleksandra	AHTAPol, Poland	

WP4

Appendix 2

Minutes of WP4 meeting in November 2010

EUnetHTA Joint Action

Work Package 4

Minutes of

WP4 2nd Ftf Meeting

November 25th -26th , 2010
Regus Centre, Rome, Italy

Organized by
The Agency for Regional Healthcare (Age.na.s, Italy),
in collaboration with the Finnish Office for Health Technology Assessment
within the National Institute for Health and Welfare (FINOHTA/THL, Finland)

This document contains the minutes of WP4 2nd Ftf meeting held in Rome on the 25th -26th November 2010. On November 25th there was a joint meeting for all WP4 member agencies (both Strands A and B). On November 26th, two parallel workshops were organized for members of WP4 Strand A, one for the Online Tool and Service and another one for the Screening application of the HTA Core Model. Participants were divided into discussion groups based on the main focus of their agency within Strand A (Online tool & service vs. Screening application).

All presentations are available online at the EUnetHTA web site, Members Only section, WP4 Workroom.

Contents

WP4 Meeting, Thursday, 25th November

Chairs: Kristian Lampe (FINOHTA/THL) and Marina Cerbo (AGENAS)
Meeting room: Tosca-Norma (Regus Centre, Rome)

Participants:
Akiola Linda (THL, Finland), Antoine Sunya-Lee (DIMDI, Germany), Becla Lidia (AHTAPol, Poland), Børlum Kristensen Finn (NBoH, Denmark), Carletto Angelica (University Hospital "A.Gemelli", Italy), Cerbo Marina (AGE.NA.S, Italy), Corio Mirella (AGE.NA.S, Italy), Crabb Nick (NICE, UK), de Laet Chris (KCE, Belgium), Derksen Joke (CVZ, Netherlands), Ferroni Eliana (AGE.NA.S, Italy), Frønsdal Katrine (NOKC, Norway), Gasparetto Teresa (Regione del Veneto, Italy), Giorgi Rossi Paolo (Laziosanità, Italy), Groth Jensen Lotte (Dept of Health Services Research and HTA, Denmark), Harrington Patricia (HIQA, Ireland), Imaz Iñaki (ISCIII, Spain), Jefferson Tom (AGE.NA.S, Italy), Kleijnen Sarah (CVZ, Netherlands), Lampe Kristian (THL, Finland), Lo Scalzo Alessandra (AGE.NA.S, Italy), Mäklin Suvi (THL, Finland), Marlow Mirella (NICE, UK), Mathis Stefan (LBI-HTA, Austria), Pasternack Iris (THL, Finland), Perrini Maria Rosaria (AGE.NA.S, Italy), Pertl Daniela (GÖG, Austria), Raatz Heike (SNHTA, Switzerland), Rosén Måns (SBU, Sweden), Ruggeri Matteo (University Hospital "A.Gemelli", Italy), Rüther Alric (IQWiG, Germany), Saalasti-Koskinen Ulla (THL, Finland), Saarekas Oskari (THL, Finland), Saluse Janek (UTA, Estonia), Schnell-Inderst Petra (University of Health Sciences, Austria), Segnan Nereo (ARESS - Regione Piemonte, Italy), Soeterdal Ingrid (NOKC, Norway), Tringali Michele (Regione Lombardia, Italy), Turk Eva (IPH-RS, Slovenia), Vieira Isaura (INFARMED, Portugal), Vignatelli Luca (ASSR-RER, Italy), Werkö Sophie (SBU, Sweden), Wilbacher Ingrid (HVB, Austria).

9:00 – 9:15 Kristian Lampe and Marina Cerbo welcomed the participants.

9:05 – 9:25 Welcome addressed by Dr. Ruocco chief director of department of International Affairs at Italian Ministry of Health. He highlighted the importance of EUnetHTA Joint Action and the interest of the Ministry of Health in the international collaboration.

9:25-9:35 Marina Cerbo presented the meeting agenda and some practical information was given about the breaks and the social dinner. Then participants were invited to present themselves.

9:35 – 10:10 WP4 Strand A and Strand B (FINOHTA & AGENAS): first year objectives and deliverables
Marina Cerbo and Kristian Lampe gave an overview of the WP4 activities after one year. Marina showed the objectives, commitments by year, the activities to be undertaken each year. Kristian, after reminding the objectives and deliverables of the whole WP4, focused his presentation on strand A tasks and activities status. In addition Kristian introduced the Stakeholder Involvement policy in WPs. In particular he presented the Modes of participation through Stakeholder Advisory Group (SAG), procedures and the upcoming activities of SAG in WP4.

10:10 – 10:30 Strand A & B policies (FINOHTA)

Kristian Lampe introduced the proposals related to the process and timeline for crafting policies relevant for HTA Core Model / Online Tool & Service and the proposal of WP4 working groups structure.

Comments/questions:

1. One participant wondered if the number of persons in the proposed Coordination Working Group was too large (see below, within conclusions).
2. It was pointed out that there is likely to be less availability of expertise in some of the 9 domains (legal, ethical) and that agencies should pay particular attention in identifying persons with expertise in various domains.

11:00 – 11:45 STRAND B First Results (AGENAS)

Alessandra Lo Scalzo and Maria Rosaria Perrini presented the results of the three surveys conducted by Agenas, within the strand B.

Alessandra showed the results of the first two surveys, focusing respectively on Stakeholder Involvement practices and Topic Selection-Priority Setting experiences among WP4 partners. Both the surveys were based on a questionnaire agreed with WP4 partners and submitted to all of them.

Comments/questions:

1. Were the connection between the nature of the adoption of an official transparent process of priority setting and the use of criteria for prioritizing explored? They were not. Only a descriptive elaboration of the data has been performed.
2. Good material for a publication.
3. It could be useful to specify the "other" criteria used by the partners for prioritizing.

Alessandra recalled the methodological procedure to be followed for the topics selection for the production of two Core HTAs. That procedure was agreed in the 1st ftf meeting of WP4 held in Helsinki in March 2010. After showing the results and critical points resulting from the application of the procedure, Alessandra described the new Topic Selection-Priority Setting methods for the 2 Core HTAs agreed with all partners after the meeting in Helsinki.

Maria Rosaria presented the results of the topic proposals collected from the WP4 partners through an *ad hoc* identification form previously agreed with all partners.

11:45 – 13.00 DISCUSSION

Summary table of results

1. It was proposed that the core HTAs produced within Strand B should not be seen as something that can be used for real. Kristian L reminded the participants that during the planning phase of the JA it was discussed that this time the core HTAs should be more "for real" than during the previous project, where even the HTA Core Model was still under lot of development. The concern raised by some participants was to justify the inconsistency with the agreed procedure to the European Commission (EC); but it was pointed out by some attendees that operating in a testing / pilot phase less rigorously should not compromise the meaning and value of the project (if any objection would raise from the European Commission). Hence the core HTAs can still be regarded as pilot products, with possible shortcomings. The idea of the tighter timeline (as compared with 2006-2008 project), however, is that the information would be adequate and current at the time of publication.
2. In addition many participants expressed their concern about the broad scope of the selected technologies, especially the genetic test for cancer (Diagnostics). On the one hand someone

stated the need to define the scope in more specific terms, but on the other hand, it was argued that this should be a matter to be solved within the editorial teams of two core HTAs.
3. Most of the participants recognized the need to provide more information to narrow the scope of the topic for the core HTA. The proposal was to select the topics for the two Core HTAs collecting the interest of all the partners on the technologies already proposed
4. The majority stated that a new procedure is needed to achieve this goal.

14:00 – 14:30 Adaptation – initial proposal for procedure to be discussed in the meeting (FINOHTA)

Iris Pasternack presented the proposal for the Adaptation of HTA information across documents. In particular Iris explained the users, the purposes and the tools useful for the adaptation. The actual work on adaptation will commence only in March/April 2011 the earliest.

Comments/questions:

1. How is adaptation related to the handbook? It will probably be a part of the handbook. Do we really need an adaptation tool? Adaptation should be a part of reporting and part of the handbook.
2. The Adaptation toolkit /from the earlier project is available in EUnetHTA Members Only website.
3. While creating the elements in Core HTA, they could be marked so that you could see which elements could be adapted easily.

It was agreed that there is a need for a working group to continue with this. Voluntary can turn to Iris.

14:30 – 15:30 Collaborative Models and Methodological issues (FINOHTA & AGENAS)

Marina Cerbo showed the organisational structure of WP4 and proposed to test two different models of collaboration among WP4 partners in order to produce jointly the two Core HTAs. The two Collaborative Models were presented: in the Collaborative Model 1 each domain (9) is composed by researchers from different agencies participating to WP4B; in the Collaborative Model 2 each of the 9 domains is managed by a different Associated Partner that has a specific expertise on that domain. Some issues to be discussed among the attendees were pointed out. Kristian Lampe emphasized the need of active involvement of APs, inviting them to assume the responsibility of the domain's groups.

Comments/questions:

1. Most of the participants agreed on the need to define the technologies to be assessed, before choosing the collaborative model to test. The next step will be to make the working groups for the two Core HTAs and the nine Domain teams within each Core HTA.
2. A procedure is needed to achieve this goal.

16:00 – 16:30 Conclusions

POLICY

Coordination Working Group (CWG)

- Some issues raised about the number of persons in this WG (Inaki Imaz proposes a smaller group) the same observation has been posed by Mans Rosen from SBU "smaller groups working better" so KL suggested to reconsider this issue (but as KL asked if someone

thought that the size could be problematic most attendees – through raised hands – said no). It was agreed tentatively that a larger group would be more appropriate to ensure wide representation.

PROCEDURES

- No comments or observations, everyone agreed with the proposals for the next activities.

CORE HTAs

Choosing the topics

- The participants shared the idea to submit a new survey to all partners (the form was agreed and validated in the conclusions session) asking them to indicate their interest in the specific technologies already proposed (distinguishing among the three macro categories). The partners will be also asked to provide at the same time a rank of their interests – in the column (grades rank). It was also agreed to add information about the diseases related to each technology proposed.
- After this 1st phase and after analyzing the data provided by the responders, a new form will be sent to all members in order to collect their interest in being involved in the assessment of 1 or more domains for the technologies selected. All partners will weight their preferences with a rank (from 1 – the most interesting, to 5 – less interesting), and will also specify if they wish to take part in the Domain Teams in collaboration with others, by themselves or either of them and finally as Primary Investigator. An example of the form was shown to the attendees. The results will be analyzed to build up the Core HTAs Team (choosing between collaborative model 1 and collaborative model 2) and within each Core HTA the Domain Teams.

  Several considerations have been raised from the audience:
  - There are 19 Associated Partners involved in the WP4 strand B, each AP should have the responsibility of at least one domain. So each AP will have to indicate its interest for at least one domain.
  - In addition it is important that the partners with experience in the development of Core Models and the previous Core HTAs (on DES and MSCT), indicate their preference in being Primary Investigator of Domain Teams' participant.
  - As about the Collaborative Model 2 (where Domain Teams will be composed by members of a single partner), the warning is to be flexible on some domains e.g. legal aspects and ethical aspects, where it is more difficult to suppose that a single partner could assess the domains alone.
- Agenas proposed to plan an e-meeting, after having the results of the first questionnaire, to discuss and agree on the topics identified.

At 16.30 the meeting ended.

20:00 – Social Dinner

WP4 Strand A meeting, Friday, 26th November

The minutes below are common for the two parallel workshops: Online Tool and Service and HTA Core Model Application for Screening Technologies

Chairs: Kristian Lampe and Iris Pasternack
Meeting rooms: Tosca-Norma and Carmen (Regus Centre, Rome)

Participants:
Akiola Linda (THL, Finland), Antoine Sunya-Lee (DIMDI, Germany), Becla Lidia (AHTAPol, Poland), Børlum Kristensen Finn (NBoH, Denmark), Carletto Angelica (University Hospital "A.Gemelli", Italy), Cerbo Marina (AGE.NA.S, Italy), Corio Mirella (AGE.NA.S, Italy), Crabb Nick (NICE, UK), de Laet Chris (KCE, Belgium), Derksen Joke (CVZ, Netherlands), Ferroni Eliana (AGE.NA.S, Italy), Filippi Chiara (Regione Veneto, Italy), Frønsdal Katrine (NOKC, Norway), Gasparetto Teresa (Regione Veneto, Italy), Giorgi Rossi Paolo (Laziosanità, Italy), Groth Jensen Lotte (Dept of Health Services Research and HTA, Denmark), Harrington Patricia (HIQA, Ireland), Imaz Iñaki (ISCIII, Spain), Kleijnen Sarah (CVZ, Netherlands), Lampe Kristian (THL, Finland), Lo Scalzo Alessandra (AGE.NA.S, Italy), Mäklin Suvi (THL, Finland), Marlow Mirella (NICE, UK), Pasternack Iris (THL, Finland), Perrini Maria Rosaria (AGE.NA.S, Italy), Raatz Heike (SNHTA, Switzerland), Rosén Måns (SBU, Sweden), Ruggeri Matteo (University Hospital "A.Gemelli", Italy), Rüther Alric (IQWiG, Germany), Saalasti-Koskinen Ulla (THL, Finland), Saarekas Oskari (THL, Finland), Saluse Janek (UTA, Estonia), Schnell-Inderst Petra (University of Health Sciences, Austria), Segnan Nereo (ARESS - Regione Piemonte, Italy), Soeterdal Ingrid (NOKC, Norway), Turk Eva (IPH-RS, Slovenia), Vieira Isaura (INFARMED, Portugal), Vignatelli Luca (ASSR-RER, Italy), Werkö Sophie (SBU, Sweden), Wilbacher Ingrid (HVB, Austria).

9:00 – 9:15 Welcome

Participants were welcomed to the second day of the meeting. Most participants were the same as during the first day.

Workshop on Core Model for screening at 9:00 - 15:00

Workshop participants split themselves into domain teams. Effectiveness, costs, ethical and organisational domains formed their own teams; domains with only few participants merged together (HPCU & DTC and Social & Legal); Safety domain team was missing.

The teams worked with one or several of the tasks described below in italics. The aim is to produce a draft of the Screening Model for WP4 Stakeholder Advisory Group review by December 15. All updated documents should be sent to Iris by Dec 13 to achieve that.

We discussed also about how to proceed with preparing the Introduction section for the Screening Model deliverable. It was agreed that Iris makes the first draft, circulates it first to the Coordination and Editing team, and then to all Domain investigators. Final version goes for Domain reviewers for comments.

Task 1 Editing the Domain methodology section

Problem: *The Domain Methodology text should be brief and easy to read on screen. Longer text pieces should be linked as separate pdf-files, "Guidelines". Text that is relevant also for other Domains should separated into "Common methodologies" pool.*
Task: *Go through the Methodology text of your Domain and*

a) Identify and mark text that belong to the ***general or sharable methodologies****, e.g.*

- *Guidance to critical appraisal of published*
  - *HTAs*
  - *Systematic reviews*
  - *Trials*
  - *Observational studies*
  - *Modelling studies*
  - *Statistics*
  - *Register data*
- *Guidance on how to do*
  - *Scoping/PICO*
  - *Systematic review*
  - *Modelling*
  - *Register analysis*
  - *Questionnaire*
  - *Interview*

b) Identify and mark text that is specific for this Domain but can be presented as ***independent pdf-document*** *behind a link e.g.*

- *Description of the translational model (in Organisational Domain)*
- *Quadas quality assessment tool (in Safety Domain)*

Task 2 Editing the 'Information source' field in the AE-table

Problem: *The 'Information source' text will pop up in a small window in the Core Model Online protocol, in conjunction with the assessment elements. It should give something AE-relevant additional information. It should not repeat the information that is given in the Methodology section.*

- *In some Domains the problem is that the 'Information source' fields are empty: please try to fill in them but only if there is something specific for that AE.*
- *In other Domains there may be too much text that repeats the general principles given in the Methodology section.*

Examples of good 'Information source' texts:

- *"Inquiry of technical officers at the Ministry of Health"*
- *"Horizon scanning databases"*
- *"EMEA web site"*
- *"Comparative policy studies"*

Examples of less useful 'Information source' texts:

- *"Systematic review of literature"*
- *"Qualitative research methods"*

Task:
Go through the 'Information source' fields in your AE-table. The field should give a hint about

- *where to find information to this question and*
- *what kind of information should I look for.*

Check that the information is specific for that particular assessment element and that it does not repeat general principles that are given in the Domain Methodology section. Be specific; give details and links to relevant sources.

Task 3 Identifying possible overlapping issues and "order of doing"

Problem 1: *Some elements are for the first sight overlapping. Usually it is intentional that there are similar element in two Domains because the viewpoint is meant to be different. Anyhow there is a risk that the HTA doers search, and read the same articles and do double work if this is not coordinated.*
Problem 2: *There are certain elements (or Domains) that require information from certain other element (or Domain) in order to be able to start even formulating research questions. These requirement of order should be somehow marked in the Model.*
Task: *Go through the elements in your Domain.*

- *Identify issues in other AE-tables (preferably at ID level) where there is a* ***possible overlap.***
- *Identify issues in other AE-tables (ID or Domain level) where there is a need to consider* ***order of doing.***

E.g. Order of doing:
Organisational Domain could consider:

- *In order two answer the question in our ID G0005 we need to have the information from HPCU Domain ID A0011*

or

- *The information in our ID G0007 is probably valuable for the effectiveness domain D0026 before they start assessing it.*

Task 4 Editing the 'Clarification' field in the AE-table

Problem:

- *The clarifications are often missing*
- *Current content is heterogenous*
  - *Describes issue in other words (can be helpful, but sometimes is not)*
  - *Gives an example of the issue*
  - *Hints additional aspects*
  - *Hints methodology (avoid this)*
  - *Interpretation*

Task:

- *Go through the elements in your domain.*
- *Analyse the clarifications and harmonize. Examples are illustrative ways to clarify the issue.*

Workshop on Online tool and service at 9.00-15.30

Participants: Akiola Linda (THL, Finland), Børlum Kristensen Finn (NBoH, Denmark), Cerbo Marina (AGE.NA.S, Italy), Crabb Nick (NICE, UK), de Laet Chris (KCE, Belgium), Ferroni Eliana (AGE.NA.S, Italy), Gasparetto Teresa (Regione Veneto, Italy), Imaz Iñaki (ISCIII, Spain), Kleijnen Sarah (CVZ, Netherlands), Lampe Kristian (THL, Finland), Rüther Alric (IQWiG, Germany), Saarekas Oskari (THL, Finland), Soeterdal Ingrid (NOKC, Norway), Werkö Sophie (SBU, Sweden).

GENERAL DISCUSSION
Kristian Lampe first presented some key concepts, most of which were already agreed on in the previous project 2006-2008.
Assessment elements defined by the HTA Core Model are divided into core elements and non-core elements. The motivation for this is to reduce the vast number of elements into a more manageable set within each application (e.g. "screening model"). The status as core/non-core may be different for each element within different applications, since some piece of information may be more important in the context of assessing certain types of technologies. The core/non-core status is defined by the assumed *importance* and *transferability* of the element (or actually its information content) within each application (see original article).

During the discussion it became apparent that actually transferability may be different on the following three levels:

1. Assessment element level
   Transferability is largely an assumption, an "educated guess", at least until we have more data to measure transferability directly.
2. Core HTA level
   Answers to an issue defined by an assessment element may have different transferability depending on the topic of the Core HTA. Transferability on this level may even be in two different categories: before answering the question (assumption) and after answering the question (more accurate assumption as one knows what kind of data has been found).
3. Local report
   This represents the "real" transferability of information, as it is judged by those who produce local reports.

In the previous project it was agreed that assessment elements are described in more details as element cards that contain information on e.g. where to find answers or the origin of the element. The structure of entering the results need to be defined for the Online Tool & Service. The original idea of previous project of including also the answers as "cards" was confirmed in the discussion. Hence an answered issue defined by an assessment element will be recorded in the database as a "result card" or "answer card" that contains the answer + relevant metadata (such as authors, dates, etc.).
Framing of various domains still requires thinking. It was agreed that a core HTA project clearly needs a common scope, i.e. agreed on focus of analysis that all domains should include in their analysis. The framing may be different in separate domains due to methodological reasons or available research materials. We still need to decide whether domain framing should be done prior the research. The group agree that prior agreement on also domain framing would be a good idea.

The image describing the structured HTA information (SHTAI), core HTAs and local HTAs requires amendments. The shortcut from SHTAI to local reports needs to be made clearer. Also, we need new types of intermediary projects (parallel to core HTAs), such as rapid HTA, REA HTA. On the right hand side there should also be a "My HTA", which is a self-defined template that uses the elements from the HTA Core Model.
As during the previous project, it was suggested that the HTA Core Model could and should be used also in such a manner that answers to elements are filled in into the cards using an existing HTA report. This can be viewed as possibly a very useful method of increasing the volume of the SHTAI that can then again be used for core HTAs and/or local reports.
Core HTAs and other types of intermediary products serve as more detailed structures that also promote the international collaboration of agencies interested in similar topics.
Jurisdiction needs to be defined for various structures and products. Whereas local reports and "My HTAs" are property of individual (national/regional) agencies, the SHTAI, core HTAs and REA HTAs are primarily controlled by EUnetHTA. There is actually shared responsibility of most parts, as national agencies cannot use the HTA Core Model in whatever way they want (Terms of Use are set) and on the other hand EUnetHTA should not define/dictate rules that agencies are not comfortable with.
The following rules are (at least) required for each intermediary project type (e.g. rapid review template):

1. Set of elements that are used
2. Whether relevance assessment is required or all elements of set should always be used
3. Whether justification for irrelevance is required
4. Whether answers to relevant questions are required (or whether they can be skipped due to e.g. lack or resources or time).

FEEDBACK FROM FIRST PILOT

Participants received a table in which all relevant textual feedback from the first pilot has been compiled. There is a vast number of feedback comments and there was time to discuss only some of the most difficult issues. The remaining issues will be discussed later through email. Conclusions of the discussion are included below:

- Users should be able to retrieve different versions of the core HTA protocol (e.g. with and without the methodological guidance), also in different formats (HTML, PDF, RTF/WORD). Also locking and opening the protocol should be made easier.
- Domain-level framing requires further thinking and discussion with screening model developers. In the meantime the domain framing step in the tool should have project scoping options preselected by default to speed up protocol design.
- "Complete" boxes have raised some concern/objections, people feel that the system should bring things automatically forward. They were included so that larger groups could view the intermediate data without proceeding. A button for easily marking a step completed and moving on to the next incomplete step should be added whenever manually marking a step completed provides no benefit (e.g. when only one person is responsible for completing the step).
- The process of judging the relevance of assessment elements and translating them into research questions and including justifications for irrelevant issues was perceived as very arduous by some respondents. It was agreed that we cannot change the nature of the process, as creating a HTA protocol is always quite a big task. The process itself has been agreed on earlier. The translation of elementary questions needs to be done as the Model needs to be

very technology-independent. Explanation why something is irrelevant has also been commented on positively several times earlier. We need to explore possibilities of making this process smoother, for example by providing the possibility of translating the question immediately after marking it as relevant and providing a possibility to define the explanation of irrelevance at a later stage. Instead of always having to write a free form explanation the system should in addition provide some predefined frequently used explanations to choose from.

- Project manager can manage the roles.
- Questions/comments:
    - Can you revise it later, after it is finished?
    - Version control and end user added value are important.Earlier publishing for some parts (before the HTA is ready)?
- Information in the pool is important because a mistake can go unnoticed for a long time. That is why original sources are important.

EUnetHTA WP4 Face to Face meeting
Rome, Italy
November, 25th - 26th,2010 09:30 – 16:30

Organised by: Agenas
Address of the meeting venue: Rome, Via Salandra, 18

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Participants List

November 25th, 2010

WP4 2nd Face to face Meeting

Attendee	Organisation	Signature November, 25th
Daniela Pertl	GÖG-Gesundheit Österreich GmbH/Geschäftsbereich BIQG-Bundesinstitut für Qualität im Gesundheitswesen	
Stefan Mathis-Edenhofer	LBI – HTA Ludwig Boltzmann Institute Health Technology Assessment	
Ingrid Wilbacher	HVB - Hauptverband der Österreichischen Sozialversicherungsträger (Association of Austrian Social Insurance Institutions)	
Petra Schnell-Inderst	UMIT – University of Health sciences	
Chris de Laet	KCE, Belgian Health Care Knowledge Centre	
Finn Børlum Kristensen	NBOH – National board of health	
Lotte Groth Jensen	CPH – HTA & Health Services Research, Center for Public Health	
Janek Saluse	UTA, Department of Public Health, University of Tartu	
Linda Akiola	THL – National Institute for Health and Welfare	
Kristian Lampe		
Suvi Mäklin		
Iris Pasternack		
Ulla Saalasti-Koskinen		
Oskari Saarekas		
Sunya Lee Antoine	DIMDI, Deutsches Institut für Medizinische Dokumentation und Information	

Attendee	Organisation	Signature November, 25th
Alric Rüther	IQWIG, Institute for Quality and Efficiency in Health Care	
Patricia Harrington	HIQA, Health Information and Quality Authority	
Nereo Segnan	ARESS, Agenzia Regionale per i Servizi Sanitari (Piedmont Health Care Agency)	
Valeria Romano		
~~Marco Marchetti~~ MATTEO RUGGERI	University Hospital "A.Gemelli"	
Angelica Carletto		
Teresa Gasparetto	Regione Veneto	
Chiara Filippi		
Luciana Ballini	ASSR - RER, Agenzia Sanitaria e Sociale Regionale Regione Emilia Romagna	
Luca Vignatelli		
Paolo Giorgi Rossi	Laziosanità	
Soeterdal	NOKC, Norwegian Knowledge Center for the Health Services	
Katrine Froensdal		
Lidia Becla	AHTAPol – Agency for Health Technology Assessment in Poland	
Isaura Vieira	INFARMED, National Authority of Medicines and Health Products	
Eva Turk	IPH-RS, Institute of Public Health of the Republic of Slovenia	
Iñaki Imaz	ISCIII, Instituto De Salud Carlos III	
Sophie Werkö	SBU, Swedish Council on Technology Assessment in Health Care	
Måns Rosén		
Heike Raatz	SNHTA, Swiss Network for HTA	
Sarah Kleijnen	CVZ, Health Care Insurance Board	
Joke Derksen		
Nick Crabb	NICE - National Institute for Health and Clinical Excellence	

Attendee	Organisation	Signature November, 25th
Mirella Marlow	NICE - National Institute for Health and Clinical Excellence	
Marina Cerbo	Agenas - Agenzia Nazionale per i Servizi Sanitari Regionali	
Alessandra Lo Scalzo		
Mirella Corio		
Maria Rosaria Perrini		
Eliana Ferroni		
MICHELE TRINGALI	REGLOMB	
TOM JEFFERSON	AGENAS	

EUnetHTA WP4 Face to Face meeting
Rome, Italy
November, 25th - 26th,2010 09:30 – 16:30

Organised by: Agenas
Address of the meeting venue: Rome, Via Salandra, 18

eunethta

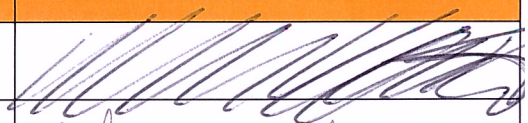
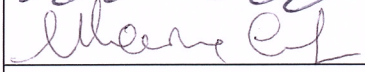
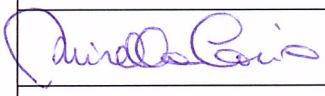
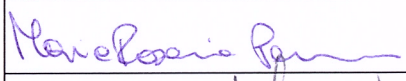
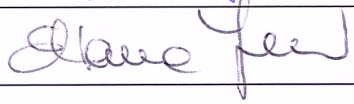
Participants List

November 26th, 2010

WP4 2nd Face to face Meeting

Attendee	Organisation	Signature November, 26th
Daniela Pertl	GÖG-Gesundheit Österreich GmbH/Geschäftsbereich BIQG-Bundesinstitut für Qualität im Gesundheitswesen	
Stefan Mathis-Edenhofer	LBI – HTA Ludwig Boltzmann Institute Health Technology Assessment	
Ingrid Wilbacher	HVB - Hauptverband der Österreichischen Sozialversicherungsträger (Association of Austrian Social Insurance Institutions)	
Petra Schnell-Inderst	UMIT – University of Health sciences	
Chris de Laet	KCE, Belgian Health Care Knowledge Centre	
Finn Børlum Kristensen	NBOH – National board of health	
Lotte Groth Jensen	CPH – HTA & Health Services Research, Center for Public Health	
Janek Saluse	UTA, Department of Public Health, University of Tartu	
Linda Akiola	THL – National Institute for Health and Welfare	
Kristian Lampe		
Suvi Mäklin		
Iris Pasternack		
Ulla Saalasti-Koskinen		
Oskari Saarekas		
Sunya Lee Antoine	DIMDI, Deutsches Institut für Medizinische Dokumentation und Information	S. Antoine

Attendee	Organisation	Signature November, 26th
Alric Rüther	IQWIG, Institute for Quality and Efficiency in Health Care	
Patricia Harrington	HIQA, Health Information and Quality Authority	
Nereo Segnan	ARESS, Agenzia Regionale per i Servizi Sanitari (Piedmont Health Care Agency)	
Valeria Romano		
MATTEO RUGGERI Marco Marchetti	University Hospital "A.Gemelli"	
Angelica Carletto		
Teresa Gasparetto	Regione Veneto	
Chiara Filippi		
Luciana Ballini	ASSR - RER, Agenzia Sanitaria e Sociale Regionale Regione Emilia Romagna	
Luca Vignatelli		
Paolo Giorgi Rossi	Laziosanità	
Soeterdal	NOKC, Norwegian Knowledge Center for the Health Services	
Katrine Froensdal		
Lidia Becla	AHTAPol – Agency for Health Technology Assessment in Poland	
Isaura Vieira	INFARMED, National Authority of Medicines and Health Products	
Eva Turk	IPH-RS, Institute of Public Health of the Republic of Slovenia	
Iñaki Imaz	ISCIII, Instituto De Salud Carlos III	
Sophie Werkö	SBU, Swedish Council on Technology Assessment in Health Care	
Måns Rosén		
Heike Raatz	SNHTA, Swiss Network for HTA	
Sarah Kleijnen	CVZ, Health Care Insurance Board	
Joke Derksen		
Nick Crabb	NICE - National Institute for Health and Clinical Excellence	

Attendee	Organisation	Signature November, 26th
Mirella Marlow	NICE - National Institute for Health and Clinical Excellence	
Marina Cerbo	Agenas - Agenzia Nazionale per i Servizi Sanitari Regionali	
Alessandra Lo Scalzo		
Mirella Corio		
Maria Rosaria Perrini		
Eliana Ferroni		

WP4

Appendix 3

Minutes of WP4 meeting In April 2011

EUnetHTA JA WP4 Strand B / Core HTA Workshop 1
Date: ***2011, 6th-7th April***

Organised by *AgeNaS*
Agenzia Nazionale per i Servizi Sanitari Regionali, Italy

WP4/B Meeting "Core HTA – Workshop 1", Wednesday, 6th April

Chairs: Marina Cerbo (Agenas) and Tom Jefferson (Agenas)
Meeting room: Botticelli (NH Hotel Vittorio Veneto, Rome)

Participants:
Petra Schnell-Inderst (UMIT, Austria),Daniela Pertl (GÖG, Austria), Gottfried Endel (HVB, Austria), Stefan Mathis-Edenhofer (LBI, Austria), Mirjana Huic (AAZ, Croatia), Lotte Groth Jensen (Central Denmark, Denmark), Anne Lee (SDU/CAST, Denmark), Janek Saluse (UTA, Estonia), Kristian Lampe (FinOHTA/THL, Finland), Iris Pasternak (FinOHTA/THL, Finland), Suvi Mäklin (FinOHTA/THL, Finland), Sunya-Lee Antoine (DIMDI, Germany), Michelle O'Neill (HIQA,Ireland), Teresa Gasparetto (Regione Veneto, Italy), Angelica Carletto (A. Gemelli, Italy), Emilio Chiarolla (Agenas, Italy), Mirella Corio (Agenas, Italy), Eliana Ferroni (Agenas, Italy), Antonio Migliore (Agenas, Italy), Maria Rosaria Perrini (AgeNaS, Italy), Nicola Vicari (AgeNaS, Italy), Luciana Ballini (ASSR RER, Italy), Susanna Maltoni (ASSR RER, Italy), Luca Vignatelli (ASSR RER, Italy), Paolo Giorgi Rossi (Laziosanità, Italy), Renzo Pace Asciak (SSD/MSOC, Malta), Katrine B. Frønsdal (NOKC, Norway), Ingvil Sæterdal (NOKC, Norway), Lidia Becla (AHTAPol, Poland), Isaura Vieira (INFARMED, Portugal), Eva Turk (IPH-RS, Slovenia), Aurora Llanos-Mendez (AETSA, Spain), Iñaki Imaz (ISCIII-AETS, Spain), Heike Raatz (SNHTA, Switzerland), Nick Crabb (NICE, United Kingdom).

Apologies:
Alric Ruether (IQWiG, Gemrnay)
Marco Marchetti (A. Gemelli, Italy)

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1. **Welcome and introduction of participants / Welcome address**
   Marina Cerbo, Tom Jefferson
2. **Where are we now? - Team preferences on Topics and Collaborative Models for Core HTAs Production. Survey on Domain Interest: Results and Domain Teams building**
   Maria Rosaria Perrini, Mirella Corio
3. **Preparing a Core HTA: practical guidance**
   Iris Pasternack
4. **Introduction to Online Tool**
   Kristian Lampe
5. **Discussion on Domain Teams Gaps**
   Kristian Lampe
6. ***Interactive session: Where do we need to be and how do we get there?***

Discussant: Tom Jefferson, Kristian Lampe

7. ***Conclusion***

April 7th

8. **Working groups (Editorial teams) organisation**
   Tom Jefferson
9. **Results of each working group**
10. *Vice-Chairs*
    Conclusion

Next e-meeting – September, 2011 in Wien

10.10 – 10.30: Welcome and introduction of participants / Welcome address

Marina Cerbo and Tom Jefferson welcomed the participants and gave some practical information about the meeting program, timetables and social event.

10.30 – 11.15: Where are we now? - Team preferences on Topics and Collaborative Models for Core HTAs Production. Survey on Domain Interest: Results and Domain Teams building

Maria Rosaria Perrini and Mirella Corio gave an overview of the WP4 Strand B, ,describing the activities completed, the methodological processes followed and the results reached so far. Specifically the processes and activities undertaken were reminded: to select the two topics for the Core HTAs; to identify the two collaborative approaches to be experimented; and to build up the working teams. The Core HTAs working teams were presented to the participants and some critical points were highlighted, remitting a more in depth discussion in the session focusing on the domain teams gaps. Beside it was explained which activities have to be completed in the next months. Next steps of WP4 Strand B and the timetable were shown at the end of the presentation, focusing on Core HTA Production

Comment/Questions:

1. Could Primary Investigators and Investigators from the same Agency be in the same domain?
   Tom Jefferson answered that it should be discussed also considering the Domain gaps that should be resolved.
2. The timing for protocol design and research is not clear.
   Kristian Lampe answered that JA1 agreed that CORE HTA reports should be prepared before end of 2012.

11.30 – 12.15: Preparing a Core HTA: practical guidance

Iris Pasternack from FinOHTA gave an overview of the Core HTA Production using the experiences from previous pilot projects, focusing particularly on the main phases and issues that were faced during the work done.

Comment/Questions:

1. How is it possible, if it is, to update information searched during the Core HTA production?
   Iris Pasternack answered that it is not defined how to update information gathered. In previous experiences some updating was done but it could be useful to have suggestions on how to do that.

14.30 – 15.00: Introduction to Online Tool

Kristian Lampe from FinOHTA described the on-line tool (www.corehta.info) and explained how the tool is structured and how it should be used, starting from the creation of a new Core HTA Protocol, project definition, access and rights of participants, selection of relevant questions, etc.

Kristian Lampe showed also a practical use of the Online Tool explaining the main functions of the website.

The results of a survey on the improvement of the online tool, based on the answers from different testers, were shown at the end of the presentation.

Comment/Questions:

After several questions on practical use of the on-line tool, Kristian remarked that the feedback from each researcher who will use the tools is important, as the work is in progress and changes could be implemented in the on-line tool and its structure, in particular as data are added to the tool.

Furthermore, the current version of the on-line tool does not help investigators in the research phase: it should be used only to insert and organize the previously searched information.

As questions and discussion were made during this session, there was no time for final discussion.

14.30 – 15.00: Discussion on Domain Teams Gaps

Tom Jefferson and Kristian Lampe made a brief summary of the issues connected with the Domain Teams building, as there were different gaps in some domains in both Core HTAs.

In the discussion, the following points where shared:

- There are some Associated Partners (APs) that gave no indications about their involvement in Domain Teams, even if they are committed do to so. This issue should be resolved within the WP4 but, if it is not possible, it will be reported to WP1 Coordination in order to solve it;
- As there is no rule against it, also Collaborating Partners (CPs) could be involved as more active partners;
- It is important that each agency, giving its preferences, took into account its expertise and experiences and also the amount of work that should be done for each Core HTA;
- In the Collaborative Model 2 the number of Reviewers is important, as a single Institution is responsible for a Domain. As the number of Reviewers is quite small in this Collaborative Model (CollMod), Tom Jefferson proposes to have another round and ask to all Partners to find (inside their structure or asking to allied organizations) some more Reviewers for this CollMod and also for CollMod1.
- It is necessary to clarify how the recruitment of external experts will work, both for timing and budgeting.

Result of discussion (to be shared via e-mail after the meeting):

Genetic Test

- Renzo Pace Asciak (SSD/MSOC, Malta) will be Investigator in Health problem and Current use domain (CUR) and Reviewer in the Ethical domain (ETH);
- Gottfried Endel (HVB, Austria) confirms the availability of HVB to be involved also in the Legal Aspects domain (LEG). For this domain, as for the ETH one, HVB has some experts who could be involved;
- As regards the Safety domain (SAF) Iris Pasternack (FinOHTA, Finland) expresses their availability to be involved as Primary Investigator ;

- Michelle O'Neill (HIQA, Ireland) provides her availability to be committed in the assessment of some more domains (scrivere quali) as reviewer;
- Isaura Vieria (INFARMED, Portugal) is available to be also Investigator in LEG domain;
- Eva Turk (IPH-RS, Slovenia) provides her availability to be investigator in the clinical effectiveness domain (EFF) and reviewer in Safety domain (SAF) or Costs and economic aspects (ECO);
- Researchers from A. Gemelli (Italy) will indicate updated names and contacts in the domain chosen;
- Researchers from AHTAPol (Poland) will indicate updated names and contacts in the domain chosen.
- Petra Schnell-Inderst will discuss within UMIT whether they could take a more active role as a CP.

AAA Screening

- HVB will lead the Legal aspects domain(LEG), and Ingrid Wilbacher will be the Primary Investigator.

15.00 – 16.30: Interactive session: Where do we need to be and how do we get there?

Tom Jefferson made a short introduction of the next session in which Partners had to decide how to organize the work and to plan the next steps.

First step was to define and share the composition of Editorial Teams for each CollMod, taking into account that there will be 1 Chair (Tom Jefferson for both Editorial Teams). It was explained that each editorial team is comprised of "members from all WP4 strand B partners focused on that Core HTA" plus one chair and one vice chair. The need to define in detail which members should be part of the Editorial team was highlighted (only the primary investigators or other representatives of domain teams?).

For some participants it was not clear which role and duties a Vice-Chair would have. Therefore, Tom Jefferson and Kristian Lampe explained that Vice-Chairs will be the middle-man contact between Domain Teams and Editorial Team Chair, considering that there are more than 30 researchers involved in the Domain Teams. Someone proposed to have more than one vice-chair for each Editorial teams, representing a cluster of similar domains.

After discussing on composition, cluster of domains, which type of Editorial Teams should be used ("PI driven" or "Mixed"), it was decided to have just 1 Vice-Chair per CollMod instead of 2.

3. Conclusion

As there were no more questions for this session, Tom Jefferson quickly summarized what had been done and what will be decided in the next day.

The elected Vice-Chairs will do a presentation after lunch on 7april summarizing what each working groups (Genetic Test and AAA screening) will decide during the morning session of April 7th.

WP4/B Meeting "Core HTA – Workshop 1", Thursday, 7th April

Chairs: Marina Cerbo (Agenas) and Tom Jefferson (Agenas)
Meeting room: Botticelli and Mascagni (NH Hotel Vittorio Veneto, Rome)

Working groups (Editorial teams) organisation
Tom Jefferson

Participants were divided in two groups for the morning session and each groups worked separately on the different protocol.

Results of each working group

Genetic Test for Cancer

Tom Jefferson (Agenas, Italy), Petra Schnell-Inderst (UMIT, Austria), Mirjana Huic (AAZ, Croatia), Iris Pasternak (FinOHTA/THL, Finland), Sunya-Lee Antoine (DIMDI, Germany), Michelle O'Neill (HIQA,Ireland), Teresa Gasparetto (Regione Veneto, Italy), Angelica Carletto (A. Gemelli, Italy), Emilio Chiarolla (Agenas, Italy), Mirella Corio (Agenas, Italy), Eliana Ferroni (Agenas, Italy), Antonio Migliore (Agenas, Italy), Maria Rosaria Perrini (AgeNaS, Italy), Luciana Ballini (ASSR RER, Italy), Susanna Maltoni (ASSR RER, Italy), Luca Vignatelli (ASSR RER, Italy), Renzo Pace Asciak (SSD/MSOC, Malta), Ingvil Sæterdal (NOKC, Norway), Lidia Becla (AHTAPol, Poland), Isaura Vieira (INFARMED, Portugal), Eva Turk (IPH-RS, Slovenia), Heike Raatz (SNHTA, Switzerland), Nick Crabb (NICE, United Kingdom).

After a short discussion and a voting round in which each partner explained its availability and possibility to be Vice-Chair, it was decided that Heike Raatz (SNHTA, Switzerland) will be Vice-Chair for Genetic Test group.
Main point of discussion and final consideration was the following:

a. Scoping: as Genetic Test is a broad field, first step is to narrow the scope of the test.
   After a wide discussion on which test should be assessed, it was decided that Eva Turk will send info about main area of interest in cancer research in Europe (asking to JA European Partnership for Action Against Cancer); this information will be shared with all partners.
   Agenas will then prepare and send to all Agencies involved in Genetic Test Core HTA production a survey in which each Agency should choose and rank 3 specific tests.
   Each Agency should then indicate 3 specific test and give further information on each (i.e: specific indications, how it affects the treatment, specific population, etc.). Answers should be send within April 28th.
   Agenas will then prepare an e-meeting on May 12th in which results of survey will be discussed and scope will be defined.
b. After this phase, Isaura Vieria (Infarmed) will made a basic literature search and the references will be send to all Domain Teams in different formats in order to facilitate the use of these information with different Reference Managers softwares

AAA Screening

Marina Cerbo (Agenas, Italy), Daniela Pertl (GÖG, Austria), Gottfried Endel (HVB, Austria), Stefan Mathis-Edenhofer (LBI, Austria), Lotte Groth Jensen (Central Denmark, Denmark), Anne Lee (SDU/CAST, Denmark), Janek Saluse (UTA, Estonia), Kristian Lampe (FinOHTA/THL, Finland), Suvi Mäklin (FinOHTA/THL, Finland), Nicola Vicari (Agenas, Italy), Paolo Giorgi Rossi (Laziosanità, Italy), Katrine B. Frønsdal (NOKC, Norway), Aurora Llanos-Mendez (AETSA, Spain), Iñaki Imaz (ISCIII-AETS, Spain)

After a short discussion, it was decided that Vice-Chair for this group will be Katrine B. Frønsdal (NOKC, Norway).
Main points of discussion and final consideration were the following:

a. A project leader from AGENAS (Nicola Vicari) will manage the creating of the project on the on-line tool (final version of on-line tool should be ready within mid of April)
b. New researcher that should be added to this group will be communicated to Chair of Editorial Team
c. PICO:
   - P: men aged from 60 and up
   - I and C: two comparisons
      - pop screening
      - opportunistic screening, noscreening
d. Timeline: agreement to keep the one suggested by AGENAS (screening model available next week ready to be used/validated);
   Within end of May, assessment elements will be selected in the on-line tool;
   Within end of June: draft protocol should be send to SAG;
e. Background info : initial scoping search (Stefan Mathis-Edenhofer, LBI, Austria);
f. Need to organize literature found in RefMan (Lotte);
g. For practical communication, there will be folders in the workroom (one for management, one for project domains) of EuNetHTA website;
h. Regulary e-meetings will be arranged by editorial team.

4. Discussion

Each Vice-Chair summarized the work done in the two groups. During the discussion the possibility of postponing the deadline of June 2011 for submitting a draft of each protocol to SAG was evaluated; after considering and discussing the timing of the whole project, it was decided that the Genetic Test group should decide (in 1 week) if they would like to postpone this deadline.

5. Conclusions and future plans and timetable

Marina Cerbo made a brief speech on present activities and future plans, also in relation to Joint Action 2, which is under definition.

Timelines, deadlines and teams

Both Working Groups

- *May 15th 2011* *Phase 1 - Project Definition*
- *June 2011:* *Phase 2- Core HTA Protocol Definition - 1st draft of core protocol for SAG review*
- *May-June 2012:* *Phase 3- Research*
- *Summer-Fall 2012:* *Phase 4 - Reviewing*

In addition:

For Genetic Test

- *April 28th 2011:* *Survey for 3 specific genetic test for choosing the one to be assessed*
- *May 12th 2011:* *E-meeting: discussion on scoping results*
- *June 10th 2011:* *Core HTA protocol of each Domain Team must be submitted to other Domain team and Reviewers for reviewing*

For AAA Screening

- *May 15th 2011:* *initial scoping search, collection and organization of results*

Teams

Collaborative Model 1 - Genetic Test for Cancers		
Primary Investigator	**Investigator**	**Reviewer**
CUR (Health Problem and Current use)		
S.L.Antoine (DIMDI) sunya-lee.antoine@dimdi.de	**T.Gasparetto (Reg. Veneto)** teresa.gasparetto@regione.veneto.it	**S.Mathis-Endenhofer (LBI-HTA)** stefan.mathis@hta.lbg.ac.at
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		L.Ballini (ASSR-RER) final reviewer only luballini@regione.emilia-romagna.it
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Collaborative Model 2 - AAA Screening		
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CUR (Health Problem and Current use)		
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SAF (Safety)		
ISCIII - AETS	**Iñaki Imaz** imaz@isciii.es	**_____ (NOKC)**
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		M.Huic (AAZ) mirjana.huic@aaz.hr
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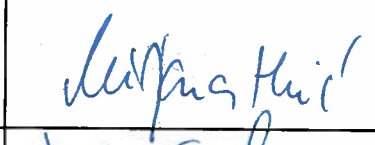
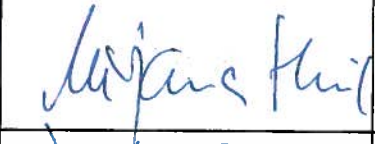
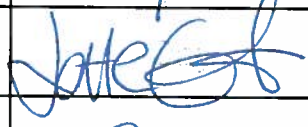
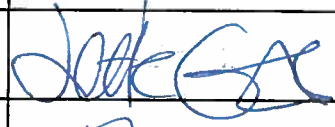
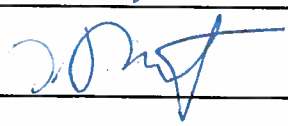
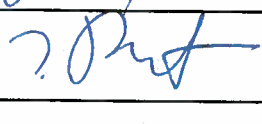
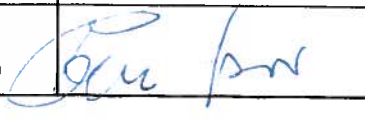
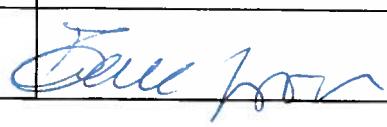
LEG (Legal aspects)		
HVB	**I. Wilbacher** ingrid.wilbacher@hvb.sozvers.at	

EUnetHTA JA WP4/Strand B 1st face to face meeting
Rome, Italy
April, 6th-7th 2011
Organised by: Agenas
Address of the meeting venue: NH Hotel Vittorio Veneto, Corso d'Italia 1

eunethta

Participant Signatures

Name	Signature April 6th	Signature April 7th	Organisation	Country
Petra Schnell-Inderst			UMIT - University for Health Sciences, Medical Informatics and Technology	*Austria*
Daniela Pertl			GÖG - Gesundheit Österreich GmbH/Geschäftsbereich BIQG-Bundesinstitut für Qualität im Gesundheitswesen	Austria
Gottfried Endel			HVB - Hauptverband der Österreichischen Sozialversicherungsträger	Austria
Stefan Mathis-Edenhofer			LBI - Ludwig Boltzmann Institute Health Technology Assessment	Austria
Mirjana Huic			AAZ - Agency for Quality and Accreditation in Health Care, Department for Development, Research and Health Technology Assessment	*Croatia*
Lotte Groth Jensen			Central Denmark - Centre fro Public Health (CPH), HTA & Health Services Research	Denmark
Anne Lee			SDU/CAST - Centre for Applied Health Services Research and Technology Assessment, University of Southern Denmark	Denmark
Janek Saluse			UTA - Department of Public Health, University of Tartu	Estonia
Kristian Lampe			FinOHTA/THL - National Institute for Health and Welfare	Finland
Suvi Mäklin				
Iris Pasternak				
Sunya-Lee Antoine			DIMDI - Deutsches Institut für Medizinische Dokumentation und Information	Germany
Alric Ruether			IQWiG - Institute for Quality and Efficiency in Health Care	Germany
Michelle O'Neill			HIQA - Health Information and Quality Authority	Ireland
Teresa Gasparetto			Regione del Veneto	Italy

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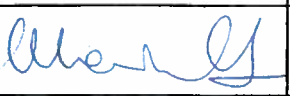
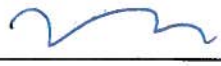
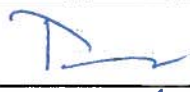
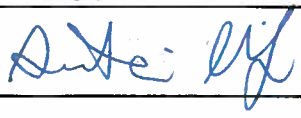
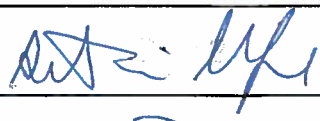
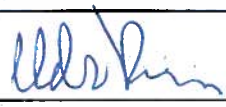
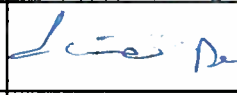
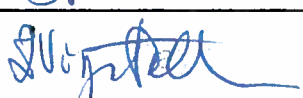
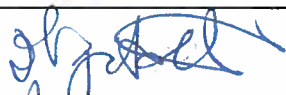
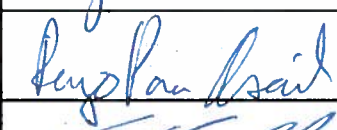
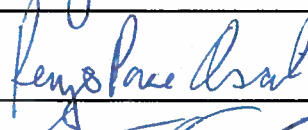
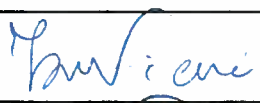
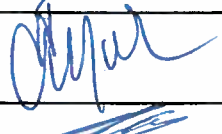
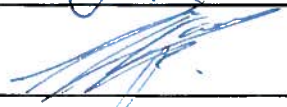
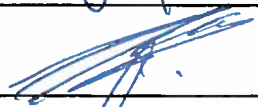
Angelica Carletto			A. Gemelli - University Hospital "A.Gemelli"	Italy
Marco Marchetti				
Marina Cerbo			AgeNaS - Agenzia Nazionale per i Servizi Sanitari Regionali	Italy
Mirella Corio				
Eliana Ferroni				
Tom Jefferson				
Antonio Migliore				
Maria Rosaria Perrini				
Nicola Vicari				
Luciana Ballini			ASSR RER - Agenzia Sanitaria e Sociale Regionale Regione Emilia Romagna	Italy
Susanna Maltoni				
Luca Vignatelli				
Renzo Pace Asciak			SSD/MSOC - Ministry for Social Policy, Strategy and Sustainability Division	Malta
Katrine Frønsdal			NOKC - Norwegian Knowledge Center for the Health Services	Norway
Ingvil Sæterdal				
Lidia Becla			AHTAPol - Agency for Health Technology Assessment in Poland	Poland
Isaura Vieira			INFARMED - National Authority of Medicines and Health Products	Portugal
Eva Turk			NIPH - National Institute of Public Health	Slovenia
Aurora Llanos-Mendez			AETSA - Andalusian HTA Agency	Spain
Iñaki Imaz			ISCIII-AETS - Instituto De Salud Carlos III	Spain
Heike Raatz			SNHTA - Swiss Network for HTA	Switzerland

05-04-2011

Nick Crabb	N Crabb	N Crabb	NICE - National Institute for Health and Clinical Excellence	United Kingdom
PAOLO GIORGI ROSSI			LAZIO SANITÀ ITALIA	ITALY
EMILIO CHIAROLLA			AGENAS	ITALY

WP4

Appendix 4

Minutes of WP4 meeting in September 2011

EUnetHTA JA WP4 Strand B / Core HTA Workshop 2
Date: ***2011, 15th-16th September***

Organised by *AgeNaS (Italy) and HVB (Austria,)Agenzia Nazionale per i Servizi Sanitari Regionali, Italy*

WP4/B Meeting "Core HTA – Workshop 2", 15th Sept.

Chairs: M. Cerbo (AGENAS) K. Lampe/I.Pasternak (THL)

Participants:
Daniela Pertl (GÖG, Austria), Sophie Brunner (GÖG, Austria), Gottfried Endel (HVB, Austria), Ingrid Wilbacher (HVB, Austria), Stefan Mathis-Edenhofer (LBI, Austria), Narine Sahakyan (UMIT, Austria), Mirjana Huic (AAZ, Croatia), Lotte Groth Jensen (Central Denmark, Denmark), Anne Lee (SDU/CAST, Denmark), Janek Saluse (UTA, Estonia), Kristian Lampe (THL, Finland), Iris Pasternak (THL, Finland), Suvi Mäklin (THL, Finland), Julia Kreis (IQWiQ, Germany), Michelle O'Neill (HIQA,Ireland), Mirella Corio (Agenas, Italy), Tom Jefferson (AgeNaS, Italy), Antonio Migliore (Agenas, Italy), Nicola Vicari (AgeNaS, Italy), Angelica Carletto (A. Gemelli, Italy), Marco Marchetti (A. Gemelli, Italy), Katrine B. Frønsdal (NOKC, Norway), Ingvil Sæterdal (NOKC, Norway), Anna Panasiuk (AHTAPol, Poland), Isaura Vieira (INFARMED, Portugal), Eva Turk (IPH-RS, Slovenia), Iñaki Imaz (ISCIII-AETS, Spain), Heike Raatz (SNHTA, Switzerland), Jennifer Butt (NICE, United Kingdom), Nick Crabb (NICE, United Kingdom).

Apologies:
Teresa Gasparetto (Regione Veneto, Italy),

September 15th 2011

1.	Welcome and introduction of participants – *G. Endel (HVB)*	10.00 - 10.15
2.	Introduction: update on Work Package 4 – *K. Lampe (THL)*	10.15 - 10.45
3.	Strand B: State of the art – *T. Jefferson (AgeNaS)*	10.45 – 11.15
4.	Genetic Test: update – *H. Raatz (SNHTA)*	11.30 – 12.00
5.	AAA Screening: update – *K. B. Frønsdal (NOKC)*	12.00 – 12.30
6.	Discussion both working groups	12.30 – 13.00
7.	Working Group Session: Genetic Test and AAA Screening each group will be moderated by 1 from THL Team and 1 from Agenas Team	14.00 – 17.00
8.	1st day remarks	17.00 – 17.30

September 16th 2011

1.	Working Group Session (cross fertilization)	09.00 – 10.30
2.	Coffee break	10.30 – 10.45
3.	Next steps: research phase – *T. Jefferson (AgeNaS)*	10.45 – 11.30
4.	Discussion on the research phase	11.30 – 12.30
5.	Lunch	12.30 – 13.30
6.	Working Group Session research phase : Genetic Test and AAA Screening each group will be moderated by 1 from THL Team and 1 from Agenas Team	13.30 – 15.30

7. Conclusions and final remarks – *K. Lampe (THL), T. Jefferson (AgeNaS)* 15.30 – 16.00

September 15th 2011

Welcome and introduction of participants

Gottfried Endel from HVB welcomed the participants of the meeting.

Introduction: update on Work Package 4 – Kristian Lampe

Kristian Lampe (THL) made a short update on the Work Package 4, illustrating the activities done by the various working groups that are in WP4.
For Strand A, it was presented the situation of Online Tools and Service, with the latest developments (i.e.: single sign-on access, basic functions, etc) and the under-construction updates (i.e.: information search, concept paper, etc.).
It was then illustrated the structural development of the Online Tool, such as collections and they will be organized and managed.
Kristian Lampe then presented the last updates on the policies, at present in revision by CWG after a survey among partners.
For the Adaptation task, it was presented the state-of-the-art, with the set-up of the task force, the objectives and scheduled activities.
For Strand B Kristian Lampe made a brief presentation of the activities done and what has to be completed in the next months (research phase for both Core HTAs, next face-to-face meeting, etc.)
After that Kristian Lampe presented the next scheduled activities for both strands, such as the technical and financial reporting for 2011, deliverables for next year and validation of Core HTAs.
A note was made on publication of scientific articles: it is recommended but not mandatory.
Final remarks include a recommendation to all partners to try to do a good job, as this project will interest different parties and it will be analyzed in deep by them.

Questions / Comments

Marina Cerbo stressed the importance of quality assurance both in Joint Action 1 and in next JA2.

Strand B: State of the art – Tom Jefferson

Tom Jefferson made an update on the activities of WP4 Strand B, reviewing what has been done so far, from topic selection to the 1st draft of the protocol sent to SAG.
Tom Jefferson then reviewed the main issues encountered by researchers in this first phase of the project (see slides for further details).
Regarding the 1st draft of the protocol sent to SAG, Tom Jefferson showed the 2 comments received (note: we've received other comments after the meeting; we'll gather and send to all the complete comments from SAG).
It was then showed the timeline for the next phase (2011-2012) and proposed to have timely regular e-meeting for each working group with the help of Agenas.

Genetic Tests: update – H. Raatz (SNHTA)

Heike Raatz presented the state-of-the-art of Genetic Test group – see slides

AAA Screening: update - K. B. Frønsdal (NOKC)

Katrine B. Frønsdal presented the state-of-the-art of AAA Screening group – see slides

Questions / Comments

After the 2 presentation from the Vice-Chairs, a discussion was made on different topics connected to the work done and the research to be done.

Kristian Lampe highlighted the importance of previous experiences in creating and using the Core Model and the On-line Tool, keeping in mind the "production" of HTA viewpoint.

Regarding the number of AEs and their overlaps, it was reported that for each question there should be only a short answer (i.e. 1 phrase) and a number of these answers will be common among different AE; for overlaps the group has to decide which domain will answer to the question.

Ingrid Wilbacher proposed also to share the work between the 2 groups for some domain (i.e.: SOC, LEG and ETH) as in these domains the experiences from the 2 technologies could be important.

It was the proposed to continue the next phase following a cascading of domain and of Assessement Elements, i.e. some domains will do the work first and the other domain will use that work in a logical sequence of AEs.

Working Group Session: Genetic Test and AAA Screening

During the working group session it was discussed how to manage the overlaps among AEs in the different domain, how to set up a sequential process of answering to the question and who will answer to each AE.

September 16th 2011

Working Group Session

The discussion in the two groups continued also in the second morning.

Conclusion of Working Group sessions

For Genetic Tests for BC Group: it was discussed how to manage the AE overlaps: some overlaps between some domains (mainly TEC, ECO, ORG) were identified and discussed by e-mail in the weeks before the meeting without reaching a clear agreement. As the deadlines were close, it was decided, for this project, to leave all the AEs in their original domains (with few exceptions).

It was then decided to follow the usual working method in HTA report, starting from some domains (CUR and TEC) then move to others; according to this criterion the workflow will develop as following: i) CUR and TEC; ii) SAF and EFF; iii) ORG and ECO; iv) LEG, SOC, and ETH.

It was clarified that the information coming from the first domains will be quickly shared with others, and will serve as bases for the development of the following steps. As the workload has been divided in steps according to a time sequence, the people in the Group agreed to support the domain teams that will start as first. It was also highlighted the importance of sharing information needs between the different domains.

For AAA Screening Group: it was decided to take the list of overlapping AEs and analyse each elements and each overlaps. As it will take a lot of time, it was decide that each PI will discuss with PIs of other domains who should what.

In this process no elements will be deleted, it will be just explained why one element will be assessed by one domain and by another.

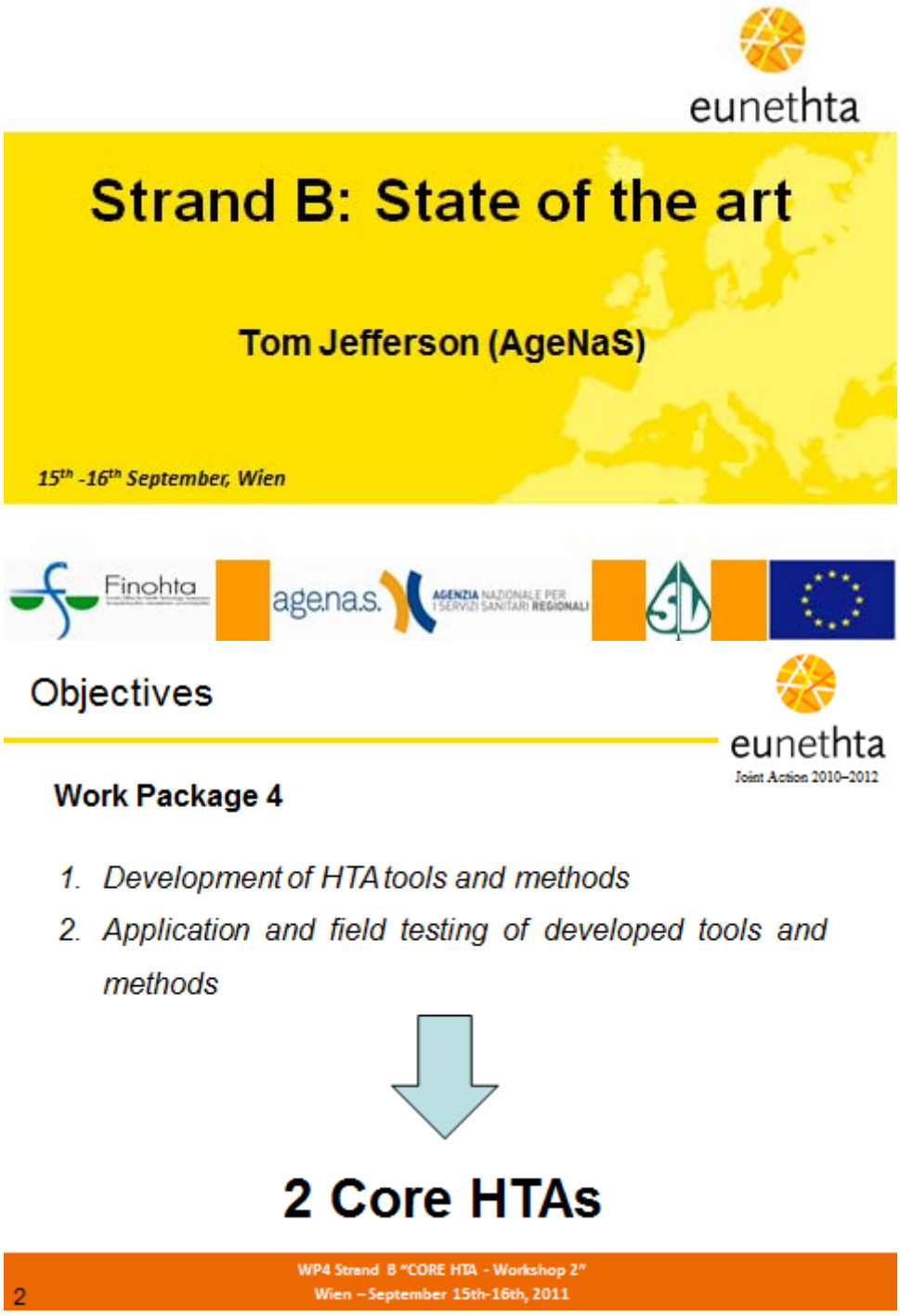
It was also decided that the TEC domain will be the first domain that will answer to questions as the information provided by this domain will be used by other domains.

It will be also decided to try to assign a code to each answer to AEs to identify if the answer will be something more descriptive or something like a value.
Finally it was decided to exclude 3D technologies from the assessment.

Conclusions and Final Remarks

Kristian Lampe briefly resumed the 2 working days and the main issues emerged during the discussions. (please see attached slides).

State of the art – Tom Jefferson



Core HTAs

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Joint Action 2010–2012

Core HTA 1 – Genetic Tests for Breast Cancer

(uPA/PA1 – MammaPrint® – OncotypeDx™)

- ***Collaborative Model 1**: researchers from different agencies contributing to one domain*
- ***8** Primary Investigators / **24** Investigators / **14** Reviewers*

Core HTA 2 – Abdominal Aorta Aneurysm Screening

- ***Collaborative Model 2**: one agency contributing to one domain*
- ***9** Partners with **13** Primary Investigators / **15** Reviewers*

(no commitment comparison possible because of diff models)

WP4 Strand B "CORE HTA - Workshop 2"
Wien – September 15th-16th, 2011
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so far…in 2011

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Joint Action 2010–2012

- **Topic Selection**
- **Domain Teams composition**
- **Editorial Teams** (chair, vice-chair, …)
- **Workshop 1** (Roma)
- **E-meetings** (8, from April to July)
- **Assessment elements selection for each domain**

1st Protocol Draft

(sent to SAG in July, few feedback until now)

WP4 Strand B "CORE HTA - Workshop 2"
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Critical issues

- **Topic Selection** (for Genetic Test only) → **Time consuming**
- **Domain Teams composition**
  Too few Researchers / Reviewers → **Manpower**
- **Assessment Elements Selection**
  Overlaps among domains → **Duplicate work?**
- **Burgeoning jargon**
  EUnetHTA speaks → **Misunderstanding**
- **Searches:** what, who, where and where to → **???**
- **Core HTA reports** → **Structure**

WP4 Strand B "CORE HTA - Workshop 2"
Wien – September 15th-16th, 2011
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Domain Team – Genetic Tests for BC

Primary Investigator	Investigator	Reviewer
CUR (Health Problem and Current use)		
D. Kasier (DIMDI)	T.Gasparetto (Reg. Veneto)	S.Mathis-Endenhofer (LBI-HTA)
	I.Vieira (INFARMED)	E.Ferroni (Agenas)
	S.Baggaley (NICE)	A.Migliore (Agenas)
		A. Llanos-Mendez (AETSA)
		R. Pace Asciak (SSD/MSOC)
		L.Ballini (ASSR-RER)
TEC (Description and technical characteristics of technology)		
A.Migliore (Agenas)	L.Becla (AHTAPol)	B.Corbacho (AETSA)
	M.Orzel (AHTAPol)	M.O'Neill (HIQA)
	F. McCkracken (NICE)	L. Varela Lema (AVALIA-t)
SAF (Safety)		
I.Pasternack (THL)	E.Chiarolla (Agenas)	T.Gasparetto (Reg. Veneto)
	L. Varela Lema (AVALIA-t)	A. Migliore (Agenas)
	N. Sahakyan (UMIT)	P.Schnell-Inderst (UMIT)
		S.Maltoni (ASSR-RER)
		E.Turk (IPH-RS)
EFF (Clinical effectiveness)		
M.Huic (AAZ)	A.Panasiuk (AHTAPol)	P.Giorgi Rossi (Laziosanità)
	K.Sejbuk (AHTAPol)	L.Varela (AVALIA-t)
	P.Schnell-Inderst (UMIT)	L.Vignatelli (ASSR-RER)
	H.Raatz (SNHTA)	M.O'Neill (HIQA)
	G.Jhuti (NICE)	
	E.Turk (IPH-RS)	
ECO (Cost and economic evaluation)		
	J.Saluse (UTA)	M.R.Perrini (Agenas)
	M.Corio (Agenas)	H.Bell (NICE)
	M.Ruggeri (A.Gemelli)	M. Oradei (A.Gemelli)
		M.O'Neill (HIQA)
ETH (Ethical analysis)		
I.Vieira (INFARMED)	D.Sacchini (A.Gemelli)	P.Schnell-Inderst (UMIT)
	P.Refolo, (A.Gemelli)	R. Pace Asciak (SSD/MSOC)
	P.Giorgi Rossi (Laziosanità)	M. Marlow (NICE)
ORG (Organizational aspects)		
J.Butt (NICE)	M.Marchetti (A.Gemelli)	A.Lee (SDU/CAST)
	A.Cicchetti (A.Gemelli)	S.Mathis-Endenhofer (LBI-HTA)
	A.Carletto (A.Gemelli)	P.Giorgi Rossi (Laziosanità)
	C.Filippi (Reg.Veneto)	
SOC (Social aspects)		
M.Marchetti (A.Gemelli)		A. Lo Scalzo (Agenas)
LEG (Legal aspects)		
M.Marchetti (A.Gemelli)	I.Vieira (INFARMED)	

Domain Team – AAA Screening

Institution	Primary Investigators	Reviewers
CUR (Health Problem and Current use)		
LBI - HTA (Austria)	Stefan Mathis-Endenhofer (LBI-HTA)	Raul Kiivet (UTA) Lotte Groth Jensen (Central Denmark) P.Giorgi Rossi (Laziosanità)
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SDU/CAST (Denmark) Central Denmark (Denmark)	Anne Lee Lotte Groth Jensen Claus Loevschall	Felix Gurtner (SNHTA) Alessandra Lo Scalzo (Agenas)
LEG (Legal aspects)		
HVB (Austria)	Ingrid Wilbacher	

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Stakeholder Advisory Group

1st draft submitted (July 15th) **but only 4 responders** (of 14 members)

- **2 "no comment": the documents are OK**

Other Feedbacks:

Genetic test:

1. The model covers to a great extent the assessment elements for the genetic test. Clear and good considerations regarding the merging/omissions of the different elements.
2. The feedback document does not help to give a proper feedback. It should be possible to provide feedback directly in the document.
3. There is an ambiguous approach from the beginning. The title is misleading: this is not about all genetic tests, or genetic test, it is on specific ones.

AAA Screening:

1. The model is clear and effectively presents how a core model for screening works.
2. The feedback document does not help to give a proper feedback. It should be possible to provide feedback directly in the document.

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Genetic Tests on Breast Cancer - domains feedback

Domain	Feedback
CUR	• Concerning the format, it is very difficult to read the description like it is presented in a pack of sentences. It should also be clear of where does this information come from. • Too many questions are too broad (genetic testing) and not focused on the subject.
TEC	• Some concepts used in the question need clarification.
SAF	• Some concepts used in the question need clarification (could it be limited to harm?).
EFF	• Information sources concerning elements examining patient opinion could be complemented with patient satisfaction studies/surveys.
ECO	• Information from companies/manufacturers could be relevant for ECO1/E0001, ECO2/E0002 • Some concepts used in the question need clarification (costs? indirect costs?). • Having outcomes with costs and economic evaluation seems odd.
ETH	• This part is a mix a very different items that do not seem to fit with ethics: rights, (why not only in legal), why legislation (why not only in legal), effectiveness?
ORG	• Some concepts used in the question need clarification (centra/local?).
SOC	
LEG	• Some concepts used in the question need clarification (healthcare tourism? Subsidised by the society?).

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Stakeholder Advisory Group

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AAA Screening - domains feedback

Domain	Feedback
CUR	• The description and the part on use of technology could benefit from some rewording.
TEC	• Some concepts used in the question need clarification.
SAF	• Some concepts used in the question need clarification (could it be limited to harm?).
EFF	
ECO	• Some concepts used in the question need clarification (costs? indirect costs?). • Having outcomes with costs and economic evaluation seems odd.
ETH	• This part is a mix a very different items that do not seem to fit with ethics: rights, (why not only in legal), why legislation (why not only in legal), effectiveness?
ORG	• Some concepts used in the question need clarification (central/local?).
SOC	
LEG	• Some concepts used in the question need clarification (healthcare tourism? Subsidised by the society?).

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Timetable

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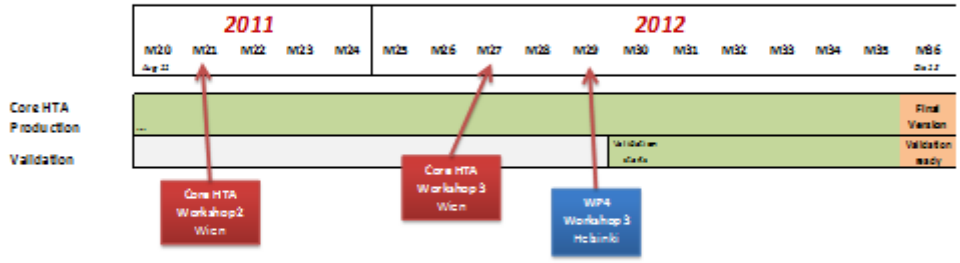

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Timeline Proposal

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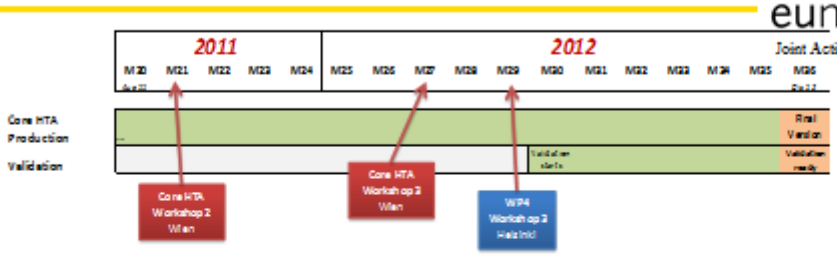

By Workshop 3 (Wien, March 2012)

- Monthly e-meeting for each domain (end of each month) – open to all PIs and Investigators (first e-meeting: ***end of October*** ?)
- General e-meeting (both Teams) – if needed, before end of 2011 and before March 2012
- Single domain e-meeting – if needed, each domain can organize internal e-meeting

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Genetic Tests: update – H. Raatz (SNHTA)

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Progress and problems
Core HTA on prognostic tests in breast cancer

Heike Raatz
15th -16th September, Vienna

SNHTA Swiss Network for Health Technology Assessment

Where we stand

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Scoping/ Protocol:

- Done in all domains

Feedback from 5/9 domains:

- Description and technical characteristics of technology (TEC)
- Clinical effectiveness (EFF)
- Cost and economic evaluation (ECO)
- Ethical analysis (ETH)
- Organizational aspects (ORG)

Scope

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Problems/ Issues encountered

- Project name should be more specific (EFF)
- Detail of information required in scope unclear (EFF)

Protocol I

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Problems/ Issues encountered

- Evaluation of prognostic tests ➔ Frame adjusted for study designs (EFF) ➔ **FP-7**
- Online Tool is not up to date (EFF)
- Criteria for relevance/order of assessment elements are not clear
- Overlapping research questions with other domains/risk of duplicating work (EFF, ECO, ORG, ETH, TEC)

Protocol II

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Inadequate methodology? (ORG)

- Format of systematic review often not adequate in order to answer questions.
- Relevance of assessment elements/domains dependant on answers from other domains
- Identification of organisational issues rather than specific output as results dependant on time and place.

Varia I

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Form of collaboration

- Quality of collaboration varies across domains (ECO,ORG, TEC)
- Role of team/ co-ordinators unclear (TEC)

Technical

- Instruction re locking domains in phase 2 is incorrect (EFF)
- New option „consider later" for assessment elements? (EFF)
- Needed: Possibility to view protocol of all domains for all investigators (EFF, ORG)
- Platform for e-meetings: difficult to use and unreliable (ORG)

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Varia II

- Terminology, concepts and tools need to be learned (ECO,TEC)
- Standardize terminology across domains (EFF)
- Deadlines too short (ECO)
- Work for some domains can only be done when they have the answers from other domains (ETH, ORG)

Varia III

- Decision analytic modeling – is there any methodology developed within EUnetHTA? (EFF)
- *Plan next steps* /literature search (EFF, ECO)
- *Have common methodology (ECO)*

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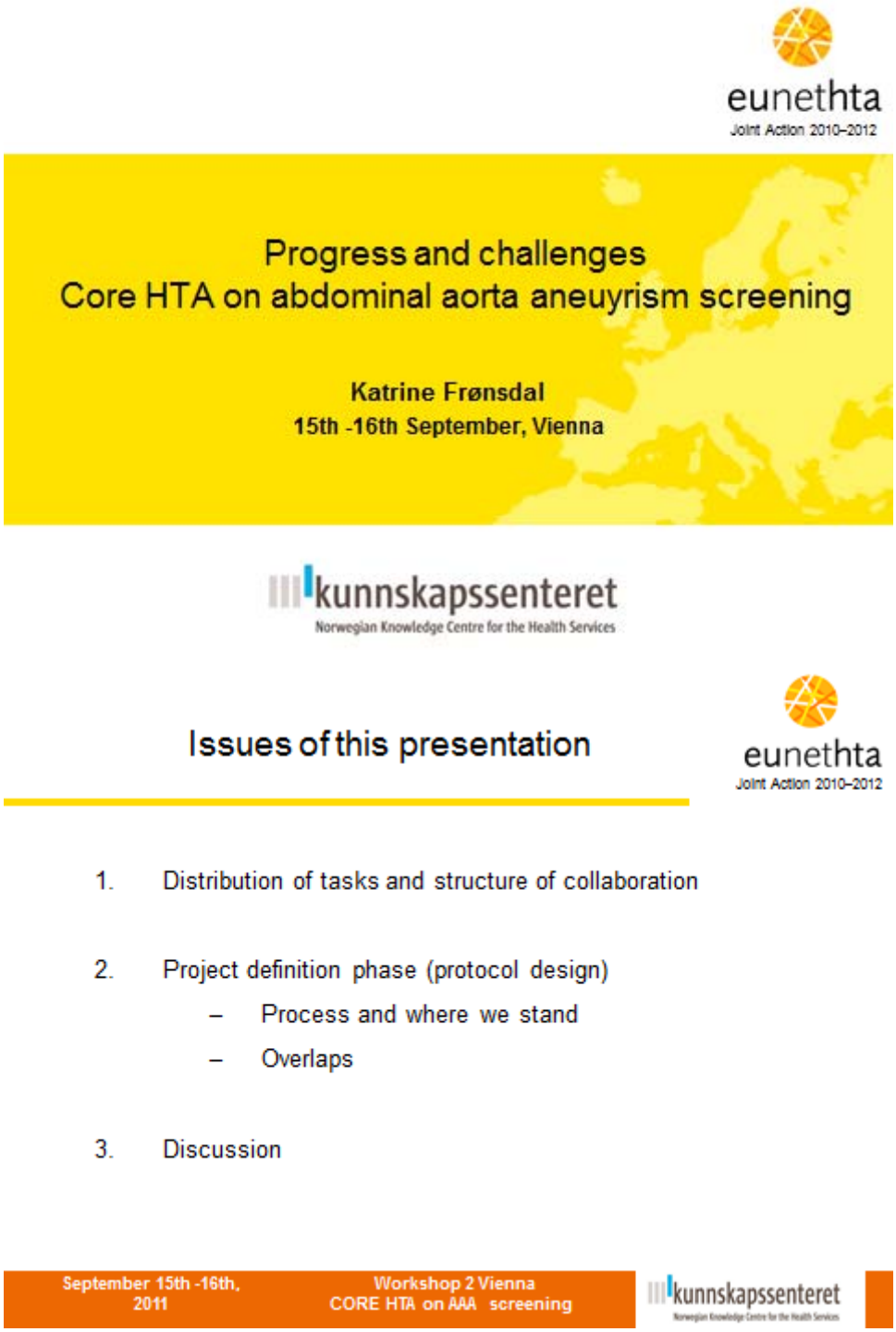
AAA Screening: update - K. B. Frønsdal (NOKC)



Distribution of tasks and collaboration

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Core HTA 2 – Abdominal Aorta Aneurysm Screening

- ***9** Partners with **13** Primary Investigators / **15** Reviewers*
- ***Collaborative Model 2**: one agency contributing to one domain*

Institution	Primary Investigators	Reviewers
CUR (Health Problem and Current use)		
LBI - HTA (Austria)	Stefan Mathis-Endenhofer (LBI-HTA)	Raul Kivet (UTA) Lotte Groth Jensen (Central Denmark) P.Giorgi Rossi (Lazioserntà)
TEC (Description and technical characteristics of technology)		
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EFF (Clinical effectiveness)		
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ECO (Cost and economic evaluation)		
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Project definition (protocol design) I

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FROM…

PICO

- P: men aged from 60 and up
- I and C: two comparisons
  - pop screening vs nothing
  - opportunistic screening vs nothing

(Rome)

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Project definition (protocol design) II

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TO..

Table 1 Project scoping

Technology	Indication	Comparison
Describe the technology detailed enough to distinguish it from relevant other technologies. There is possibly need to restrict to e.g. to the newer device generations only (e.g. studies published year 2000 or later) or certain sub-types (e.g. multi-slice CT with >64 slices). Provide ATC Code and MeSH term if available.	*The technology can be used in multiple indications.* • *Describe the target condition, disease or other health condition. Provide ICD-10 code and MeSH-terms for it.* • *Describe the target population, possible age or sex limitations, all patients or certain subgroups, people at low/moderate/high risk, or healthy individuals? Provide Mesh-terms.* • *Describe the purpose of the use of the technology: preventing, screening, diagnosing, treating, imaging (ruling in or ruling out), treating, or monitoring the condition, or other. Provide MeSH-terms.*	*The technology can be compared to e.g. another specific technology, management pathway without the technology, usual care, not doing anything, placebo intervention, or other. This should be described detailed enough to distinguish it from other relevant comparators. Provide MeSH-terms.*
Population-based Abdominal Aortic Aneurysm Screening. This intervention includes one time invitation for the whole target population to do one ultrasound scan examination. The above described intervention must be taken into account as a base intervention. Variations in that intervention could also be assessed, paying special attention to opportunistic screening strategies.	**Target condition** Abdominal aortic aneurysm **Target population** Men aged from 60 and up **Purpose of use** To detect abdominal aortic aneurysm in a pre-clinical phase in order to treat those aneurysms with high risk of rupture.	Current practice

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Project definition (protocol design) III

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TO:

Project information

Application: HTA Core Model Application for Screening Technologies (draft - work in progress)

Technology description	Population-based systematic abdominal aortic aneurysm (AAA) screening (1) This includes one single invitation for the whole target population to do one ultrasound scan examination. and/or Opportunistic abdominal aortic aneurysm (AAA) screening (2) This includes primarily screening suggested by the general practitioner, but the general practitioner has some guidelines to follow, when selecting people for screening. Purpose of use: Detect abdominal aortic aneurysm in unruptured phase in order to treat those aneurysms with high risk of rupture. Target condition: Abdominal aortic aneurysm (AAA) MeSH: "Mass screening"
Use of technology	For (1): all men and women aged 65 There is some international variance in the prevalence of AAA. In the western countries the prevalence varies between 5 to 10 % for the 65 – 74 years old men. In Japan the prevalence is 1 % for the same group of men. The prevalence increases with age. In England the prevalence is 2 % for men aged 50 – 64 year and 12 % for men aged 80 years or older. In Denmark the prevalence is 4 % for men aged 65 – 69 and 6 % for men aged 70 – 74 years old. The prevalence for women is significant lower than the prevalence for men. For (2): population at risk including smokers, people with ischaemic heart disease, apoplexy, arteriosclerosis, hypertension or COPD A relative in first order to patients with AAA has 2 – 4 times the risk of getting an AAA. Smoking is connected with the risk of having an AAA. The risk is 3 – 6 times higher among smokers than among non smokers. There is a significant comorbidity connnected with AAA. Ischaemic heart diseases, apoplexy, arterio scelroses, hypertension and Chronic Obstructive Pulmonary Disease are frequent among patients with AAA. Information about mortality related to AAA is problematic to interpret because the studies are old and the prevalence and treatment for AAA has changed a lot. The mortality rate varies from 44 men pr 100.000 men a year age 65-69 to 169 men pr. 100.000 med a year age 80+ and there are some variance acros contries.
Comparison	No screening (at all) This includes incidental detection of AAA without age or sex limitation while performing abdominal ultrasound examinations due to other/unclear clinical indications.

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Were we stand: the protocol

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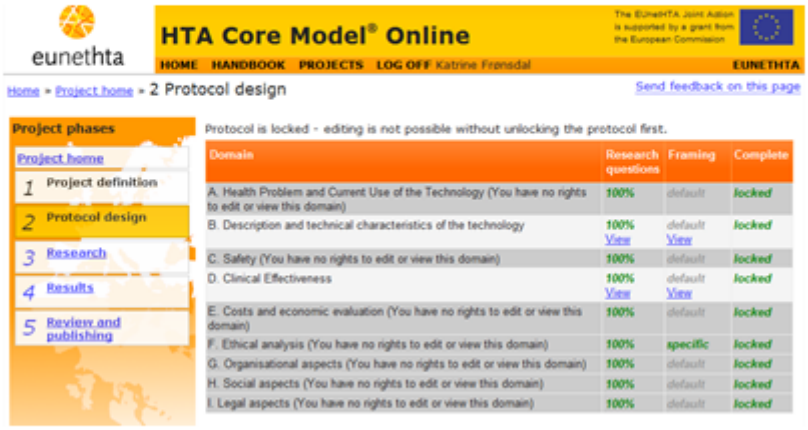

Were we stand: Assessment Elements

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Domain	Questions
Health Problem and Current Use of the Technology	25
Safety	9
Costs and economic evaluation	7
Ethical analysis	10
Organisational aspects	18
Social aspects	11
Legal aspects	6
Clinical Effectiveness	34
Description and technical characteristics of the technology	15

Total: 135 !!!!!!!

Challenge: reduce amount of AEs?

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- Are all AEs initially selected 'still' **really** relevant?
- Are there **overlapping** questions within each domain?
- Are there **overlapping** questions between domains?

E-meeting 25 July 2011

Each domain to check for overlapping questions
and
report back before f-t-f in Vienna

There are potentially many overlapping or at least partly overlapping questions…

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Domain	Questions	Overlaps or partly overlaps
Health Problem and Current Use of the Technology	25	2
Safety	9	9
Costs and economic evaluation	7	4
Ethical analysis	10	9
Organisational aspects	18	8 + merging some AEs?
Social aspects	11	10
Legal aspects	6	-
Clinical Effectiveness	34	18 + merging some Aes?
Description and technical characteristics of the technology	15	15

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Discussion

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- How do we manage overlaps?
- Come to an agreement – how do we proceed?
- The way forward
  - Plan for the research part
  - Schedule
- …

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Proposal

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- Relations between assessment elements across domains by topic should be dealt with by grouping questions, assigning questions on a shared case-by-case basis and allocating sequence (if necessary).
- [forecast answer bullets]

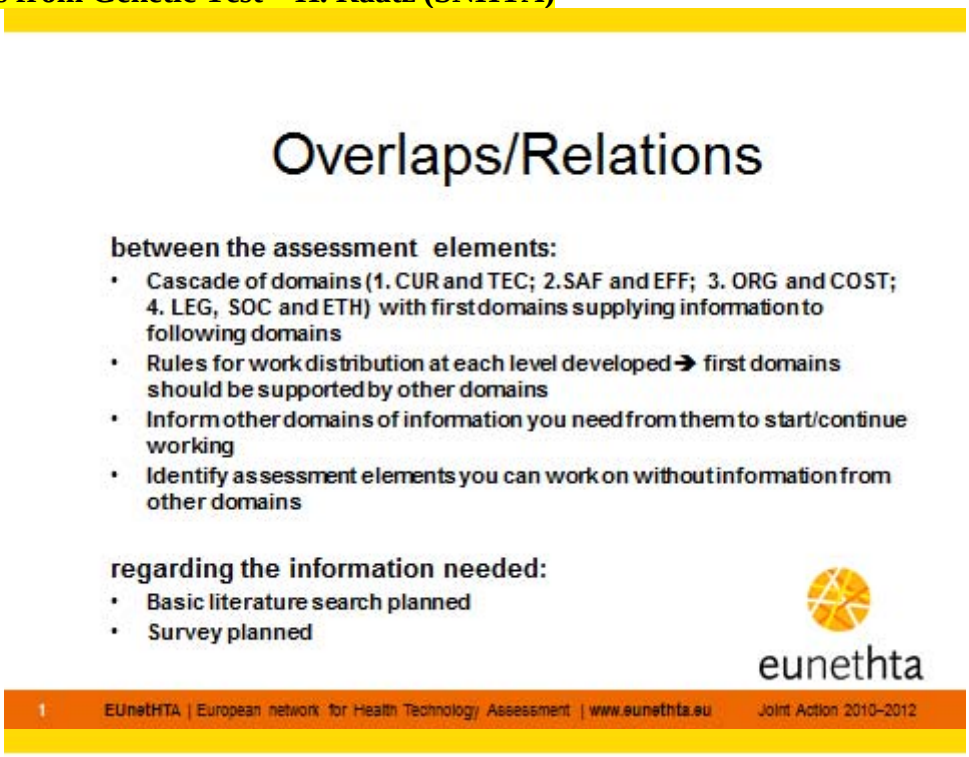
- Does this model of relation defining work for our two topics?

(would this rule allow us to do our work by June 2012 with a tolerable level of overlap).

- Quality of elements (categorization into descriptive and vaue or primary, secondary etc)

SNHTA

Conclusions from Genetic Test – H. Raatz (SNHTA)



Conclusions from AAA Screening – K. B. Frønsdal (NOKC)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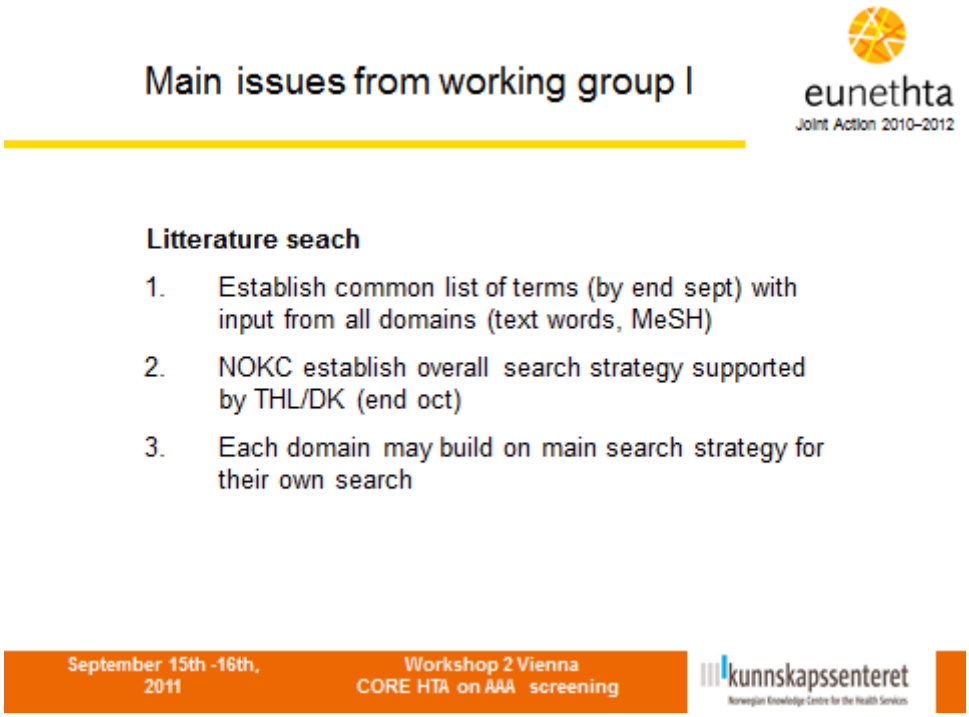
Who does what by when?
Workplan for AAA Screening HTA
WP4 Meeting
15th -16th September, Vienna


Main issues from working group I
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Litterature seach
1. Establish common list of terms (by end sept) with input from all domains (text words, MeSH)
2. NOKC establish overall search strategy supported by THL/DK (end oct)
3. Each domain may build on main search strategy for their own search
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Workshop 2 Vienna
CORE HTA on AAA screening
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Main issues from working group I

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3. Each domain may build on main search strategy for their own search

Main issues from working group II

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Full text articles

1. How do we deal with articles that do not have free access? Property rights?
2. Kristian will ask EUnetHTA secretariat.
3. For now we keep full text art. in one repository accessible everybody

Time schedule I

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1. Overlap/relation management and needs from other domains Rd by early october
2. Deadlines set according to needs of domains SOC ETH (worked backwards)
3. Deadlines are end of....
4. Drafts
   1. First draft includes preliminary results
   2. Second draft includes advanced results
   3. Draft ready for validation
5. We work on the online tool made word documents and make them available to all domains in the MO/site

Time schedule II

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	2011				2012											
	SEP	OCT	NOV	DEC	JAN	FEB	MAR	APR	MAY	JUN	JUL	AUG	SEP	OCT	NOV	DEC
CUR Health problem and current use	search terms	Rd / 1D		2D						1D						
TEC Descriptionand technical characteristics of tecnology	search terms	Rd /1 D		2D						1D						
SAF Safety	add terms	Rd		1D		2D				1D						
EFF Clinical effectiveness	search terms	Rd			1D		2D			1D						
ECO Cost and economic evaluation	search terms	Rd				1D		2D		1D						
ETH Ethical analysis	add terms	Rd	general Frame for screeni ng				1D		2D	1D						
ORG Organizational aspects	add terms	Rd	1D		2D					1D						
SOC Social aspects	add terms	Rd				1D		2D		1D						
LEG Legal aspects	add terms	Rd				1D		2D		1D						
Survey		mid/de finition		answe rs/resu lts												

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Survey

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1. To whom / addressed to EUnetHTA members

2. About
   1. Opportunistic screening
   2. Costs
   3. Guidelines…

3. Goes out end of october
4. Elaborated by CUR TEC supported by ORG and ECO domains

The way ahead

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1. E meeting reporting from each domain early November
2. Ftf meeting in March
3. Ftf meeting in May
4. Write scientific papers (process, per domain)
5. Validation issues
6. Identify relevant stakeholders
   1. Manufacturer
   2. Vascular surgeons…
   3. SAG and Stakeholder forum (before March meeting)

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Final remarks – Kristian Lampe

Final remarks

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- Core HTA projects provide feedback to model applications (screening model, diagnostic model) and OTS
- Model versions 1.0r (2008) -> 1.1 (THL/2009, minor modifications) -> 1.2 (2011, major modifications)
- Relevance of AEs: look only at technology in the specified use (NOT: "we don't have resources", "this is not ethics/effectiveness etc.", "we don't normally look at this") Be pragmatic, European utility

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Wien – September 15th-16th, 2011

Final remarks

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- **From 'overlap' to 'relevance':**
  - Sequential: Is it about time? (I need information from another AE, another AE needs information from my AE)
    If so, be aware of your and others' requirements/needs (qualitative, quantitative info) and prioritize wisely, consider communicating/using preliminary results for drafts and update later.
  - Content similarity: Does my analysis answer the same question as another AE? Is it fully or partially the same answer?
    If same -> coordinate who answers, let the others review and amend it, and let model developers know
    If truly different -> collaborate with the others whenever useful, but keep answers separate.

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Wien – September 15th-16th, 2011

Final remarks

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- **Terminology/jargon**
  - Derives from novelty of concepts AND politics
  - Ultimate goal: use simple terminology, do not alienate users of OTS and information within it
  - But: for now we need to bear with it as developers
- **Identify stakeholders of your core HTA**
- **OTS/protocol design improvements (current/future)**
  - Add clarification into full protocol
  - For each element:
    - **Which elements contain information you are likely to need when answering this one?**
    - **Which elements are likely to depend on this one?**

WP4 Strand B "CORE HTA - Workshop 2"
Wien – September 15th-16th, 2011

Final remarks

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- **OTS - Research phase**
  - Currently very limited, help us to improve
    - **Domain-specific templates for research plan, including methodology**
  - Overall principle: no overlapping work, all information fed into the system is fully utilized (e.g. methodology research plan -> reporting)
  - Current workflow: Use MS Word or any text editor (preferably with "track changes") -> manually copy-paste to online-tool when "ready enough", i.e. only small changes necessary.
  - Workflow in the future: Use standard template (.doc or .rtf) with any text editor. Save in specified format and feed into the system automatically.

WP4 Strand B "CORE HTA - Workshop 2"
Wien – September 15th-16th, 2011

Final remarks

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- **Participants**
  - More reviewers welcome to assist the production (not peer-review of final document)
  - Think the role: member of team or "other contributor" to be acknowledged.
  - Formal of informal agreement between a WP4 member agency and the contributor, not THL/AGENAS

WP4 Strand B "CORE HTA - Workshop 2"
Wien – September 15th-16th, 2011

Final remarks

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- **Quotes from Vienna:**
  - *"Be ambitious!"* T Jefferson on the 16th of September, 2011
  - *"Aim high enough!"* K Lampe on the 15th of September, 2011

WP4 Strand B "CORE HTA - Workshop 2"
Wien – September 15th-16th, 2011

EUnetHTA JA WP4/Strand B Workshop 2
Wien, Austria
September, 15th-16th 2011
Organised by: Agenas and HVB
Address of the meeting venue: Hauptverband der österreichischen Sozialversicherungsträger 1st floor, meeting room 101 & 102

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Participant Signatures

Name	Signature September 15th	Signature September 16th	Organisation	Country
Daniela Pertl			GÖG - Gesundheit Österreich GmbH/	Austria
Sophie Brunner				
Gottfried Endel			HVB - Hauptverband der Österreichischen Sozialversicherungsträger	Austria
Dagmar Bernardis				
Ingrid Wilbacher				
Stefan Mathis-Edenhofer			LBI - Ludwig Boltzmann Institute Health Technology Assessment	Austria
Narine Sahakyan			UMIT - Private Universität für Gesundheitswissenschaften, Medizinische Informatik und Technik GmbH	Austria
Mirjana Huic			AAZ - Agency for Quality and Accreditation in Health Care, Department for Development, Research and Health Technology Assessment	*Croatia*
Lotte Groth Jensen			Central Denmark - Centre fro Public Health (CPH), HTA & Health Services Research	Denmark
Janek Saluse			UTA - Department of Public Health, University of Tartu	Estonia
Iris Pasternak			THL - National Institute for Health and Welfare	Finland
Kristian Lampe				
Suvi Mäklin				
Julia Kreis			IQWiG - Institute for Quality and Efficiency in Health Care	Germany
Michelle O'Neill			HIQA - Health Information and Quality Authority	Ireland

EUnetHTA JA WP4/Strand B Workshop 2
Wien, Austria
September, 15th-16th 2011

Organised by: Agenas and HVB
Address of the meeting venue: Hauptverband der österreichischen Sozialversicherungsträger 1st floor, meeting room 101 & 102

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Teresa Gasparetto			Regione del Veneto	Italy
Antonio Migliore			AgeNaS - Agenzia Nazionale per i Servizi Sanitari Regionali	Italy
Marina Cerbo				
Mirella Corio				
Tom Jefferson				
Nicola Vicari				
Angelica Carletto			A. Gemelli - University Hospital "A.Gemelli"	Italy
Marco Marchetti				
Katrine Frønsdal			NOKC - Norwegian Knowledge Center for the Health Services	Norway
Ingvil Sæterdal				
Anna Panasiuk			AHTAPol - Agency for Health Technology Assessment in Poland	Poland
Isaura Vieira			INFARMED - National Authority of Medicines and Health Products	Portugal
Iñaki Imaz			ISCIII-AETS - Instituto De Salud Carlos III	Spain
Heike Raatz			SNHTA - Swiss Network for HTA	Switzerland
Jennifer Butt			NICE - National Institute for Health and Clinical Excellence	United Kingdom
Nick Crabb				
EVA TURK			NIPH	Slovenia
Anne Lee			CAST	Denmark

WP4

Appendix 5

Minutes of WP4 meeting in March 2012

EUnetHTA JA WP4 Strand B / Core HTA Workshop 3
Date: ***2012, 29th-30th March***

Organised by *AgeNaS (Italy) and LBI-HTA (Austria)*

WP4/B Meeting "Core HTA – Workshop 3", 29th March

Chairs: M. Cerbo (AGENAS) K. Lampe (THL)

Participants:
Daniela Pertl (GÖG, Austria), Gottfried Endel (HVB, Austria), Ingrid Wilbacher (HVB, Austria), Stefan Mathis-Edenhofer (LBI, Austria), Claudia Wild (LBI, Austria), Judit Erdos (LBI, Austria), Narine Sahakyan (UMIT, Austria), Petra Schnell-Inderst (UMIT, Austria), Anders Lamark Tysse (DG Sanco, Belgium), Anne Lee (SDU/CAST, Denmark), Kristi Liiv (UTA, Estonia), Kristian Lampe (THL, Finland), Angelica Carletto (A. Gemelli, Italy), Marco Marchetti (A. Gemelli, Italy), Mirella Corio (Agenas, Italy), Maria Rosaria Perrini (Agenas, Italy), Tom Jefferson (AgeNaS, Italy), Antonio Migliore (Agenas, Italy), Nicola Vicari (AgeNaS, Italy), Luciana Ballini (ASSR-RER, Italy), Katrine B. Frønsdal (NOKC, Norway), Lidia Becla (AHTAPol, Poland), Isaura Vieira (INFARMED, Portugal), Marjetka Jelenc (IPH-RS, Slovenia), Iñaki Imaz (ISCIII-AETS, Spain), Heike Raatz (SNHTA, Switzerland), Jennifer Butt (NICE, United Kingdom), Nick Crabb (NICE, United Kingdom).

Apologies:
Suvi Mäklin (THL, Finland), Valentina Prevolnik Rupel (IER, Slovenia)

March 29th 2012

Welcome and introduction of participants – S. Mathis	10.00 - 10.15
Introduction: update on Work Package 4 – K. Lampe (THL)	10.15 - 10.45
Strand B: history and future – T. Jefferson (AgeNaS)	10.45 – 11.15
Genetic Test: update on progress, issues and challenges – H. Raatz (SNHTA)	11.30 – 12.00
AAA Screening: update on progress, issues and challenges – K. B. Frønsdal (NOKC)	12.00 – 12.30
Discussion both working groups	12.30 – 13.00
Working Group Session: Genetic Test and AAA Screening	14.00 – 17.00
1st day remarks – T. Jefferson (AgeNaS)	17.00 – 17.30

March 30th 2012

Working Group Session	09.00 – 10.30
Next steps: validation phase – K. Lampe (THL)	10.45 – 11.30
Discussion on the validation phase	11.30 – 12.30
Working Group Session: Genetic Test and AAA Screening	13.30 – 14.30
Conclusions and final remarks – K. Lampe (THL), T. Jefferson (AgeNaS)	14.30 – 15.00

March 29th 2012

Welcome and introduction of participants
Claudia Wild and Stefan Mathis-Edenhofer from LBI-HTA welcomed the participants of the meeting, giving basic informations on the venue and on the organization of the meeting.

Introduction: update on Work Package 4 – Kristian Lampe
Kristian Lampe (THL) made a brief update on the Work Package 4 addressing the various aspects and issues of the work done such as:

- New version and functionalities of the On-line Tools and Service (OTS);
- Proposal for policies for OTS;
- Updating of Screening Model;
- Validation of Core HTAs;
- New key developments of HTA Core Model;
- Scoping, framing and results in Core HTAs and On-line Tools and Service;

For additional details, please see the slides from Kristian Lampe's presentation.

Questions / Comments
Luciana Ballini (ASSR-RER) raised the issue of the distinction between dissemination and information gathered in the HTA Core Structure; Kristian Lampe highlighted the importance of the difference between local information and EUnetHTA/Core HTA information.
Nick Crabb (NICE) asked for clarification on quality assurance of Core HTAs information and Result Cards (RC); Kristian Lampe explained that a peer review system will be set-up with an Editorial Board that will review the Core HTAs and Result Cards;
Claudia Wild (LBI-HTA) asked information on Intellectual Property Rights (IPR); Kristian Lampe explained that the author of each RC has to agree on its use in other collections but every RC will be clearly related to its author. Luciana Ballini asked to clearly indicate in each RC if it refers to a Core HTA or to a Rapid HTA.
Katrine Frønsdal (NOKC) raised the issue of the policies for updating the Result Cards; Kristian Lampe explained that will be defined a period during which only the author of a RC or a collection can change/updated it; in this period if another researcher/group would like to start a similar collection, he will be connected to the first author. EUnetHTA will try to identify common topics and needs and information to be updated.
Jennifer Butt (NICE) asked information on the differences in Core HTA and Rapid HTA; Kristian Lampe explained that it has to be decided yet; methodology will be different but the structure will be probably the same; anyhow a RC created for Rapid HTA is not necessarily similar than one created for a core HTA, but a core HTA research group may decide on case-by-case basis whether a card originally created for a rapid HTA can be used in their current core HTA.

Strand B: history and future – T. Jefferson (AgeNaS)
Tom Jefferson made an update on the activities of WP4 Stand B focusing on the results of EFF Domain of Core HTA 1 (Genetic Tests for Breast Cancer) as these results can affect the future development and organization of Core HTAs.
In his presentation, Tom Jefferson made also some proposals on the future of EUnetHTA diagnostic and prognostic evidence synthesis.
For further details, please see the attached slides from Tom Jefferson's presentation.

Questions / Comments

Nick Crabb (NICE) highlighted the importance of using also the low level of evidence and of the involvement of experts in the research phase of Core HTAs.

Luciana Ballini (ASSR-RER) said that it will be difficult to use modeling in the Core HTAs.

Kristian Lampe (THL) proposed not to stop the domains work in Core HTA 1 due the EFF domain results (absence of evidences on the tests); the Core HTAs scheduled in this Joint Action are a test and final results has to be still developed. We need input from all domains to make a decent demonstrator project.

The discussion continued on the various issues emerged after the Core HTA 1 EFF domain work.

Genetic Test: update on progress, issues and challenges – H. Raatz (SNHTA)

Heike Raatz, as Vice Chair of Core HTA 1, presented the state-of-the-art of Genetic Test group – see slides for more details.

Jennifer Butt presented the results of the survey sent to EUnetHTA agencies (one for each country) on the use of Genetic Tests for breast cancer. She focused on the few results and asked to participants their availability to answer to the surveys or to find an expert that can answer to them.

Questions / Comments

The discussion on Core HTA 1 focused on the general lack of active researchers in some domain and of reviewers. It was also highlighted that in some agency there is a lack of internal resources that can work on EUnetHTA; moreover there is a general difficulty in substitution of researchers that, temporarily or definitely, changed job. This issue was also connected to lack of budget for this WP.

Kristian Lampe said that the budget for WP4 was made taking into account what emerged during the previous project (EUnetHTA 2006-2008). Hence the lack of resources should not be dependent on the actual total funds, but rather on division between agencies and their staff situation.

AAA Screening: update - K. B. Frønsdal (NOKC)

Katrine Frønsdal, as Vice-Chair of Core HTA 2, presented the state-of-the-art of AAA Screening group – see slides for more details

Questions / Comments

Jennifer Butt introduced the discussion on differences between Collaborative Models; Kristian Lampe said that in his opinion the Collaborative Model 2 (one agency develop one domain) seems to work better with the scarcity of resources but Collaborative Model 1 (different researchers from different agencies develop) should have a more complete look on the topic assessed.

Kristian Lampe raised the question on the start of validation phase: it is scheduled in June 2012; Anders Lamark Tysse (DG Sanco) explained that the European Commission knows that during a project there could be issues or problems so that some internal deadlines can be changed, remaining with a final end of the project for the end of 2012. On this topic, Kristian Lampe suggested that changing the start of the validation phase involve the risk of having too few time for the validation itself and hence we should not change it

Working Group Session: Genetic Test and AAA Screening

During the working group session, each group discussed on the state-of-the-art and on the work to be done.

Genetic Tests for Breast Cancer

The discussion within the group addressed the following topics:

- Time of publication of the report
- Integration of information from other domains
- Report of EFF domain results: after a long discussion, it was decided to prepare a rough description of procedures/aspects of evaluation in case clinical effectiveness data become available. Tom Jefferson will prepare a brief summary (1 page) of the 23 studies assessed while the complete work will be published in the on-line tool with comments.

AAA Screening Group.

After a short discussion on the scope and framing of the project, it was decided to:

- Change the Technology Description as follows:
  Population-based systematic abdominal aortic aneurysm (AAA)screening. This includes one single invitation for the whole target population to do one ultrasound scan examination .Purpose of use: Detect abdominal aortic aneurysm in the pre-rupture phase in order to treat those aneurysms with high risk of rupture. Target condition: Abdominal aortic aneurysm (AAA) MeSH: "Mass screening"
- Changing the Comparison text as follows:
  No population-based AAA screening (at all) This includes incidental detection of AAA without age or sex limitation while performing abdominal ultrasound examinations due to other/unclear clinical indications and various opportunistic AAA-screening practices
- Include in the study all people from 64 years old, as large trials included in high quality SRs have age 64 and up; so the protocol. Text will be changed as follows:
  All men and women aged 64 or more. There is some international variance in the prevalence of AAA. In the western countries the prevalence varies between 5 to 10 % for the 65 – 74 years old men. In Japan the prevalence is 1 % for the same group of men. The prevalence increases with age.
- The project scope is built up as TICO (Technology-Intervention-Comparator-Outcomes). But it should be emphasized that the outcomes are defined primarily within the different domains.

A round table followed during which each domain made an update of the work done; in details the main topics addressed and the solution agreed was as follows:

- More interaction between domains
- Find out what is the critical information other domains need and prioritize these AEs
- Timing of reviewer involvement
- Missing reviewer in LEG domain
- possibility of widening domain and/or AE frame (ORG domain: very little info, so maybe widen to include other screenings/examples from UK ?)
- legal aspects: any issues encountered in other domains to be communicated to LEG
- how to judge an AE transferable? No guidance available
- from now on until June we will have E-meeting every 2,5 weeks (organized by Agenas)
- Stefan Mathis will leave LBI-HTA in April; Agenas will approach LBI-HTA for replacement in order to have a CUR domain finished
- deadline for finishing work on each domain is 20 of June - after that date starts the work for the editorial teams to edit and write summary and introduction
- the survey on AAA Screening will be sent put to PIs for other answers

- It was decided to prepare a report on the surveys on AAA Screening that will be added as appendix to the final report (Core HTA 2); Agenas will coordinate the production of this report involving partners that developed the surveys.

[Post meeting point: Sarah Baggaley from NICE agreed to act as CUR domain PI.

1st Day Remarks – Tom Jefferson

As the discussion was fruitful and useful it was decided to continue the separate working group session until the end of the day.

March 30th 2012

Working Group Session

Heike Raatz and Katrine Fronsdal, as Vice-Chairs of the two Editorial Teams, made a quick recap of the situation of the two groups and how the working group session of the 1st day went. For further details see the attached slides.

The discussion followed the topics and issues highlighted during the remarks of the 1st day; in details:

- It was decided that the final deadline for the Domains of the two core HTAs will be June 20th; after that date, each change must be communicated to others PIs with a description of the changes and the motivations.
- It was agreed to think on a new system to have better surveys (with a better involvement of EUnetHTA agencies and external experts)
- It was proposed to have a survey for identify experts in the topics under assessment

Next steps: validation phase – K. Lampe (THL)

Kristian Lampe introduced the Validation phase which is scheduled for June 2012.
In the forthocoming months (from Aprile to June) THL and Agenas will develop the Validation Plan, based on the previous experiences.
For further details on Validation phase, please see the attached slides.

Conclusions and Final Remarks

Kristian Lampe briefly resumed the 2 working days and the main issues which emerged from the discussions.

EUnetHTA JA WP4/Strand B Workshop 3
Wien, Austria
March, 29th-30th 2012
Organised by: LBI-HTA / AgeNaS
Address of the meeting venue: EDU4You Seminar Centre (Frankgasse 4/Garnisongasse 8) / LBI-HTA (Garnisongasse 7)

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29/3 30/3

Participant Signatures

Name	Signature September 15th	Signature September 16th	Organisation	Country
Daniela Pertl			GÖG - Gesundheit Österreich GmbH/	Austria
Gottfried Endel			HVB - Hauptverband der Österreichischen Sozialversicherungsträger	Austria
Ingrid Wilbacher				
Stefan Mathis-Edenhofer			LBI - Ludwig Boltzmann Institute Health Technology Assessment	Austria
Narine Sahakyan			UMIT	Austria
Petra Schnell-Inderst			UMIT - Private Universität für Gesundheitswissenschaften, Medizinische Informatik und Technik GmbH	Austria
Anders Lamark Tysse			DGSanco	Belgium
Anne Lee			SDU / CAST	Denmark
Kristi Liiv			UTA - Department of Public Health, University of Tartu	Estonia
Kristian Lampe			THL - National Institute for Health and Welfare	Finland
Suvi Mäklin				
Angelica Carletto			A. Gemelli - University Hospital "A.Gemelli"	Italy
Marco Marchetti				
Antonio Migliore			AgeNaS - Agenzia Nazionale per i Servizi Sanitari Regionali	Italy
Marina Cerbo				
Mirella Corio				

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Tom Jefferson				
Maria Rosaria Perrini			AgeNaS - Agenzia Nazionale per i Servizi Sanitari Regionali	Italy
Nicola Vicari				
Luciana Ballini			ASSR-RER	Italy
Katrine Frønsdal			NOKC - Norwegian Knowledge Center for the Health Services	Norway
Lidia Becla			AHTAPol - Agency for Health Technology Assessment in Poland	Poland
Isaura Vieira			INFARMED - National Authority of Medicines and Health Products	Portugal
Valentina Prevolnik Rupel			IER	Slovenia
Marjetka Jelenc			NIPH	Slovenia
Iñaki Imaz			ISCIII-AETS - Instituto De Salud Carlos III	Spain
Heike Raatz			SNHTA - Swiss Network for HTA	Switzerland
Jennifer Butt			NICE - National Institute for Health and Clinical Excellence	United Kingdom
Nick Crabb				
CLAUDIA WILD			LBI-HTA	Austria
JUDIT ERDŐS			LBI-HTA	Austria

WP4

Appendix 6

Minutes of WP4 meeting in June 2012

EUnetHTA Joint Action

Work package 4

Minutes of

WP4 Workshop 3

June 4-5, 2012
Conference Hotel Rantapuisto, Helsinki, Finland

Organized by
The Finnish Office for Health Technology assessment
within the National Institute for Health and Welfare (FINOHTA/THL, Finland)
in collaboration with the Agency for Regional Healthcare (Age.na.s, Italy)

Chairs: Kristian Lampe, Nicola Vicari, Tom Jefferson

Contents

Participants

Name	**Organisation**	**Country**
Brunner-Ziegler, Sophie	Gesundheit Österreich GmbH	Austria
Endel, Gottfried	HVB	Austria
Schnell-Inderst, Petra	UMIT	Austria
Cleemput, Irina	KCE	Belgium
Huic, Mirjana	AAZ	Croatia
Lee, Anne	CAST University of Southern Denmark	Denmark
Groth Jensen, Lotte	CFK - Central Region Denmark	Denmark
Liiv, Kristi	UTA	Estonia
Autti-Rämö, Ilona	KELA	Finland
Akiola, Linda	THL	Finland
Haula, Taru	THL	Finland
Lampe, Kristian	THL	Finland
Leipälä, Jaana	THL	Finland
Raustia, Leena	THL	Finland
Saalasti-Koskinen, Ulla	THL	Finland
Saarekas, Oskari	THL	Finland
Sihvo, Sinikka	THL	Finland
Sauerland, Stefan	IQWiG	Germany
Harrington, Patricia	HIQA	Ireland
Gillespie, Francesca	Agenas	Italy
Jefferson, Tom	Agenas	Italy
Migliore, Antonio	Agenas	Italy
Vicari, Nicola	Agenas	Italy
Ballini, Luciana	ASSR RER	Italy
Kleijnen, Sarah	CVZ	Netherlands
Sæterdal, Ingvil	NOKC	Norway
Becla, Lidia	AHTAPol	Poland
Vieira, Isaura	INFARMED	Portugal
Prevolnik Rupel, Valentina	Institute for Economic Research	Slovenia
Jelenc, Marjetka	National Institute of Public Health	Slovenia
Imaz, Iñaki	AETS-ISCIII	Spain
Rosen, Måns	SBU	Sweden
Werkö, Sophie	SBU	Sweden
Raatz, Heike	SNHTA	Switzerland
Crabb, Nick	NICE	UK

Agenda

June 4th, Monday
Meeting room: 1-2, ground floor

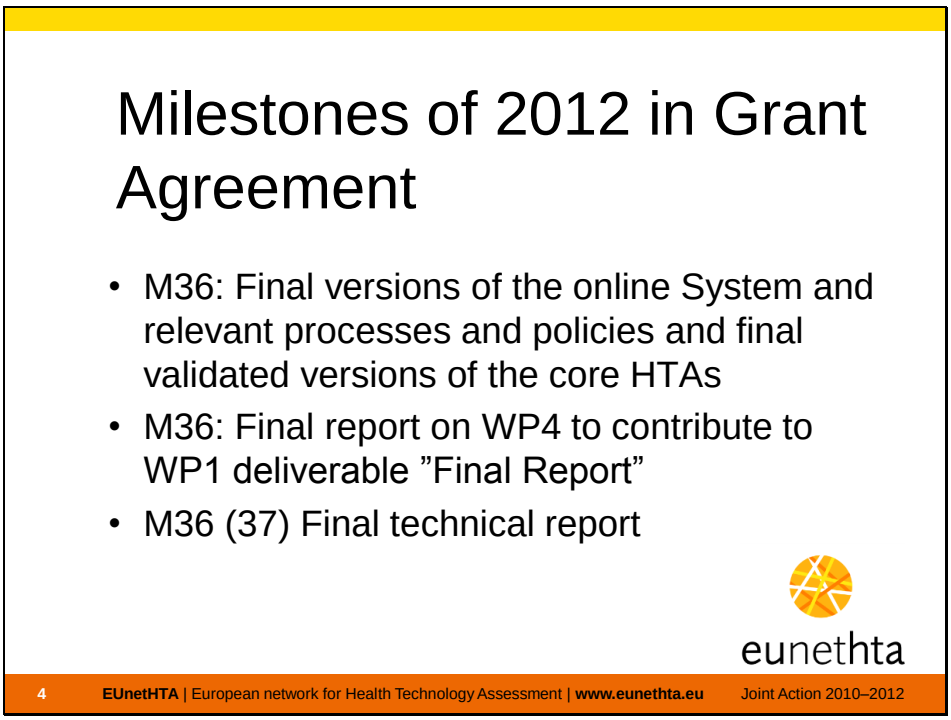
Lunch *Main Dining Hall*	*12:30 – 13:30*
Welcome and practical information	13:30 – 13:45
Timeline for the remaining 2012: what, when and by whom? (both strands)	13:45 – 14:15
Validation of WP4 deliverables (both strands)	14:15 – 15:00
Advanced functionalities of the Online tool and service (strand A)	15:00 – 15:30
Coffee break	*15:30 – 16:00*
Group discussions Meeting rooms: 1-2, 9 & 15	16:00 – 17:15
Sauna for women Sauna at the Seashore	17:30 - 19:00
Sauna for men Sauna at the Seashore	19:00 – 20:30
Dinner at the hotel Banquet Hall	20:30 —

June 5th, Tuesday
Meeting room: 1-2, ground floor

Introduction to the tasks of the day	9:00 – 9:30
Group discussions Meeting rooms: 1-2, 9 & 15	9:30 – 11:30
Lunch *Main Dining Hall*	*11:30 – 12:30*
Results from group discussions	12:30 – 13:30
Coffee break	*13:30 – 13:45*

Timeline for the remaining 2012: what, when and by whom?

Due to a technical problem, part of the slides intended for the first day were available only on the second day. Here they are all, however, listed in their original order.



Specific activities of 2012 in Grant Agreement

- Core HTA production (B)
- Advanced functionality and final refinement & testing of the OTS (A)
- Public consultation (incl. Stakeholders) on the OTS and relevant policies (A)
- Final versions of the policies and results of the analyses performed (A/B)
- Validation and/or peer-review of WP deliverables (including online surveys)
- Scientific articles (A and B)

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In more detail…

What?	Start	By when?	Primary responsibility?
CORE HTAs			
Drafts from domain teams ready	Now	Jun 20	PIs + Agenas
Final adjustments to domain texts	Jun 21	Jun 30	PIs + Agenas
General texts for core HTAs (e.g. Summary, Introduction)		Jun 20	PIs + Agenas
Enter materials into OTS	Jun 21	Jun 30 (Jul 3!)	PIs (domain) + Agenas (general) + THL (technical support)
Publish core HTAs in OTS	Jun 18	Jul 5	THL (tech) + Agenas (check + ok)
Convert core HTAs into coherent PDF	Jul 5	Jul 10 ?	Agenas?
Final adjustments by domain teams (post validation)	Oct 19	Nov 19	PIs + Agenas
Final adjustments and approval by editorial team	Nov 19	Dec 14	PIs + Agenas
VALIDATION			
Validation surveys ready	Now	Jun 25	THL + Agenas
Convert validation surveys into online format	Jun 25	Jul 10 ?	THL + Agenas
Send validation surveys		Jul 10 ?	THL + Agenas
Public feedback start		Jul 10 / End of Aug?	THL + Agenas
Validation responses deadline		Sep 28	THL + Agenas
Analysis of results + communication to core HTAs	Sep 28	Oct 19	THL + Agenas
Feedback to feedback (particularly SAG)	Oct 19	Dec 14	THL + Agenas

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In more detail…

What?	Start	By when?	Primary responsibility?
POLICIES			
Feedback from agencies to proposed policy set		Jun 6	THL
ExCom		Jun 13	THL
Refinement and consultations	Jun 13	Aug 31	THL
ExCom		Sep	THL
Public consultation + SAG consultation	Sep/Oct	End of Oct	THL
Final version to ExCom		Nov	THL
Updated version of Terms of Use		Nov	THL
OTS			
Advanced functionalities	Now	Oct 12	THL
Piloting of advanced functionalities	Oct 12	Nov 9	THL
Final adjustments	Nov 9	Dec 14	THL
Final version of Concept paper		Dec 14	THL
Handbook		Dec 14	THL
Quick Reference Guide		Dec 14	THL
Leaflet		Dec 14	THL

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Validation of WP4 deliverables

Basic starting points

- Defined in Grant Agreement *"…validated for local and European utility."*
- Use of similar methods as in project 2006-2008 to enable comparisons (quantitative data)
- Identification and analysis of personal experience in addition to quantitative data
- Target has several features: difficult to consider best methodology
- Pragmatic approach: validity in the real setting for which each deliverable is meant for, e.g.:
  - Core HTAs: producers of local reports
  - OTS: producers of local reports and producers of core HTA information
  - Screening model: producers of core HTA information
  - Policies: EUnetHTA agencies and stakeholders (?)

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Method

- Five surveys
  1. OTS + Screening Model (EUnetHTA organizations as core HTA information producers)
  2. Core HTAs + OTS (EUnetHTA organizations as producers of local reports)
  3. Core HTAs + OTS + ColMods (Members of domain teams as core HTA producers)
  4. = 1 + 2 in less detailed format (SAG)
  5. = 4 except OTS (General public)
- Analysis with comparison to previous project
- Challenges:
  - Impact of ColMod and individuals on deliverables and vice versa?
  - Now OTS, in 2006-2008 only paper/PDF

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Survey 3:
Those who were involved in core HTA production

Focus:

Experience in using the Screening Model and the Online Tool and Service, collaborative models and final products.

Information?

The producers themselves were content with the tools and processes they used and with the final end products

Structure of the questionnaire

Part A:

Experience in using the Screening Model, the Online Tool and Service, as well as the collaborative models and final products.

Part B:

Qualitative analysis of data and experience acquired within the process

[Further feedback is sought also through a semi-structured interview based on a questionnaire relative to gray information. ???]

Who is expected to respond?

All those who were involved in core HTA production (PI, I, Editorial Team and ?...)

Strongly agree/disagree /cannot say

Reasons for agreeing/disagreeing (important to fill out!)

Part A
Online Tool & Service

- supported definition and the answering of the research questions.
- process of answering the questions and entering the information
- overall experience of using the online tool

Collaborative model

- Overall experience
- Identify points of weakness and strength of the chosen model
- Other influencing factors
- Problems do to the chosen model
- Methodology for choosing the collaboration models
- Organizational set up

HTA Core Model

- feasible and useful tool to improve the contents and format of health technology assessments
- benefits clearly outnumber the particular difficulties
- the problems can be resolved ?and how?

PART B:
Qualitative……WHY? HOW?

- content with the overall experience acquired within the process
- process of decision making at all steps well managed.
- content with the experience gained in the topic selection and prioritization process.
- I was content with the experience gained in the production of the core HTA

In the discussion it was emphasized that there are many people involved with different roles. Agencies should check their roles to avoid that an agency validates its own work.

It was suggested that the domains could be divided into three groups and agencies would be asked to validate one domain from each group. This to avoid too many validations for the more common or familiar domains (e.g. effectiveness).

Some key slides

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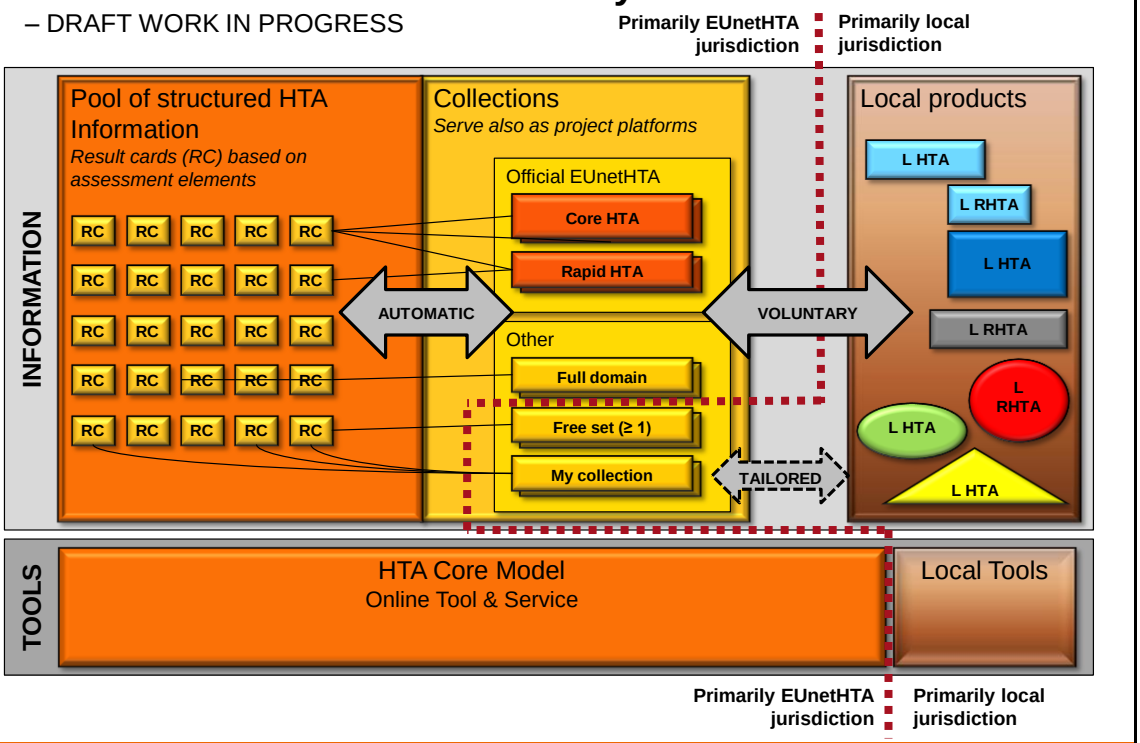
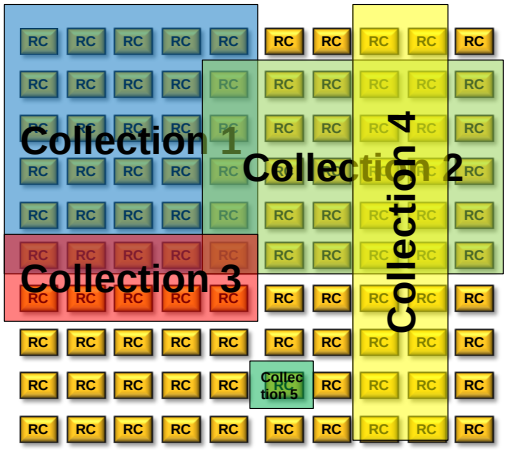
Core HTA Structure 2012 and beyond?

– DRAFT WORK IN PROGRESS



Result cards and collections



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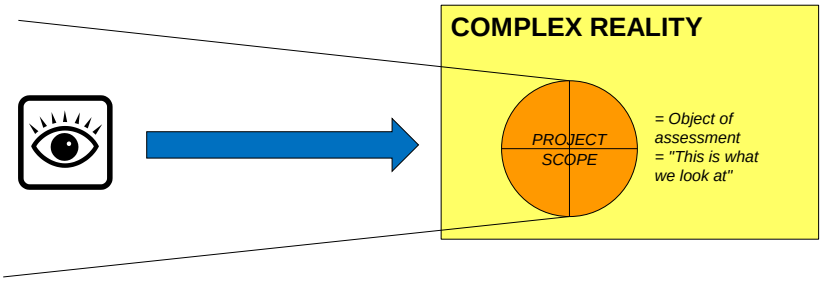
Scoping of Core HTAs

- Common scope for the whole project



- Extent of analysis may differ between domains through domain framing
- This page subject to further changes (more detailed info will be gathered to assist in further phases)

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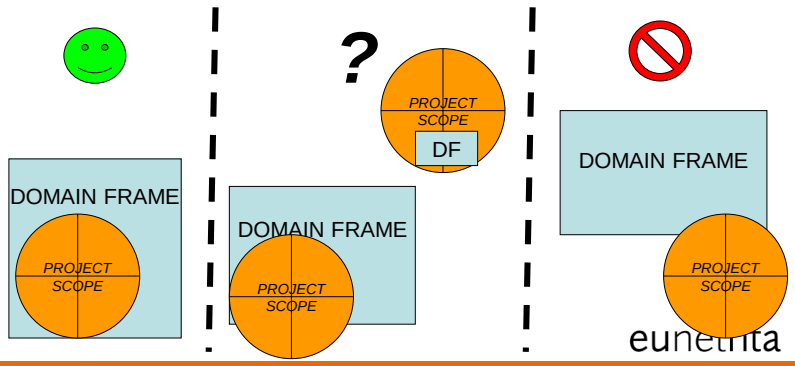
Domain framing

- Project scoping as default for each domain
- Can be changed for any domain as domain framing
- Domain scope must fit into domain framing



Entering results in the OTS (= Phase 4)

- Collection-level information
  - Whole collection
    - Introduction
    - Methodology ???
    - Summary of findings
- Domain-level information
    - Introduction
    - Methodology
    - Discussion
    - References
    - Appendices
    - Assessment element table (automatic)
- Individual assessment elements
  - Methods (modified or unmodified version of the domain methodology)
  - Result = Answer to the question (1-2 pages)
  - Comment (optional)

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Group discussions

Groups

- Three groups (core HTA 1&2, others)
- Discussion topics
  - 1. Validation plans & processes (45 minutes)
  - 2. Advanced functionalities of the Online Tool and Service - practical needs of information search and retrieval & adaptation of information (45 minutes)
  - 3. What have we learnt within Joint Act 1 and how can be make the best of WP4, WP5 and WP8 in JA2? (1 hour)
    Examples of subtopics:
    a) How should the the HTA Core Model ontology be further developed?
    b) Core HTA process from the viewpoint of using the HTA Core Model
    c) Core HTA process from the viewpoint of working together in international collaboration (including pros and cons of the two collaborative models)
  - 4A. Finalizing the Core HTAs (45 minutes only for groups 1 and 2)
  - 4B. Integration of HTA Core Model into the overall EUnetHTA Collaboration, e.g. aims, tools, business model, etc. (45 minutes only for group 3).

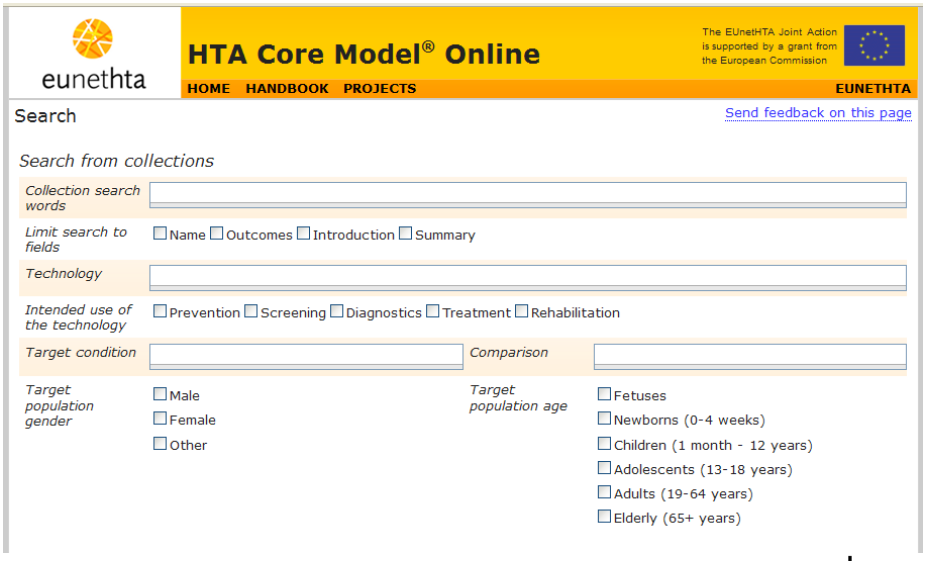
    Anything else?

Advanced functionalities of the Online tool and service

Online tool development 2012

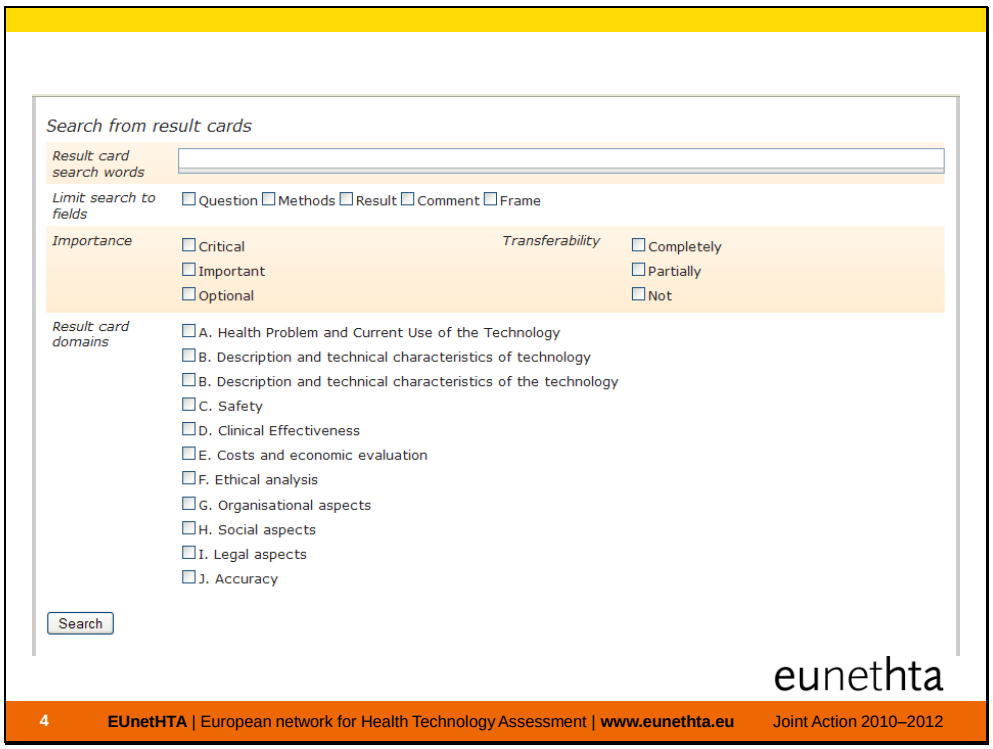
- **Phase 4: entering results (appendices)**
- **Phase 5: viewing results (+browsing)**
- **Improved user interface**
- **Advanced functionalities: search**

eunethta



eunethta


Search from domains
Domain search words
Limit search to fields
Intro Summary Methods Discussion Appendices
Domains
A. Health Problem and Current Use of the Technology
B. Description and technical characteristics of technology
B. Description and technical characteristics of the technology
C. Safety
D. Clinical Effectiveness
E. Costs and economic evaluation
F. Ethical analysis
G. Organisational aspects
H. Social aspects
I. Legal aspects
J. Accuracy
eunethta
3
EUnetHTA | European network for Health Technology Assessment | www.eunethta.eu
Joint Action 2010–2012


Search from result cards
Result card search words
Limit search to fields
Question Methods Result Comment Frame
Importance
Critical
Important
Optional
Transferability
Completely
Partially
Not
Result card domains
A. Health Problem and Current Use of the Technology
B. Description and technical characteristics of technology
B. Description and technical characteristics of the technology
C. Safety
D. Clinical Effectiveness
E. Costs and economic evaluation
F. Ethical analysis
G. Organisational aspects
H. Social aspects
I. Legal aspects
J. Accuracy
Search
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Joint Action 2010–2012

Items found

Type	Name	Pub.year
View collection	***Abdominal Aorta Aneurysm Screening*** *AAA Screening compared to not doing anything in the screening of Abdominal Aorta Aneurysm (AAA) in elderly at moderate risk of developing AAA*	2012
View collection	***Prognostic tests for breast cancer recurrence (Oncotype DX, MammaPrint, FEMTELLE)*** *UPA/PAI-1 - FEMTELLE - MAMMAPRINT compared to Standard of care in selecting treatment for Assessment of risk of breast cancer recurrence*	2012
View result card	***TEC3 (B0001): What is the MammaPrint® test?*** *B. Description and technical characteristics of technology, Features of the technology in Prognostic tests for breast cancer recurrence (Oncotype DX, MammaPrint, FEMTELLE)*	2012
View result card	***ETH7 (F0008): Does the implementation or use of uPA/PAI-1, Oncotype or Mammaprint affect human dignity?*** *F Ethical analysis, Human Dignity in Prognostic tests for breast cancer recurrence (Oncotype DX, MammaPrint, FEMTELLE)*	2012
View result card	***CUR17 (A0019): In which phase is the development of AAA screening?*** *A. Health Problem and Current Use of the Technology, Life-Cycle in Abdominal Aorta Aneurysm Screening*	2012

The overall approach was agreed on, there are still several functionalities to implement.

It was noted that in the future there should be interaction between the OTS and POP database.

Notes from Group 1

Group 1
Validation plans & processes

SURVEYS 1 and 2

Clarify:

Contact and answer per agency (interviewee decided at agency)

The interviewees (agencies) to the survey (text p. 3+4) not very consistent (only EUnetHTA partners

Prioritize surveys for “one-man HTA agencies”

Suggestions:

Anyone who produces HTA: aim for broad

Identify as soon as possible the timelines to answer the surveys, type of surveys and time to perform it and inform agencies

Possibility to access a trial version of OTS or limited access

Coverage of all domains – divided in 3 groups; hit list by domains answer; answer what they feel its important at national level and decision makers

Be aware of redundancies between surveys

Group 1
Validation plans & processes

SURVEY 3

Clarify:

Topics covered by core HTA 1 and 2 members

Who will be interviewee

Characteristics/role of the respondents (reviewer, investigator, etc)

Suggestions:

All domains covered by agency should be part of the survey

Revise the wording of survey – “I was content..” Ex: The Online Tool & Service supported …

Survey should not contain questions but statements, more clear cut questions

Comparability with previous survey

Introduce the question: Would your agency use this tool?

Include a question about what could be prerequisites to improve the use

Group 1
Validation plans & processes

SURVEY 4 and 5

Suggestions:

Introduction of question about changes that have been made or adapted since the last survey (valid for all surveys)

Depends on the aim of the surveys: checking for trends or analyse if the changes were good

Group 1
Advanced functionalities OTS

Suggestions:

Save search history

Time limit for publication date

Meta search

- nr. Core HTA; nr. Rapid HTA; nr. Result cards
- tabs ex. CRD for HTA; HEED
- nr. in progress; nr. finished

MeSH – database terminology for ex. like PubMed

Possibility to submit suggestion for new key words

Introduce boolean operators and search with wild cards

Use generic names or trade names

Identified lead authors/agencies

Group 1
What have we learnt

Suggestions:

Consider the feedback from Vienna meeting

Collection of practical issues/workshop for the newcomers

Plan projects using hierarchic order for domains

Limit nr. of people per domain (investigators/reviewers?)

Flexibility of AEs order (prioritize depending on technology)

Core Model for prognostic/predictive care

Readability of core HTA – reduced due to repetitions in result cards

Group 1
What have we learnt

Suggestions:

Readability of core HTA – reduced due to repetitions in result cards

Aim of Core HTA (visibility of products):

- collection of “result cards” to adapt to national production?
- or “complete collaborative Core HTA”?
- or both?

Aggregate AEs to produce Core HTA - flexibility and less formatted, avoid inconsistencies at updating

Use AEs as points to think of

Flexibility of AEs order (prioritize depending on technology)

Group 1
What have we learnt

Suggestions:

Collaborate Model 1 better quality due to,

Exchange between agencies but,

is more difficult to organize

JA2 both models

Workrooms should be more used by each domain

Technical difficulties uploading/downloading documents

EUnetHTA license for reference management and compatibility advice

EUnetHTA house style /wording for reports (word spelling to reduce editorial work)

Notes from Group 2

1. Validation plans & processes

- Aim of survey should be made clear
- Method: Plan for evaluation of surveys

Before start:

- **Indicate who you are, your experience etc.**
- **Terminology should be defined.**

We suggest TWO surveys

Survey 1	**Survey 2**
Outsiders (users) + insiders (EUnetHTA)	**Insiders (Only EUnetHTA, both users and non users of the online tools and the collaborative model)**
Screening model	Online Tool and Services
Core HTA information (genetic test and AAA)	Collaborative model
	EUnetHTA partners have that have access to the Online Tool and also to colleagues that have worked with the core model (screening model).
• Need a way to evaluate the two responding groups separately	
Content of surveys:	
Structure of screening model	Structure of screening model
Pilot of core HTA information	Pilot of core HTA information
	Online Tool access
	Information about organizations, how did they solve the different collaborative models' tasks? Collaborating models, experiences or minutes from ftf meetings

Addition: Separate (extra) set of questions for people (agencies) that have recently performed a HTA on similar topics (screening). The aim is to compare them. Also possible to have separate questions for specific domains.

AIM of the surveys

- Quality of the deliverables of JA1
- Information for future potential development
- Usability of the products (Tools and services, Core HTA information and structure of the screening model)

2. Advanced functionalities

Online Tool and Services (information service) and the Core Model

What do we miss?

- Search engine/facility
- My collection (flexibility of output – domain order, summary and conclusions?)
- Split production (work in progress)/presentation sites (fixed information)
- Work direct in the tool
- Possible to create pdf files by a click
- Interfaces for import/export (POP database, Reference Manager,……)
- Authoring (signatures)

3. What have we learnt (Lessons learnt)

- Project management. We learned that the information from other domains did not arrive in time. Our work was delayed. We started out without a plan. Should a project management tool be integrated in the EUnetHTA platform?
- Administration of access (trust/confidentiality)
- Redundancies in questions. Quite a lot of overlap or relations between questions
- We will need a team for maintenance of the Core Model (alter the ontology based on input from members/users)
- Topic selection
- Very good to work with local colleagues for each domain, but difficult to interact/discuss between domains
- Lack of coordination by the editorial team, should have been regular e-meeting (teleconferences) between the editorial team and the Primary Investigators of each domain
- Access to drafts from all domains (could be solved by working directly in the Tool)
- People need to be prepared before attending the meetings and also need to be informed of what to prepare
- Start every project with a survey to ask for different agencies needs from the project. Will help the scoping phase.
- Overlap of people in the domains?

My Collection: Pick only some question from the Core HTA. These will vary from project to project.
My Model: A standard set of question that we always use at our agency. If you have questions that are not included in the Core HTA Model, then you can suggest altering the HTA Core Model ontology. Perhaps your question can be included in the ontology.

4A. Finalizing the Core HTAs

We did not have time to discuss this…….

All should add their latest version of their domain to the workroom within this week!!!

Notes from Group 3

Validation plans and processes

SURVEYS
Experience from WP 5:
A risk of low quality input from the responses to the surveys (”quick and dirty”), if the questionnaire is too extensive. There is a need for the respondents to understand and be familiar with the CORE Model and Online tool – on the other hand – important to not be biased.

Of the organizations represented, only one (IQWIQ) do screening HTAs frequently and SBU has done one in the last 24 months. Therefore there could be a problem of the number of organizations that would be eligible.

Survey 1: Online tool and services. Part A could be merged in with survey 2, split out B separately just for agencies that have experience of conducting a screening assessment and call it a screening survey.

Survey 2: change the phrase on p.3: ”…from the viewpoint of those who may wish to use existing EUnetHTA information to support their local HTA production.”

Surveys may not be the appropriate tool for achieving what we want to achieve here, i.e. validation. Perhaps “validation” is not the correct term. Some argued that it is more a question of feasibility. The survey will also serve the purpose of finding out whether agencies will use the Core Model or not in their own agencies.

We should not let the people who developed the models answer the survey as they’ll be biased, but it may then be that if these people were excluded, there may be no people with the expertise to do so.

Funding? Are there people in the various member countries with experience and expertise that we could find to undertake independent validation (probably not feasible) that have not been directly involved in the EUnetHTA work?

Suggested time frame for the agencies to answer the survey: Preferably 2 months, 1 month minimum.
Presupposes information in the accompanying letter what roles are needed in answering the survey, good instructions. A cover letter explaining the purpose and requirements of the survey is important.
We also want the contact person in the agencies to see the instructions beforehand and have the possibility to make comments on the clarity of the instructions. Perhaps notice from the LP to the contact person beforehand that the survey will be sent out two weeks from now etc.

Advanced functionalities

When searching: To be able to see all cards in one domain, but also to do more specific searches (so both specific, and/or general searches).

Functionalities on the outcome measurement: can you search for "mortality" – generic keywords for the cards, so that you would get all the cards that concern "mortality".

The order of the assessment element cards when they are presented – we do not consider the order of the element cards within the tool as important, especially as there is flexibility.

No restriction of the length of the summary, but a preference should be indicated for the number of words. A potential problem could be limits within each result card which we discourage.

What have we learnt?

a) How should the HTA Core Model ontology be further developed?
This has to be built up with experience. We feel the structure is as good as it can get for now and that we need experience of actually producing HTAs with the Core Model in order to know it could be further developed.

b) Core HTA process from the viewpoint of using the HTA Core Model
AND
c) Core HTA process from the viewpoint of working together in international collaboration (including pros and cons of the two collaborative models)

Reduction in duplication if the communication improves between the research teams that are doing the research questions between different domains.

The issue of timing: we would like some sort of guidance of the natural order of the domains (the sequence) and also some sort of "stopping guidance" of when to "stop" other domains if they are irrelevant due to lack of clinical effectiveness. So, when results from one domain makes another domain more important.

The methodological development is very important, especially from the viewpoint of standardizing a European quality level, as the methods are not standardized yet.

We recommend that there is a project leader looking at the whole Core HTA and this person's role is also to look at the research questions criteria in discussion with the agencies when writing the protocol. We had a feeling that currently there are many 'nice to know'- result cards, that are not all relevant.

We recommend collaboration between a few agencies in a Core HTA, rather than with many, so that the communication and consistency is easier. Other organizations can still act as reviewers, but we don't need too many reviewers as this is quite a large job. Just to cover the European perspective. There should be guidelines and checklists for the reviewers as well.

Integration of the HTA Core Model

We think that a key aspect of actual use of EUnetHTA HTA-information is a quality standard.
We would like that a result coming out of JA2 would be technical policies on quality assurance and on common standards of methodology.

More funding to the actual production of Core HTAs and on methodological matters.

Results from group discussions

In addition to the notes from different groups (see above), the following notions/opinions were recorded.

Validation Surveys
· Clarify: who answer per each agency and prioritize the surveys
· Identify timelines for answering to the survey
· Possibility to access to trial version of OTS
· Coverage of all domains
· Avoid redundancies among surveys
· For Survey 3: who will be interviewed?
· Add the question: will your Agency use the On-line tool?
· Try to find a way to compare these results with previous surveys
· Survey: few and bad responses; respondents should know what Core Model is
· Surveys may not be the best/right tool to achieve the objective.
· Developer of Core Model should not answer to Surveys
· Time: at least 2 months
· Good instructions to explain surveys

Advance functionalities of OTS
· Save search history
· Time limit for publication date
· Meta search
· Mesh database
· Possibility for new keywords
· Identify Lead Authors/Agency
· Specific searches
· Orders of AEs cards à flexibility
· No restrictions in summary but indicate a preference in word numbering

What have we learnt?
· Collection of pratical issues for new comers
· Plan project using hierarchic order of domains
· Limit the number of people per domain
· Flexibility of AEs order
· Core model for prognostic
· Readability of Core HTA – avoid repetitions
· Improve communications among domains
· Sequence of domains and stopping guidance: what to do if there is lack of clinical effectiveness
· Project Leader: roles?
· Recommend for a collaboration with few agencies in a core HTA à others can be reviewers

Integration
· More funding
· Technical policies and Q/A on methodologies in Joint Action

Challenges ahead & Future plans

Several new ideas, challenges and possibilities for the validation, OTS and core HTAs were identified. Relevant working groups need to consider which ones can be implemented during JA1 and which will require further consideration of time in the future.

Tom Jefferson emphasized the need to be very clear in writing the core HTAs, their language, references and identity of authors. The final documents should be sent to Agenas also as doc version of the final text.

Kristian Lampe emphasized that core HTA groups should always check that they have appropriate rights to any possible third-party material, e.g. images. The validation task is very challenging, as there are multiple targets (OTS, screening model, collaborative models, and the core HTAs). There is no simple way to do it, but the meeting discussion provided very good material that THL and Agenas will consider while making the final validation surveys.

Appendix: Presentation on PARENT Joint Action

During the meeting Mr Arto Vuori from THL gave a presentation on PARENT, another Joint Action, to inform workshop participants about this parallel project.

Introducing : cross border PAtient REgistries iNiTiative – PARENT Joint Action

Presentation at EUnetHTA Workshop, Helsinki 5.6.2012

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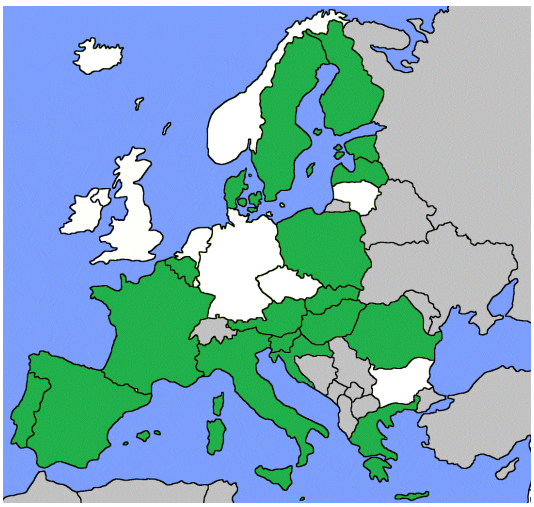
PARENT- cross border PAtient REgistries iNiTiative: Joint Action Profile

- Start: May 2012
- Duration: 30 months (end: 10/2014)
- Budget: 3.4 M€ (60% EC)
- 11 Associated partners
- 12+ Collaborating partners
- Kick-off meeting and first workshop *(Introduction to EU level patient registries state of the art)* – Brussels, 13.6.2012



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The EU perspective

- **Second programme of community action in the field of health**: PARENT addresses objective Nr. 3 (generating and disseminating health information and knowledge):
  3.3.1.4. **Cross-border e-Health instruments as supporting tools for medical information and research.**

- **Directive on cross-border healthcare, Article 14**:
  The eHealth Network shall *draw up* ***guidelines on effective methods for enabling the use of medical information for public health and research***

Medical information + eHealth instruments: Registries

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Registry

- **A patient registry is an organized system that uses obervational study methods to collect uniform data (clinical and other) to evaluate specified outcomes for a population defined by a particular disease, condition, or exposure, and that serves one or more predetermined scientific, clinical, or policy purposes.**
- **Types of registries in this category: Product registries, Disease or Condition, Health Services and Combination registries.**

The definition of the AHRQ from: Gliklich RE, Dreyer NA, eds. *Registries for evaluating Patient Outcomes: A User's Guide.* Rockville, MD: Agency for Healthcare Research and Quality. September 2010.

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Why PARENT?

- *Aim:* to rationalise and harmonise the **development and governance of patient registries**, thus enabling analyses of secondary data for public health and research purposes.
- *Goal:* support MS in developing **comparable and coherent patient registries** in fields where this need has been identified (e.g. chronic diseases, rare diseases, medical technology).
- *Goal:* support MS states in the provision of **objective, reliable, timely, transparent, comparable and transferable information** on the relative efficacy and effectiveness of health technologies.

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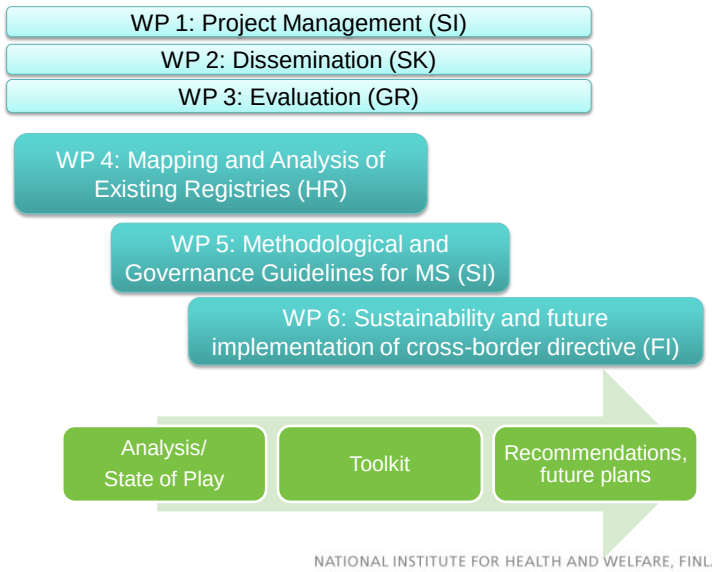
PARENT JA structure & output



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PARENT: Objectives

- Provide a **comprehensive overview** of current EU/MS situation regarding patient registries (WP4)
- Set up a **coordination mechanism** to use synergies between PARENT and related EU projects and joint actions (APG)
- Create prototype EU-level relevant source of information (**Registry of Registries**) regarding national patient registries (WP4)
- Develop and disseminate **recommendations, guidelines and IT tools** for efficient and rational governance of patient registries (WP5)
- Explore and address issues related to cross-linking and sharing of registry data. Ensure **sustainability of cross-border collaboration** on secondary use of registry data, incl. the Registry of Registries, Methodological and Governance Guidelines (WP6)
- **Provide specific plan of activities and policies** to further develop eHealth-enabled registries as a support mechanism for the implementation of the Directive on cross-border health care regarding patient registries. (WP6)

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MAIN AND ASSOCIATED PARTNERS

Country	Partner
Slovenia	**National Institute of Public Health**, MoH
Malta	Ministry of Health, the Elderly & Community Care
Slovakia	Národné centrum zdravotníckych informácií
Portugal	Direcção-Geral da Saúde
Croatia	National Institute of Public Health
Finland	National Institute of Health and Welfare
Hungary	National Institute for Quality- and Organizational Development in Healthcare and Medicines
Italy	MoH
Spain	Centro Superior De Investigación En Salud Pública/Dirección General De Salud Pública
Greece	National and Kapodistrian University of Athens

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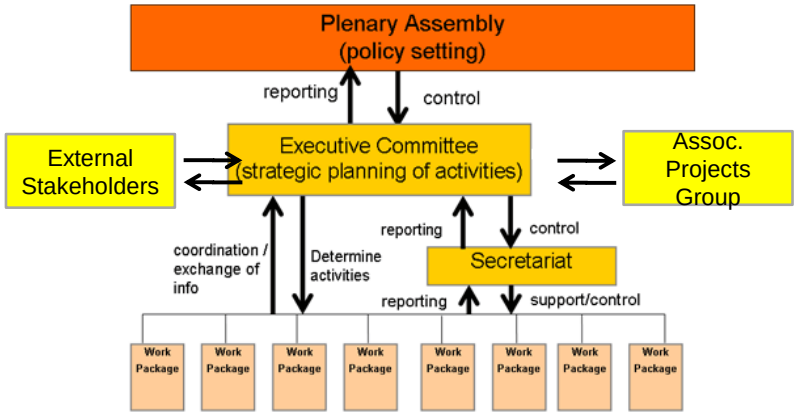
COLLABORATING PARTNERS	
Country	Partner
Austria	MoH
Poland	MoH
Estonia	MoSocial Affairs
Belgium	Public Health, Food Chain Control and Environment
Cyprus	MoH
Denmark	National Board of Health
Spain	MoH
Sweden	National Board of Health and Welfare
EU/UK	European Medicines Agency
Romania	National Health Insurance House
France	Institut national de la santé et de la recherché medicale
Intl./UK	European Academy of Allergy and Clinical Immunology
Latvia	The Centre of Health Economics
	and others.

9

PARENT JA: Management structure



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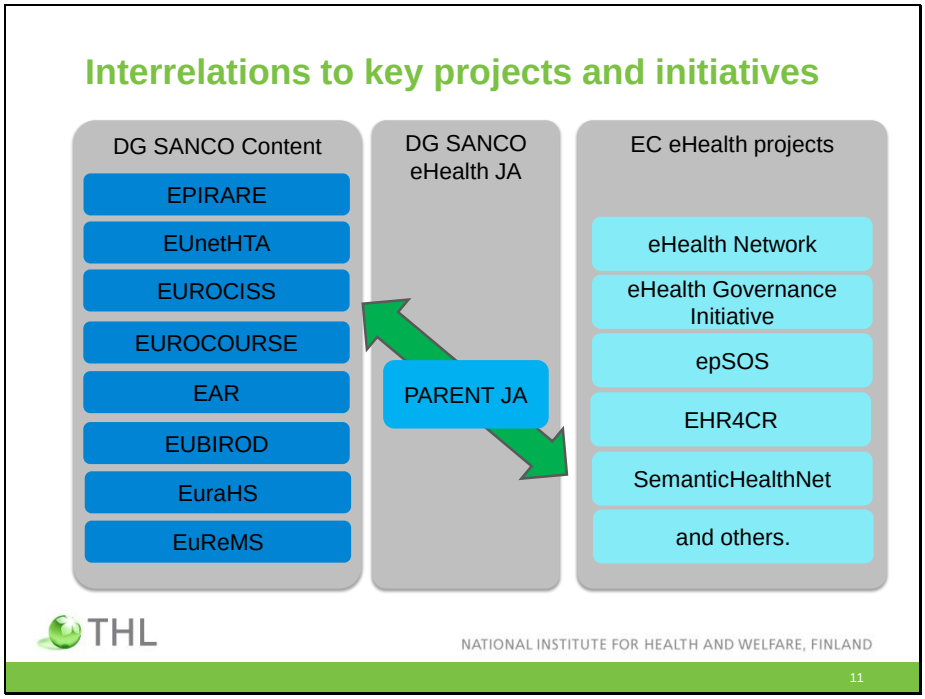
Interrelations to key projects and initiatives
DG SANCO Content
EPIRARE
EUnetHTA
EUROCISS
EUROCOURSE
EAR
EUBIROD
EuraHS
EuReMS
DG SANCO eHealth JA
PARENT JA
EC eHealth projects
eHealth Network
eHealth Governance Initiative
epSOS
EHR4CR
SemanticHealthNet
and others.
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11


cross border patient registries initiative
PARENT Joint Action
www.patientregistries.eu
parent@ivz-rs.si
arto.vuori@thl.fi
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EUnetHTA JA
WP4 face to face meeting
Helsinki, Finland
June 4-5, 2012

eunethta

Organised by: FINOHTA/THL
Contact person: Linda Akiola, Kristian Lampe
Mobile: +358 2952 47297, +358 2952 47180

Address of the meeting venue: Conference Hotel Rantapuisto Oy, Ramsinniementie 14, FIN-00980 Helsinki, Finland
Tel: +358 (0)9 31911, *Fax:* +358 (0)9 319 1400

Participant Signatures

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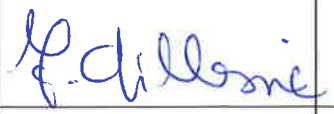
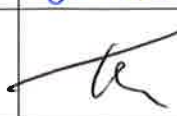
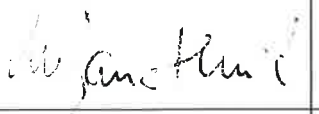
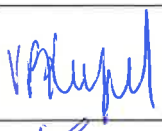
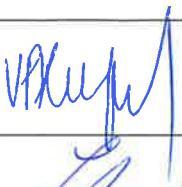
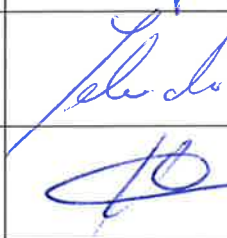
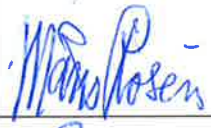
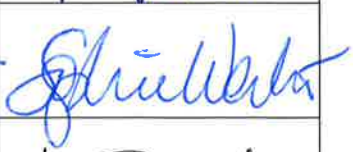
		Iris Pasternack		
		Ulla Saalasti-Koskinen		
		Sinikka Sihvo		–
		Oskari Saarekas		
		Taru Haula		
		Leena Raustia		
		Jaana Leipälä		
		Ilona Autti-Rämö		

		Linda Akiola		
Italy IT	AGE.NA.S, Agenzia Nazionale per i Servizi Sanitari Regionali	Nicola Vicari		
		Francesca Gillespie		
		Antonio Migliore		
		Tom Jefferson		
		Mirella Corio		
Austria AU	HVB, Hauptverband der Österreichischen Sozialversicherungsträger (Association of Austrian Social Insurance Institutions)	Gottfried Endel		
Austria AU	GÖG-Gesundheit Österreich GmbH/Geschäftsbereich BIQG-Bundesinstitut für Qualität im Gesundheitswesen	Sophie Brunner-Ziegler		
Austria AU	University of Health Sciences, Medical Informatics and Technology	Petra Schnell-Inderst		
Belgium BE	KCE, Belgian Health Care Knowledge Centre	Irina Cleemput		
Croatia HR	AAZ, Agency for Quality and Accreditation in Health	Mirjana Huic		
Denmark DK	SDU, Centre for Applied Health Services Research and Technology Assessment, University of Southern Denmark	Anne Lee		
Denmark DK	Dept of Health Services Research and HTA, Centre for Public Health, Central Denmark Region	Lotte Groth Jensen		
Estonia EE	UTA, Department of Public Health, University of Tartu	Kristi Liiv		
Germany DE	IQWIG, Institute for Quality and Efficiency in Health Care	Stefan Sauerland		
Ireland IR	HIQA, Health Information and Quality Authority	Patricia Harrington		

Italy IT	**ASSR, Agenzia Sanitaria e Sociale Regionale Regione Emilia Romagna**	Luciana Ballini		
Netherlands NL	**CVZ, Health Care Insurance Board**	Sarah Kleijnen		
Norway NO	**NOKC, Norwegian Knowledge Center for the Health Services**	Katrine B Frønsdal		
		Ingvil Sæterdal		
Poland PL	**AHTAPol, Agency for Health Technology Assessment**	Lidia Becla		
Portugal PT	**INFARMED, National Authority of Medicines and Health Products**	Isaura Vieira		
Slovenia SI	**IER, Institute for Economic Research**	Valentina Prevolnik Rupel		
Slovenia SI	**NIPH, National Institute of Public Health**	Marjetka Jelenc		
Spain ES	**ISCIII, Instituto De Salud Carlos III**	Iñaki Imaz		
Sweden SE	**SBU, Swedish Council on Technology Assessment in Health Care**	Måns Rosen		
		Sophie Werkö		
Switzerland SH	**SNHTA, Swiss Network for HTA**	Heike Raatz		
United Kingdom UK	**NICE, National Institute for Health and Clinical Excellence**	Nick Crabb