





eunethta
EUROPEAN NETWORK FOR HEALTH TECHNOLOGY ASSESSMENT

EUnetHTA

European network for Health Technology Assessment

FINAL TECHNICAL REPORT

delivered by the main beneficiary

National Board of Health of Denmark
Danish Centre for Health Technology Assessment (DACEHTA)

March 2009

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Abbreviations

AEG	“Access with Evidence Generation” mechanism
AETSA	Agencia de Evaluación de Tecnologías Sanitarias de Andalucía, Spain
AETS	Agencia de Evaluación de Tecnologías Sanitarias, Spain
AHRQ	Agency for Healthcare Research and Quality, USA
AHTAPol	Agency for HTA in Poland
ASR	Agenzia Sanitaria Regionale, Emilia Romagna, Italy
ASSR (AGENAS)	Agenzia per i Servizi Sanitari Regionali, Italy
AP	Associated Partner (within the EUnetHTA project)
AVALIA-T	Galician Agency for Health Technology Assessment, Spain
CADTH	Canadian Agency for Drugs and Technologies in Health (former CCOHTA), Canada
CAHTA	Catalan Agency for Health Technology Assessment and Research, Spain
CAST	Centre for Applied Health Services Research and Technology Assessment, University of Southern Denmark, Denmark
CEDIT	Comitee for Evaluation and Diffusion of Innovative Technologies, Direction de la Politique Médicale, France
CEESTAHC	Central and Eastern European Society for Technology Assessment in Health Care
CMTF	Center for Medical Technology Policy, USA
CP	Collaborating Partner (within the EUnetHTA project)
CRD	Centre for Reviews and Dissemination, University of York, United Kingdom
CVZ	College voor zorgverzekeringen, The Netherlands
DACEHTA	Danish Centre for Health Technology Assessment, Denmark
DAHTA@DIMDI	German Agency for Health Technology Assessment at the German Institute for Medical Documentation and Information, Germany
DES	Drug eluting stents
DIA	Drug Information Association
DSI	Danish Institute for Health Services Research, Denmark
EPPOSI	European Platform for Patients’ Organisations, Science and Industry
EUCOMED	European medical technology industry association
EUnetHTA	European network for Health Technology Assessment
EUPHA	European Public Health Association
EuroScan	The European Information Network on New and Changing Health Technologies
FinOHTA	Finnish Office for Health Technology Assessment, Finland
FIPRA	Finsbury International Policy & Regulatory Advisers (senior Public Policy and Regulatory Advisers network)
HAS	Haute Autorité de Santé, France
HPV	Human Papilloma Virus
HSS	Horizon Scanning System
HTA	Health Technology Assessment
HTAi	Health Technology Assessment international
HunHTA	Unit of Health Economics and Health Technology Assessment, Corvinus University of Budapest, Hungary
ICTAHC	Israeli Center for Technology Assessment in Health Care, Israel
iHIQA	Interim Health Information and Quality Authority, Ireland
INAHTA	International Network of Agencies for Health Technology Assessment
IQWIG	Institute for Quality and Efficiency in Health Care, Germany
ISPOR	International Society for Pharmacoeconomics and Outcomes Research
IPHRs	Institute for Public Health of Republic of Slovenia
IUMPS	Institut Universitaire de médecine sociale et préventive Lausanne, Switzerland
KCE	Belgian Health Care Knowledge Centre, Belgium
LBI@HTA	Ludwig Boltzmann Gesellschaft GmbH, Austria
LP	Lead Partner (within the EUnetHTA project, organisation responsible for leading and managing work in a Work Package)
MoH	Ministry of Health
MS	Member State (of the European Union)
MSAC	Medical Services Advisory Committee, Australia
NBoH	National Board of Health
NCCHTA	National Coordinating Centre for Health Technology Assessment, United Kingdom
NICE	National Institute for Clinical Excellence, United Kingdom
NOKC	Norwegian Knowledge Centre for the Health Services, Norway
OECD	Organisation for Economic Co-operation and Development
OSTEBA	Basque Office for Health technology Assessment, Spain

PHGEN	Public Health Genomic European Network
SBU	Swedish Council on Technology Assessment in Health Care, Sweden
SNHTA	Swiss Network for Health Technology Assessment, Switzerland
STAKES	National Research and Development Centre for Welfare and Health, Finland
TU Berlin	Technische Universität Berlin, Germany
UETS	Unidad de Evaluación de Tecnologías Sanitarias, Spain
UCSC	Università Cattolica del Sacro Cuore, Policlinico universitario “A. Gemelli”, Italy
WHO-HEN	World Health Organisation, Health Evidence Network
WIHE	Winterthur Institute of Health Economics, Switzerland
WP (1-8)	Work Package (within the EUnetHTA project)
ZonMw	The Netherlands Organisation for Health Research and Development, The Netherlands

Technical Fact Sheet

Project	European network for Health Technology Assessment (EUnetHTA)
Project No.	2005110(790621)
Programme	Public Health Programme 2003-2008; Health Information and knowledge 2005
Unit of DG Sanco	Risk Assessment (from January 2007; previously – Health Information)
Start Date of Project	January 1, 2006
Duration	36 months
Objectives	<p>The overall strategic objective of the network is to connect public national/regional health technology assessment (HTA) agencies, research institutions and health ministries, enabling an effective exchange of information and support to policy decisions by Member States, thus</p> <ul style="list-style-type: none"> • reducing overlap and duplication of effort and hence promote more effective use of resources, • increasing HTA input to decision-making in member states and the EU and hence increasing the impact of HTA, • strengthening the link between HTA and health care policy making in the EU and its member states, • supporting countries with limited experience with HTA
Tasks/Work packages	<p>WP1 Coordination WP2 Communications WP3 Evaluation WP4 Common Core HTA (HTA Core Model) WP5 Adapting existing HTAs to new contexts (HTA Adaptation toolkit) WP6 Transferability to health policy WP7 Monitoring development for emerging/new technologies and prioritisation of HTAs WP8 Systems to support HTA in MS with limited institutionalisation of HTA</p>
DG Sanco Representative	Mr. Panagiotis Daskaleros
EUnetHTA Project Leader	Prof. Finn Børlum Kristensen
Main Beneficiary and its WP Affiliation	National Board of Health of Denmark, Danish Centre for HTA (DACEHTA) – WP1,2,4,5,6,7
Associated Beneficiaries / Partners and their WP Affiliation	<ol style="list-style-type: none"> 1. Ludwig Boltzman Institute of Health Technology Assessment, LBI@HTA, Austria - WP1,5,7 2. KCE - Belgian Health Care Knowledge Centre, Belgium – WP2,4,5,6 3. Ministry of Health, Cyprus –WP2,8 4. CAST - University of Southern Denmark, Center for Applied Research and Technology Assessment, Denmark – WP6,7,8 5. DSI- Danish Institute for Health Services Research, Denmark - WP4,5,6 6. University of Tartu, Department of Public Health, Estonia – WP4,5,6,7,8 7. FinOHTA - Finnish Office for HTA (STAKES), Finland – WP1,4,5,6 8. HAS - Haute Autorité de Santé / French National Authority for Health, France – WP1,2,5,7 9. DAHTA@DIMDI- German Agency for HTA at the German Institute for Medical Documentation and Information, Germany – WP1,2,3,5,6 10. Technische Universitaet Berlin, Germany – WP4,5,6 11. University of Bremen, Interdisciplinary Centre for HTA, Germany – WP7 12. University of Lübeck, Institute for Social Medicine, Germany – WP4,7 13. HunHTA - Unit of Health Economics and Health Technology Assessment, Corvinus University, Hungary – WP2,8 14. iHIQA - interim Health Information and Quality Authority, Ireland – WP6,7 15. ASR - Agenzia Sanitaria e Sociale Regionale, Emilia Romagna, Italy – WP2,3,5,7

	<ol style="list-style-type: none"> 16. Università Cattolica del Sacro Cuore, Policlinico universitario "A. Gemelli", Health Technology Assessment Unit and Laboratory of Health Economics (Institute of Hygiene), Italy – WP4,5,6,7,8 17. Regione Veneto, Italy – WP2,3,5,7 18. VSMITA - Health Statistics and Medical Technology State Agency, Latvia – WP3,8 19. Ministry of Health, Republic of Lithuania – WP4 20. NOKC – Norwegian Knowledge Centre for the Health Services, Norway – WP1,3,4,5,6,7,8 21. Institute of Public Health, Republic of Slovenia – WP5,6,7,8 22. AETS - Agencia de Evaluación de Tecnologías Sanitarias, Spain – WP3,6,7,8 23. AETSA - Andalusian Agency for Health Technology Assessment, Spain – WP4,5,7 24. AVALIA-t, Galician Agency for Health Technology Assessment, Spain – WP4,6,7,8 25. CAHTA - Catalan Agency for Health Technology Assessment and Research, Spain – WP1,2,8 26. OSTEBA - Basque Office for Health Technology Assessment, Spain – WP4,5,7 27. Servicio Canario de la Salud, Spain – WP5,6 28. UETS - Unidad de Evaluación de Tecnologías Sanitarias, Agencia Laín Entralgo, Spain – WP2,6 29. SBU - Swedish Council on Technology Assessment in Health Care, Sweden – WP1,2,3,4,7 30. CVZ - College voor zorgverzekeringen, The Netherlands – WP6,7 31. ZonMw, Netherlands Organisation for Health Research and Development, The Netherlands – WP4,5 32. NCCHTA - National Coordinating Centre for HTA, United Kingdom – WP1,4,5,6 33. Cochrane Collaboration (Secretariat), United Kingdom – WP2,3,4,5,6,7,8
Collaborating Partners	<ol style="list-style-type: none"> 1. MSAC - Medical Services Advisory Committee, Australia – WP3 2. Hauptverband der Österreichischen Sozialversicherungsträger, Austria – WP5,6,8 3. Gesundheit Österreich GmbH, Austria – WP4,5 4. CADTH (former CCOHTA) - Canadian Agency for Drugs and Technologies in Health, Canada – WP2 5. HTA and Health Service Research, Center of Public Health, Århus, Denmark – WP6 6. CEDIT - Committee for Evaluation and Diffusion of Innovative Technologies, Direction de la Politique Médicale, France – WP6,7 7. German HTA Association, Germany – WP8 8. IQWiG - Institute for Quality and Efficiency in Health Care, Germany – WP6,8 9. Public Health Genomics European Network (PHGEN), German Center for Public Health Genomics (DZPHG), Germany – WP5,6,7,8 10. University of Iceland, Faculty of Medicine, - replaced by Directorate of Health in 2007, Iceland – WP4,5,6,8 11. ICTAHC - Israeli Center for Technology Assessment in Health Care, Israel – WP7 12. Agency for HTA in Poland, AHTAPol, Poland – WP2,4,5,7,8 13. CEESTAHC - Central and Eastern European Society for Technology Assessment in Health Care, Poland – WP8 14. Institute of Molecular Medicine, Portugal – WP4,5,6,8 15. SNHTA - Swiss Network for Health Technology Assessment, Switzerland – WP1,2,3,4,5,6,7,8 16. CRD - Centre for Reviews and Dissemination, University of York, United Kingdom – WP2 17. AHRQ - Agency for Healthcare Research and Quality, Center for Outcomes & Evidence, USA – WP2,6

	<p>New Collaborating Partners that joined EUnetHTA in 2007:</p> <ol style="list-style-type: none"> 1. AGENAS (ASSR), Italy (WP5, WP8) 2. National School of Public Health and Health Services Management, Romania (WP8) 3. NICE, UK (WP7) 4. CMTP, USA (WP7) 5. Ministry of Health, Serbia (WP8) <p>European/International Organisations:</p> <ol style="list-style-type: none"> 1. Council of Europe - Directorate General III - SOCIAL COHESION – WP6,8 2. European Observatory on Health Systems and Policies - WP7,8 3. EuroScan - European Information Network on New and Changing Health Technologies – WP2,7,8 4. G-I-N Executive - Guidelines International Network – WP2,4,6 5. HTAi - HTAi Secretariat – WP6,8 6. INAHTA - INAHTA Secretariat – WP2,6,8 7. OECD - Organisation for Economic Cooperation and Development – WP3,6,7 8. WHO - Health Evidence Network (HEN) – WP1,6,8
Project Contacts	<ul style="list-style-type: none"> • Ministry of Health, Czech Republic • Ministry of Health, Greece • Ministry of Health, Luxembourg • Ministry of Health, Malta

Deliverables

All deliverables were submitted to the Commisison within the timeframe of the project.

Deliverable (number, title)	Nature	Access	Confidentiality level
D1 An organisational structure for a European network for HTA – including a supporting Secretariat a) project years 2006-2008 b) EUnetHTA Collaboration proposal (years 2009 -)	Other	<ol style="list-style-type: none"> a) described on the EUnetHTA website: http://www.eunethta.eu/About_EUnetHTA/Organisation2/ b) document available (printed copy enclosed with the Technical Report and on the EUnetHTA final Technical report CD-ROM); available for download - http://www.eunethta.eu/upload/EUnetHTA_Collaboration_proposal/EUnetHTA_Collaboration_Proposal_Final_June2008.pdf 	Public
D2 An elaborate Communication Strategy of the network	Other	document available (printed copy enclosed with the Technical Report and on the EUnetHTA final Technical report CD-ROM); available for download on the EUnetHTA Members Only (NOT FOR PUBLIC) - http://www.eunethta.eu/WP2_documents/Executive_summary_EUnetHTAComStrategy.pdf	Restricted
D3 An internal evaluation of the project	Report	document available (printed copy enclosed with the Technical Report and on the EUnetHTA final Technical report CD-ROM); available for download - http://www.eunethta.eu/upload/WP3/Internal_Evaluation_EUnetHTA_2006-08.pdf	Public
D4 The framework for an external evaluation of	Other	document available (printed copy enclosed with the Technical Report and on the EUnetHTA final	Restricted

EUnetHTA

Technical report CD-ROM); available for download on the EUnetHTA Members Only (**NOT FOR PUBLIC**) - http://www.eunethta.eu/upload/WP3/D4_Framework_external_evaluation_report_2008
EUnetHTA_final.pdf

D5 A generic methodological HTA framework based on current best practices (HTA Core Model™)	Guide-lines	<ul style="list-style-type: none"> a) document available (printed copy enclosed with the Technical Report and on the EUnetHTA final Technical report CD-ROM); available for download - http://www.eunethta.eu/upload/WP4/Final Deliverables/HTA Core Model for Diagnostic Technologies 1 0r.pdf b) document available (printed copy enclosed with the Technical Report and on the EUnetHTA final Technical report CD-ROM); available for download - http://www.eunethta.eu/upload/WP4/Final Deliverables/HTA Core Model for Medical and Surgical Interventions 1 0r.pdf 	Public
D6 Two pilot examples of Core HTAs for different types of questions	Report	<ul style="list-style-type: none"> a) document available (printed copy enclosed with the Technical Report and on the EUnetHTA final Technical report CD-ROM); available for download - http://www.eunethta.eu/upload/WP4/Final Deliverables/Core HTA on Drug Eluting Stents.pdf b) document available (printed copy enclosed with the Technical Report and on the EUnetHTA final Technical report CD-ROM); available for download - http://www.eunethta.eu/upload/WP4/Final Deliverables/Core HTA on MSCT Angiography.pdf 	Public
D7 Handbook on Core HTA development	Guide-lines	Document available in electronic format (according to the Grant Agreement conditions): http://fio.stakes.fi/htacore/handbook.html	Public, electronic format
D8 HTA Adaptation toolkit – from existing HTAs into other contexts	Guide-lines	<ul style="list-style-type: none"> a) document available (printed copy enclosed with the Technical Report and on the EUnetHTA final Technical report CD-ROM); available for download - http://www.eunethta.eu/upload/WP5/EUnetHTA_HTA_Adaptation_Toolkit_October 08.pdf b) document available (printed copy enclosed with the Technical Report and on the EUnetHTA final Technical report CD-ROM); available for download - http://www.eunethta.eu/upload/WP5/Glossary of HTA Adaptation Terms November 2007.pdf 	Public
D9 Applicability testing of core information from existing HTA reports in various national environment using the toolkit	Report	<ul style="list-style-type: none"> a) document available (printed copy enclosed with the Technical Report and on the EUnetHTA final Technical report CD-ROM); available for download http://www.eunethta.eu/upload/WP5/EUnetHTA_HTA_Adaptation Toolkit Applicability testing round one response summary report December 07 update.pdf b) document available (printed copy enclosed with the Technical Report and on the EUnetHTA final Technical report CD-ROM); available for download - http://www.eunethta.eu/upload/WP5/Microsoft Word - AppTest2 Report June 2008 	

D10 A book containing a systematic overview of the HTA & health policy links "Health Technology assessment and Health Policy-making in Europe" (developed in collaboration with the European Observatory on Health Systems and Policies)	Report	review July08.pdf document available (printed copy enclosed with the Technical Report and on the EUnetHTA final Technical report CD-ROM); available for download http://www.euro.who.int/Document/E91922.pdf	Public
D11 An open EUnetHTA Stakeholder Forum to exchange views, expectations/feedback on HTA with stakeholders	Other - website	EUnetHTA Stakeholder Forum website - http://www.eunethta.eu/Stakeholder_Forum/	Public
D12 Web-based toolkit to facilitate European collaboration on evidence generation on promising health technologies	Data-base	document available (printed copy enclosed with the Technical Report and on the EUnetHTA final Technical report CD-ROM); available for download http://www.eunethta.eu/upload/Work_Package_7/WP7A_Deliverable_Dec_2008_(adjusted).pdf	Public
D13 A structured information service on high volume, costly, rapidly developing, emerging technologies	Other – <i>electronic newsletter</i>	Document available for download - http://www.eunethta.eu/Communication/Newsletter_WP7_2008/	Public
D14 A clearinghouse functionality prototype	Other	document available (printed copy enclosed with the Technical Report and on the EUnetHTA final Technical report CD-ROM); available for download - http://www.eunethta.eu/upload/Work_Package_2/EUnetHTA_e-knowledge_1Deliverable14.pdf Appendix 1 (to be viewed together with the report) - http://www.eunethta.eu/upload/Work_Package_2/V-Modell-XT-Complete-1_2_1-english.pdf	Public
D15 A handbook on HTA capacity building and institutionalising HTA	Guidelines	document available (printed copy enclosed with the Technical Report and on the EUnetHTA final Technical report CD-ROM); available for download - http://www.gencat.cat/salut/depsan/units/aatrm/pdf/eunethta_wp8_hb_hta_capacity_building.pdf	Public
D16 Final report from the project	Report	Document available in printed form and on the EUnetHTA final Technical report CD-ROM) NOTE: Deliverables with the restricted confidentiality level (according to the contract) should not be made public as a part of the report.	Public
D 17 EUnetHTA Conference "HTA's Future in Europe"	Conference	The conference was held on November 20, in Paris at Pasteur Institute (registered participants – 440). Proceedings from the conference are available for download on the conference website - http://www.eunethta.eu/Home/EUnetHTA_Conference_HTAs_Future_in_Europe/	Public

1 Introduction

This report is the final Technical Report on Implementation of the European network for Health Technology Assessment project (EUnetHTA), delivered by the main beneficiary National Board of Health of Denmark (Danish Centre for HTA (DACEHTA) to the Directorate-General Health and Consumer Protection, Directorate C – Public and Risk Assessment, Unit C7 – Risk Assessment.

The final Technical Report of EUnetHTA covers the period from January 1, 2006 to March 31, 2009 (the first 3 months of 2009 cover the activities associated with the reporting of the project results) and includes the overview of the overall project's objectives, methods, results and recommendations (activities performed in 2008 in WP1 are presented in a separate section), Work Package 2-8 individual reports - which provide the details on all activities performed, achievement of objectives manpower, partners and countries involved within each Work Package - and administrative information as stipulated in the Reporting Requirements (Annex III of the Grant Agreement 2005110 (790621)).

The first Interim Technical Report was submitted to the DG SANCO on February 28, 2007 (it covered the period from January 1, 2006 till December 31, 2006); the second Interim Technical Report was submitted to DG SANCO on March 3, 2008 (it covered the period from January 1, 2007 till December 31, 2007). Both reports are enclosed as electronic documents on the CD-ROM and as printed documents.

All deliverables have been produced and submitted to the Commission within the timeframe of the project.

The final Technical Report on Implementation of the EUnetHTA project was prepared by the main beneficiary in collaboration with the Lead Partners of the Work Packages (WPs) where the main beneficiary is not leading the work:

- WP2 (SBU, Sweden),
- WP3 (NOKC, Norway),
- WP4 (FinOHTA, Finland),
- WP5 (NCCHTA, United Kingdom),
- WP7 (HAS, France and LBI@HTA, Austria),
- WP8 (CAHTA, Spain)

According to Article I.5.2 of the Grant Agreement, the beneficiaries authorise the Commission to disseminate, communicate or publish the report concerning the action. The deliverables indicated as having a restricted confidentiality level should not be made public as per the Grant Agreement.

Additionally, the main beneficiary has submitted a consolidated financial statement for the full project period including the first 3 months of 2009 for reporting of the results.

The project is co-funded by the National Board of Health of Denmark (Danish Centre for HTA (DACEHTA) and thirty-three Associated beneficiaries of the project.

2 Overview of the EUnetHTA project (2006-2008) activities and results

2.1 Introduction

The rationale for Health Technology Assessment

The overarching values of health systems in the European Union are universality, access to good quality care, equity and solidarityⁱ. These values imply that there should be efficient use of resources on effective care that provides the best possible service for all users of the health system.

An area of debate in all health systems relates to the introduction, use and disinvestment of health technologies that might be innovative, but also complex and costly. Hence there is a need to evaluate the effects and implications of using new technology compared with existing health technologiesⁱⁱ and also to compare the value of existing technologies, to ensure equitable, high quality healthcare and efficient use of all resources. Health Technology Assessment (HTA) provides an objective process that seeks to inform policy makers about the implications of using a health technology in a particular health system so that they can formulate national/regional health policies that seek to uphold these values.

HTA is a multidisciplinary process that summarises information about the medical, social, economic and ethical issues related to the use of a health technology in a systematic, transparent, unbiased, robust mannerⁱⁱⁱ. In this context, health technology is a general term for any form of health intervention, ranging from methods for health promotion, to diagnostic processes and all forms of treatment.

The intention of HTA is to inform decision making related to the planning, delivery and monitoring of safe, effective and sustainable health services that have rapid uptake of effective health technologies and are patient focused. Indeed, at the Informal Health Council in 2007, it was stated that health care quality standards across the different health systems in the EU could be improved by HTA^{iv} and in 2008 the WHO Tallinn Charter pointed out that HTA should be used to support more informed decision making.^v

The proliferation of HTA

Health care policy is a national issue that takes account of the cultural, social, economic and systems context of a Member State and its regions. Likewise, the implications or value of a health technology must be considered in the context of a specific health system. This has led to establishment of HTA agencies that serve a country, region or hospital.

The first national agency for HTA in Europe was established in Sweden in 1987 to inform the Swedish government and county councils about the value of health technologies^{vi}. Since then the number of national and regional HTA agencies mandated to support healthcare decision making has grown steadily, especially in Western Europe. In the 2000s, national agencies were established in Austria, Belgium and Poland. By early 2008, the International Network of Agencies for HTA had 46 members worldwide, including 31 European countries^{vii}. Despite this increase in HTA activity, some Member States (e.g. Estonia, Malta, Luxembourg, Portugal, Slovakia, Slovenia) do not presently have the national expertise or capacity to form an HTA agency.

The organisation of HTA related activities in European countries varies widely, reflecting the form of their health system, their funding, type and scope of assessment, responsibilities in addition to HTA and relationship to decision making^v. However, there are some aspects of the HTA process that draw on the same evidence (e.g. evidence to determine clinical effectiveness comes from scientific publications indexed in international databases)^{viii}, but there is often duplication of effort to collect such evidence and surprisingly few joint projects to share assessment tasks.

European collaboration on HTA

The European Commission has funded three major projects over 1994 – 2002 that sought to support collaboration on HTA methods and working: EUR-ASSESS^{ix}, HTA-Europe^x and ECHTA/ECAHI^{xi}. The later projects stressed the need for a permanent structure to support HTA coordination in Europe to avoid duplication, maximise scarce resources, strengthen HTA in Member States and ultimately contribute to the better health of all European citizens. It was proposed that the structure to support HTA coordination should include all Members States via a Steering Committee, with an administrative group to support the activities of the network, mechanisms to involve relevant European expertise and funding support^{vi}.

In 2003, the European Parliament and the European Council adopted a programme of Community action in the field of public health (2003-2008)¹ that outlined the need for knowledge sharing in relation to health policies and specifically to:

- develop and maintain networks for the exchange of information on best practice in public health and the effectiveness of health policies;
- support and promote activities related to good practice and sound guidelines for public health, based on scientific data;

and

- improve the analysis and knowledge of the impact of health policy;
- develop criteria and methodologies for assessing policies and their impact on health;
- review, analyse and support the exchange of experiences on health technologies.

In 2004, the European Council concluded that the exchange of expertise and information through HTA may be enhanced through systematic EU-wide cooperation, in order to assist the Member States to plan, deliver and monitor health services effectively, based on the best available scientific evidence on the medical, social and economic implications of health technology^{xii}.

Following a recommendation by the High Level Group on Health Services and Medical Care (consisting of government representatives of EU Member States) and a call for proposals in the work programme of the European Commission Health and Consumer Protection Directorate General (DG SANCO), this three-year project called the European network for HTA (EUnetHTA) was developed by partners and supported by the European Commission. Its purpose was to create an effective and sustainable European network for HTA that would create common information frameworks for HTAs and promote the use of HTA in health care policy making in Member States. Its vision was that through sharing of work and avoidance of duplication, partners could increase high quality HTA output to inform national/regional policy making. This was set in the context of subsidiarity, recognising the responsibility of Member States for healthcare issues. Thus it was never intended to create common HTA conclusions on single technologies across Europe, but to promote effective collaboration to allow the best decisions to be made efficiently in the national context.

The EUnetHTA Project took account of the previous European collaborative work on HTA and established an organisation that sought inclusion of all Member States, with wide involvement of experts, involving 64 partners (50 from European Countries, 5 from Australia, Canada, Israel and USA and 9 international organisations) in eight Work Packages (WP1-WP8). Three-year work programme was developed and supported by a well-organised management function. On this firm basis, the EUnetHTA Project quickly established an open network supported by state-of-the-art communication tools to promote exchange of information and development of tools to assist the coordinated provision of HTA information.

2.2 EUnetHTA aims and objectives

The EUnetHTA Project was established to create an effective and sustainable network for HTA across Europe that could develop and implement practical tools to provide reliable, timely, transparent and transferable information to contribute to HTAs in Member States. The overall strategic objective of the network was to connect public national/regional HTA agencies, research institutions and health ministries, enabling an effective exchange of information and support to policy decisions by the Member States. The objectives were developed in 2005 and were adjusted reflecting the experience, needs and outcomes from the work performed in the project and changing healthcare systems policy environment.

The strategic objectives of the EUnetHTA Project were to:

- reduce overlap and duplication of effort and hence promote more effective use of resources;
- increase HTA input to decision-making in Member States and the EU and hence to increase the impact of HTA;
- strengthen the link between HTA and health care policy making in the EU and its Member States; and
- support countries with limited experience with HTA.

Specific objectives were defined to facilitate rapid, productive collaboration that would lead to the development of a range of practical tools to deliver the strategic objectives. Work Packages were aligned with specific objectives and each was expected to produce substantial deliverables, as shown in Table 1. In addition, milestones were set over the three-year project period for each Work Package, taking account of interdependencies across Work Packages.

Table 1: Objectives and planned deliverables for each Work Package

¹ 2002, Article 3.2d and Annex of Decision No 1786/2002/EC

Specific Objectives	Key Deliverables	Work Package
To establish the organisational and structural framework for the network with a supporting secretariat	The EUnetHTA organisational structure including a supporting Secretariat Final report from the project EUnetHTA conference presenting the project results	1 Coordination
To effectively disseminate and handle HTA results, information sharing and coordination of HTA activities through the development and implementation of elaborate communication strategies and description of Clearinghouse functionality	Communication strategy A clearinghouse functionality - detailed identification of the clearinghouse needs of different target groups and consecutive structure development to be ready for practical application after 3 years EUnetHTA conference presenting the project results	2 Communications
	Internal evaluation of the project Framework for external evaluation	3 Evaluation
To produce generic Core Models for HTAs on two essential categories of health technology questions: interventions and treatment, as well as Core HTAs on selected topics for each category	Core HTA structure/model 2 pilot examples of Core HTAs for different types of questions (e.g. diagnosis and treatment) A handbook on Core HTA.	4 HTA Core Model
To develop and implement generic tools for adapting assessments made for one country to new contexts	A toolkit for adapting Core HTA results from existing HTAs into other contexts including a HTA Glossary of adaptation Applicability testing of core information from 2 existing HTA reports in various national environments using the toolkit	5 HTA Adaptation Toolkit
To develop and implement effective tools to transfer HTA results into applicable health policy advice in the Member States and EU – including systems for identification and prioritisation of topics for HTAs and assessment of impact of HTA advice	EUnetHTA Open Forum for stakeholders to exchange views and expectations/feedback on HTA A book containing a systematic overview of the HTA & healthcare policy links in selected Member States & EU representing different health systems, remuneration systems, etc	6 Transferability of HTA to health policy
To structure prioritisation for HTA and provide health care decision makers with policy relevant information on new and emerging technologies	A prototype of a structured information service on high volume, costly, rapidly developing, emerging technologies	7 Monitoring development of emerging and new technologies and prioritisation of HTA
To provide tools to monitor the development of health technologies and to share data and results of this monitoring	A set of monitoring tools for emerging/new technologies	7 Monitoring development of emerging and new technologies and prioritisation of HTA
To establish a support system for countries without institutionalised HTA activity	Handbook on HTA organisations. The handbook will compile the results and information extracted from the review and the survey of HTA organisations	8 System to support HTA in Member States with limited institutionalisation of HTA

2.3 Structure and methods; partners and countries involved

The EUnetHTA Project was funded for three years from 2006 to 2008. A contract was agreed with the Main Partner, the National Board of Health of Denmark (Danish Centre for HTA) and 33 Associated Partners who all co-funded the Project. A further 30 Collaborating Partners ensured that the Project involved additional regional and national HTA agencies, research institutions and relevant international organisations (the involvement of these organisations grew from 24 at the start of the project). In addition, Ministries of Health in Member States that did not have any involvement in the Project were kept informed of progress.

The EUnetHTA Project was a complex undertaking involving the multi-disciplinary staff of 64 organisations in 33 countries across the world (See *Appendix 1* for the list of countries and partners involved in the EUnetHTA project and their WP affiliation. The individual Work Package reports will include the lists of the individuals that were involved in the WP work from each of the participating organisations. The project Financial Report provides details on the time and cost of each Associated Partner individual involved in the EUnetHTA project work). The objectives of the Project were challenging and required a high level of commitment from the Lead and Associated Partners. Each Work Package had a Lead Partner who was responsible for coordination of activities in that Work Package and timely production of all deliverables according to an agreed contract. Two Work Packages (WP2 and WP7) had two distinct streams of work and so each had a Co-Lead Partner.

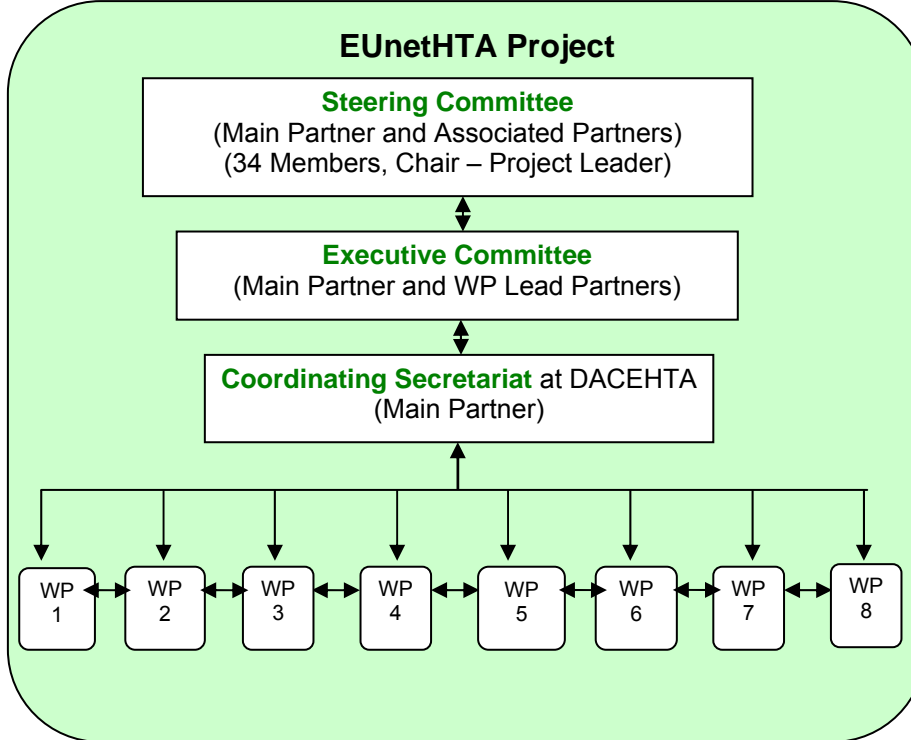
A variety of scientific approaches were used in the Work Packages including literature searches, survey questionnaires, Delphi surveys, pilot and applicability testing of tools, structured reviews of drafts, and many meetings and other forms of collaboration to build consensus. The methods used are described in detail in each Work Package report.

To ensure the achievement of objectives and consistence and high quality of work, clear delegation of management and coordination responsibilities was needed to ensure the adequate involvement and performance of each contributing organisation. This was achieved through the functioning of the Main Partner as the Secretariat and by the establishment of an Executive Committee including the Main and Work Package Lead Partners to ensure operational delivery of the project. A Steering Committee was formed and included one representative from each Associated Partner organisation. The Steering Committee was chaired by the Director of the Main Partner (Project Leader). Figure 1 shows the organisational structure of the Project. The Standard Operating Procedures (SOP) Manual was developed in the first months of the project, endorsed by the Steering Committee in May 2006, and was guiding the governance and management of the project throughout 3 years (SOP Manual is available on the Members Only area of the EUnetHTA website.)

To ensure the responsiveness of the EUnetHTA Project to the needs of the Member States and the EU, regular updates on the progress of the Project were given to DG SANCO and the High Level Group on Health Services and Medical Care. Additionally, the Secretariat regularly monitored and informed the Executive Committee and all EUnetHTA Partners about healthcare policy developments at the EU level. Partners were also encouraged by the Executive Committee to make contact with their Ministry of Health to discuss the work of the EUnetHTA Project and gain support for ongoing work nationally. Moreover, EUnetHTA Partners presented the Project in many European, international and national meetings. (See Appendix 2 for the details on the project internal and external meetings).

Key stakeholders, who are not directly involved in the EUnetHTA Project but have an interest in its work, are policy makers, patients, healthcare professionals and health technology manufacturers. Organisations representing these groups were identified and worked with in a variety of ways during the Project. Furthermore, from the outset of the Project, anyone could access information on the public website (www.eunethta.net), subscribe to regular updates and provide comments on the proposal for future collaboration on HTA in Europe and participate in the validation/commenting process for some of the project deliverables (eg, HTA Core Model, piloted Core HTAs, Adaptation Toolkit, Handbook on the institutionalisation of HTA).

Figure 1. EUnetHTA Project Organisational Structure



2.4 Results of the project

Overview

Earlier EC funded HTA projects provided good methodological guidance on HTA. The EUnetHTA Project progressed this work by placing emphasis on developing practical tools, systems and structures that would allow application of the good methodological guidance on HTA in a transnational HTA collaboration. The purpose of its work was to avoid duplication and ensure better use of resources available for HTA work, and enhance effective uptake of evidence-based input to health policy and planning. Therefore the EUnetHTA Project aimed to create tools and systems (concrete outputs) to facilitate sharing of information and coordination of HTA activities. All planned deliverables were presented by the end of the Project, as shown in the Technical Fact Sheet of this report. Additional outputs were also created, as shown by the **emboldened** entries in Table 2 and those in *italics* were altered after initial work.

Table 2: Objectives and planned deliverables for each Work Package

Work Package	Planned Key Deliverables	Actual Key Deliverables
1 Coordination	<ul style="list-style-type: none"> The EUnetHTA organisational structure including a supporting Secretariat Final report from the project EUnetHTA conference presenting the project results 	<ul style="list-style-type: none"> The EUnetHTA organisational structure including a supporting Secretariat Interim and final technical reports EUnetHTA conference presenting the project results Development of proposal for future HTA collaboration in Europe from 2009 onwards Sharing of information about assessments of two specific health technologies (HPV, age-related macular degeneration)

2 Communications	<ul style="list-style-type: none"> • Communication strategy • A clearinghouse functionality - detailed identification of the clearinghouse needs of different target groups and consecutive structure development to be ready for practical application after 3 years • EUnetHTA conference presenting the project results 	<ul style="list-style-type: none"> • Communication strategy • A clearinghouse functionality - detailed identification of the clearinghouse needs of different target groups and consecutive structure development to be ready for practical application after 3 years • EUnetHTA conference presenting the project results • Website/Information platform • <i>Working prototype of the 'HTA Information System' to enable networking and a platform for EUnetHTA tools</i>
3 Evaluation	<ul style="list-style-type: none"> • Internal evaluation of the project • Framework for external evaluation 	<ul style="list-style-type: none"> • Internal evaluation of the project • Framework for external evaluation
4 HTA Core Model	<ul style="list-style-type: none"> • Core HTA structure/model • 2 pilot examples of Core HTAs for different types of questions (e.g. diagnosis and treatment) • A handbook on Core HTA 	<ul style="list-style-type: none"> • HTA Core Model • Pilot examples of HTA core information for medical/surgical interventions and diagnostic technologies • A handbook on HTA Core Model
5 HTA Adaptation Toolkit	<ul style="list-style-type: none"> • A toolkit for adapting Core HTA results from existing HTAs into other contexts <ul style="list-style-type: none"> ◦ including an HTA Glossary of adaptation • Applicability testing of core information from 2 existing HTA reports in various national environments using the toolkit 	<ul style="list-style-type: none"> • A toolkit for adapting core HTA results from existing HTAs into other contexts published on web <ul style="list-style-type: none"> ◦ An HTA Glossary of adaptation terms • Applicability testing on the basis of existing HTA reports in various national environments using the toolkit
6 Transferability of HTA to health policy	<ul style="list-style-type: none"> • EUnetHTA Open Forum for stakeholders to exchange views and expectations/feedback on HTA • A book containing a systematic overview of the HTA & healthcare policy links in selected Member States & EU representing different health systems, remuneration systems, etc 	<ul style="list-style-type: none"> • EUnetHTA Open Forum for stakeholders to exchange views and expectations/feedback on HTA • A book containing a systematic overview of the HTA & healthcare policy links in selected Member States & EU representing different health systems, remuneration systems, etc – “HTA and health policy making in Europe: current status, challenges and potential” • A meeting with stakeholders and discussion/topic catalogue • A strategy proposal for stakeholder involvement in the future
7 Monitoring development of emerging and new technologies and prioritisation of HTA	<ul style="list-style-type: none"> • A prototype of a structured information service on high volume, costly, rapidly developing, emerging technologies • A set of monitoring tools for emerging/new technologies 	<ul style="list-style-type: none"> • A newsletter providing structured information about high impact emerging/new technologies • A web-based toolkit to facilitate European collaboration on evidence generation on promising health technologies

- Handbook on HTA capacity building for Members States with limited institutionalisation of HTA
- Handbook on HTA capacity building for Members States with limited institutionalisation of HTA, based on a survey of HTA organisations
- **Information management in HTA Organisations - Survey Report**
- **HTA Organisations report**
- **HTA curricula worldwide**

It is evident from Table 2 that the EUnetHTA Project achieved its specific objectives, with some additional achievements. However, it was not just production of the deliverable, but the quality and usability of the output that was paramount in this Project which intended to deliver *practical tools* as well as “real-time” transnational collaboration made possible by the processes and facilities developed through the project. Hence the following sections outline the rigorous methodologies used to determine users needs, gather best practice, pilot tools, refine and quality assure these deliverables. Tools to facilitate sharing of information will be addressed first, then systems to support the sharing of HTA knowledge across Europe will be presented.

Tools to facilitate sharing of information

The scope and process of an HTA is heavily dependent on the context of the Member State. HTA reports on the same technology and key policy question can often vary markedly among countries. Hence some form of harmonisation and standardisation of the structure of HTA reports and underlying assessment methods would be helpful. This would enable production of HTA reports to a certain standard and facilitate extraction of information that may be relevant to another Member State or another project.

For medicines, clinical trials methodology to support marketing authorisations has been standardised for over a decade^{xiii}. Guidance is available on the design, conduct, analysis and reporting of trials and evidence summaries. This was approved by industry groups and regulatory agencies in Europe, Japan and the USA and as regulators act as ‘enforcers’ of the guidance it has real impact. This has provided transparency of approach, clarification of the required methodology and enabled readers to use reports more efficiently. For HTA, INAHTA developed a checklist for the content of HTA reports^{xiv}. This is helpful, but the checklist is not sufficiently detailed to create a generic framework suitable for all HTA reports and there is no mandate for implementation.

The EUnetHTA Project aimed to build on all previous work that sought to improve approaches to HTA by the development of practical tools for information sharing. The key elements of this were the HTA Core Model, the HTA Adaptation Toolkit and the system for monitoring new and promising health technologies.

HTA Core Model

The HTA Core Model should define a clear structure for HTA information and provide guidance on the content, i.e. the elements to go in the structure. Standardisation of the individual elements in an HTA report in this way should not only facilitate transparency, improved quality and comprehensiveness in the development of reports, but it should allow the individual elements of information to be extracted from the report.

As the assessment of different types of health technologies can vary, it was recognised that different forms of the core model might be needed. So the EUnetHTA Project developed two applications of the HTA Core Model for the most commonly assessed health technologies, namely medical/surgical interventions and diagnostic technologies.

The HTA Core Model was developed on the basis of the multidisciplinary approach recommended in previous European projects and using the ‘domains’ first defined in the EUR-ASSESS project:

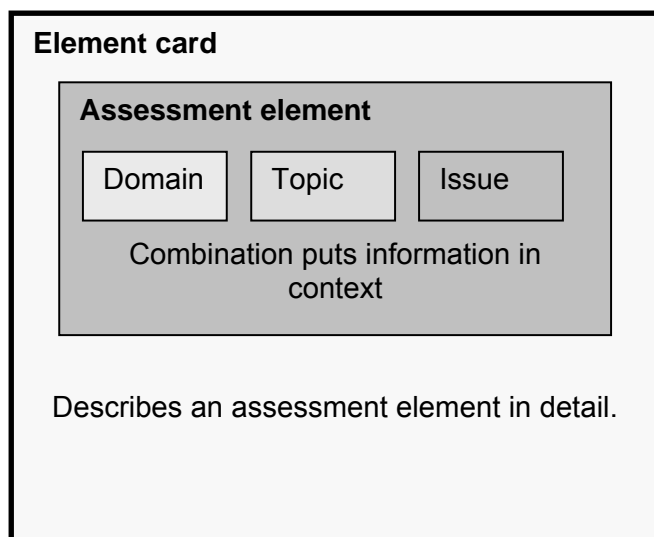
- health problem and current use of technology;
- description and technical characteristics of the technology;
- safety;
- effectiveness;
- costs/economic evaluation;
- ethical analysis;
- organisational aspects
- social aspects; and
- legal aspects.

Within each domain ‘topics’ are defined, with associated ‘issues’ which in turn should be translated to actual research questions. For example, the domain of clinical effectiveness may address the topic of mortality by one

or more questions such as 'What is the effect of the technology on mortality?'. The basic unit of the model is the 'assessment element', which is an issue in a specific topic in a specific domain. (Note there may be similar issues in other domains, e.g. mortality may be assessed in safety, so it is all three levels that define the specific element.)

Each assessment element has an 'element card' that contains the detail about the hierarchical structure of the element and an explanation of its content. This is depicted in Figure 2.

Figure 2. HTA Core Model – Element card



As an example, the final HTA Core Model for medical/surgical interventions currently contains three to eight topics within each domain and six to 29 issues, which is a total of 133 assessment elements. For the diagnostic model, there are three to nine topics in each domain, with six to 31 issues, totalling 153 assessment elements. So on average, in each model, each topic is associated with three issues.

The importance (critical, important, optional) and transferability of assessment elements determines their status in the Core HTA, as shown in Table 3.

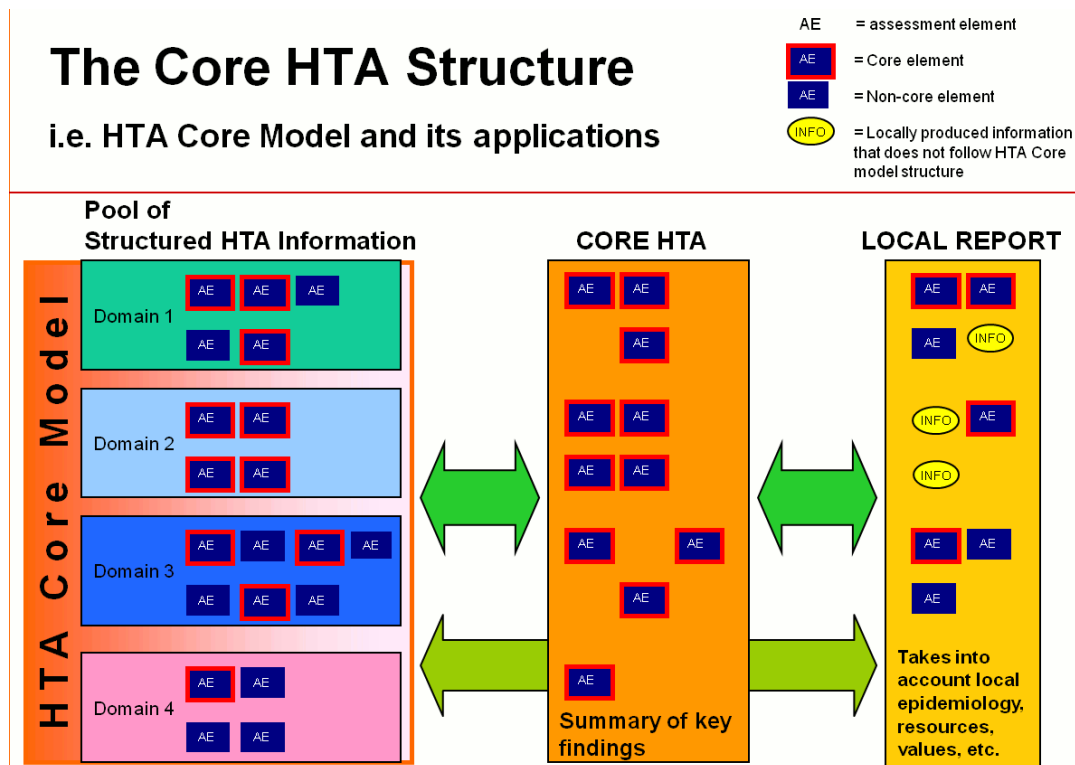
Table 3. Core elements

CORE MATRIX		Importance		
		<i>Optional</i>	<i>Important</i>	<i>Critical</i>
Transferability	<i>Complete</i>	Not core	Core	Core
	<i>Partially</i>	Not core	Core	Core
	<i>Not</i>	Not core	Not core	Core

In practice, core elements can be used to

- take an existing Core HTA and use it as the basis for a local report that considers also local circumstances, epidemiology, resources, values etc to determine recommendations about the use of the technology; or
- HTA producers can utilize the HTA Core Model to freely select elements that are relevant to their context (perhaps limiting the number of domains that are considered) and add local information to the Core HTA, including some non-core assessment elements (See Figure 3); or
- enable distributed production of HTA reports (joint working among institutions) by use of the standard structure.

Figure 3



The HTA Core Model was tested by producing two Core HTAs: one on drug eluting stents vs bare metal stents and one on multi-slice computed tomography for coronary angiography (CT). This work was purely for testing purposes, it was not to create HTA reports for decision-making. These used the distributed production approach, with over 30 investigators from 10 or more countries involved in each HTA led by the WP Lead Partner.

In addition, structured validation of the models was performed twice by Work Package members to obtain detailed feedback on the assessment elements. After the first validation exercise substantial changes were made to the safety, organisational and social domains. After the second validation exercise almost all respondents agreed or strongly agreed with the domain descriptions, methodology chapters, topics, issues and their coverage. There were a few disagreements that were resolved with clarification of terminology, removal of redundant issues and a few additions of essential issues. In this validation exercise, more than 80% of respondents agreed or strongly agreed for seven of the eight questions related to the feasibility of the HTA Core Model. The agreement was less strong for conducting Core HTAs, but still greater than 50%.

This HTA Core Model needs further development to ensure it is optimal for everyday use in HTA. In particular, the different granularity of the model in each domain varies, the terminology and definitions require further harmonisation and there is overlap of domains. The next step is to empirically test the HTA Core Model by applying it to several new HTA topics and using that experience to refine the model.

HTA Adaptation Toolkit

The HTA Adaptation Toolkit sought to facilitate better use of existing HTA reports by developing a toolkit to use parts of HTA reports that could be adapted to inform policy in other countries or contexts. This should reduce the time and costs associated with developing an HTA report and thus free HTA capacity to do more HTAs.

HTA reports can be adapted in a number of ways:

- using the existing report as background;
- building on the original search strategy;
- extracting relevant information; and
- adopting without major changes (with translation if necessary).

Only a very small number are simply adopted. Most will require adaptation of both information and data to take account of local needs, requiring the systematic evaluation and extraction of relevant data and information from an existing report.

In a survey of HTA agencies/networks, the majority of respondents felt that work in the following domains would be more applicable and adaptable across different countries and settings:

- technology use;
- safety;
- effectiveness;
- economic evaluation; and
- organisational aspects.

Consequently these domains were taken forward into the HTA Adaptation Toolkit.

The HTA Adaptation Toolkit is a series of checklists providing a systematic method to determine the policy relevance, and the reliability and transferability of data and information, in an existing report to a new context. It will help the user to determine whether the existing report (or part of it) addresses similar issues, is of sufficient quality and is applicable to the new context.

The HTA Adaptation Toolkit has two sections:

- speedy sifting – a screening tool to enable rapid sifting of existing HTA reports to assess their possibility for adaptation; and
- main toolkit – more comprehensive tool with questions on reliability and transferability.

The Toolkit went through two rounds of quality assurance/applicability testing: firstly to test each of the five domains and the speedy sifting section, then to test the Toolkit in its entirety. This led to changes that were incorporated into the final version.

As part of the HTA Adaptation Toolkit, but also as a standalone deliverable, a glossary was created of HTA terms and concepts relating to adaptation. The glossary does not provide one explanation for each term, but collates the meanings of terms from different HTA organisations and so contains 100 descriptions of 42 terms. It provides a resource for identifying issues related to different uses and meaning of various HTA terms that should be considered when adapting a report from one setting to another.

The HTA Adaptation Toolkit (including glossary) are currently available on the web in pdf form. An interactive version is planned for late 2009. Further testing, review and improvement are required, as is closer integration with the HTA Core Model.

Sharing information on emerging/new technologies and prioritisation of HTA

A growing number of agencies are investing in early identification, prioritisation and assessment of emerging and new technologies in the form of 'horizon scanning', 'alerting' or 'early warning systems'. This proliferation of work led to a call for collaboration to share information and methodologies. As a result, in 1998, the International Information Network on New and Emerging Health Technologies (EuroScan) was founded as a collaborative network of agencies for the exchange of information on important emerging new drugs, devices, procedures, programmes, and settings in health care.

The long-term aim of EuroScan is to establish a permanent network among agencies and organisations involved in early awareness and alert activities to:

- evaluate and exchange information on new and emerging health technologies;
- develop the sources of information used;
- share applied methods for early assessment; and
- disseminate information on early identification and assessment activities.

For the EUnetHTA Project to add value to horizon scanning it was agreed to develop and test a newsletter on new and emerging health technologies that would be distributed to policy makers across Europe. Since this newsletter could potentially impact national agenda setting for discussion of emerging and new technologies throughout Europe, the underlying processes of its production needed to be transparent and reproducible.

To identify potentially interesting technologies that might be suitable for the newsletter, entries that had been added to the EuroScan database in the past six months were listed. Pharmaceuticals within 6 months of authorisation or other technologies already diffused by more than 10% in the EU were removed from the list. Structured information on each of the remaining technologies was then provided to a prioritisation panel of experts from six EU countries. This process resulted in 104 technologies for consideration in a pilot issue of the newsletter and 73 for the first issue. Significance criteria and a scoring scheme were developed with the

prioritisation panel based on a system created by EuroScan and taking account of the anticipated impact of the technology. The average scores were then used to prioritise which technologies should be reported in the newsletter.

The newsletter articles were written in a standard format of one page, providing information on the technology, burden of disease, existing technologies, evidence base, potential impact and references. A pilot issue was sent to policy makers for review in spring 2007. Most felt that the newsletter was relevant (75%) and easy to understand (90%), but only 53% felt that the articles focused on substantial issues. Several wanted more information on clinical and cost effectiveness and did not understand that such information was not available at this early stage. A substantive issue was raised about the timeliness of the reporting as some technologies had already been introduced into healthcare systems. However, this had been partly caused by the use of experts across the EU to score and prioritise topics, which proved time consuming.

The first issue of 'On the Horizon', a newsletter produced by EUnetHTA in collaboration with EuroScan and the National Horizon Scanning Centre in England, was published in 2008 (www.eunetha.net/Communication/Newsletter_WP7_2008). It presented articles on technologies ranging from buccal insulin for diabetes to nicotine vaccines for smoking cessation.

This work showed the importance of sharing information on new and emerging technologies, but that collaboration needs to be developed to satisfy the needs of the intended audiences. In future, this might be better achieved by an electronic information service. Alternatively (as suggested by EuroScan) a database could be developed with a core set of early awareness information on technologies that would allow Member States to develop their own early warning assessments.

Facilitating evidence generation for promising health technologies

Decision makers face increasing pressure to adopt new health technologies as soon as they are available to the healthcare system, to ensure rapid access to innovative treatments. However, at this stage there can still be uncertainty about the real-life benefits, risks and value of the technology in the specific healthcare setting. (Here, uncertainty may relate to wide statistical variation in an estimate of effect or value judgements about the application of controlled trials to a different context). So early decisions to adopt technologies into routine care may prove medically or financially inappropriate, but delaying access could withhold potential benefits. To reduce the risk of inappropriate decisions, high quality, timely assessments with monitoring procedures may be helpful to gather additional evidence on the value of promising technologies that are expected to have a major impact on health care.

The EUnetHTA Project has defined 'Access with Evidence Generation' as a policy mechanism allowing patients access to a promising health technology whilst a critical mass of evidence is generated quickly to inform a subsequent, more robust assessment (with less uncertainty). A survey has shown that such mechanisms have been used for many years in medicines regulation in Europe, particularly in the form of conditional licensing. More recently, HTA has been used to support the reimbursement/coverage of promising technologies with the collection of specific evidence to reduce areas of uncertainty about the use of the technology in a standard clinical setting. This is often called 'conditional reimbursement' or 'coverage with evidence development'.

Several countries are developing such Access with Evidence Generation activities but information on these is not easily accessible. This is a major limitation in this new field of activity where there could be major advantages in sharing experiences. Also the collection of additional data takes time and resources and if information is not shared there could be duplication of activities, either for new clinical studies or in the establishment of systematic data collection, such as registries of prospective datasets. So there is a requirement to share information about planned, ongoing or completed systematic data collection and encourage the funding of prospective studies (including pragmatic trials) to generate new evidence.

To facilitate this sharing of information about decisions relating to Access with Evidence Generation, a web-based toolkit has been created that consists of structured questionnaires and a database for obtaining and storing information. This can be used by HTA organisations to enquire about ongoing work or to share existing work. It provides information about the level of diffusion of the technology in different healthcare systems, the status of any HTA, monitoring actions including protocols and results and use of new evidence for a final reimbursement/coverage decision.

The next step in this collaborative enterprise is to develop tools that facilitate joint working to generate evidence. This may be achieved by agreeing common criteria for data collection and then collecting data simultaneously or collaboratively across several countries.

Sharing HTA knowledge across Europe

The EUnetHTA Project has published two important books that can serve as resources for supporting the development of HTA across Europe.

HTA and health policy making in Europe^{vi} includes systematic reviews and commentaries from a range of perspectives about the relationship between HTA and healthcare policy making. Its aim is to demonstrate how HTA is used in policy making and improve the responsiveness of HTA so that it can effectively inform policy. The book includes chapters that review policy making; the use of knowledge; HTA; health systems, health policy and the link to HTA; the impact of HTA; the needs of policy makers and future challenges for HTA in Europe. It discusses factors that might enhance or hinder the contribution of HTA to policy making, summarises strategies to improve HTA utilization, identifies how HTA agencies in Europe could collaborate to tackle issues and how such efforts might be integrated into quality improvement in health systems.

The *Handbook on HTA capacity building* was based on the results of two surveys of HTA organisations and a consensus workshop discussing the scope, structure, work processes and visibility of HTA organisations. The handbook provides guidance to those establishing a national HTA organisation in a country with limited HTA capacity and is also helpful to other countries where HTA is more developed. The book contains practical advice about the aspects that should be considered when establishing an HTA agency including:

- moving from sporadic HTA to a formal HTA programme;
- aims and scope of an HTA programme;
- organisational and legal framework;
- structure – including human resources and facilities;
- HTA process; and
- dissemination of HTA products.

It includes advice on issues ranging from identification of suitable professionals and training opportunities to securing financial support and promoting interaction with decision makers. Additionally a survey on the information management in the HTA organisations and the HTA curricula compilation has been produced.

Involving Stakeholders

Another important aspect of building the knowledge base about HTA collaboration across Europe was the engagement of stakeholders. The EUnetHTA Project Steering Committee developed a definition of stakeholders that focussed on organisations and outlined the role of stakeholders, as follows:

Stakeholders are groups or organisations which potentially will be affected by, or have an interest in, and may, in a consultative role, influence the actions or aims of an organisation, project or policy direction.

As the EUnetHTA Project addressed collaboration in Europe, focus was placed on European umbrella organisations to ensure that there was no interference with national stakeholder processes.

On this basis, the EUnetHTA Project created a Stakeholder Open Forum to share information and gain feedback from stakeholders. It used a web-based discussion facility and a face-to-face meeting to discuss plans for future HTA collaboration across Europe. At this meeting it presented a draft stakeholder policy. The participants agreed that this policy should be forwarded to those responsible for taking forward collaboration in EUnetHTA in the future along with notes from the meeting and a discussion topic catalogue, which reflected the issues that stakeholders found unclear or problematic.

Communication and information system

The work of the EUnetHTA Project was supported by a state-of-the-art communication system, which included web-based tools such as an e-meeting² facility to support communication between the large numbers of members in each Work Package, who were spread widely across Europe – on average 75 e-meetings were held annually allowing efficient use of resources and reduction of the carbon footprint of the project's activities. A well structured extranet site, with separate areas for each Work Package, allowed members to interact with their own team and see the progress of other work. This created a social network that was a key enabler to the delivery of the outputs. The website had high specification tools including a calendar, group mail, discussion forums, voting functions and form templates. All these helped build the efficiency and capacity of the network.

One deliverable in relation to the EUnetHTA communication and information system was a prototype for a clearinghouse facility, which aimed to provide a single point of access to HTA related information, HTA reports, publication databases and web-based versions of the EUnetHTA tools. A detailed prototype report was published at the start of year 3 of the project, based on innovative information systems technology theories. It underwent review by the Lead Partner organisations and a gradual evolution of current communication tools was developed by the end of the EUnetHTA Project. The resulting HTA Information System platform to be further developed and

² Details of the technology used are described in the EUnetHTA Project 1st Interim Technical report.

implemented in practice includes the EUnetHTA web site, integration of tools developed in WPs, integration of information developed in WPs, a database for proposed, planned and ongoing projects, a contact database of individual members, experts, organisations and groups, communication tools, and personalisation of the website for the individual user. This will be developed further in 2009 as part of the activities of the EUnetHTA Collaboration.

Internal evaluation

Internal evaluations of the project were performed annually to determine how well this large network was working and identify and assist with any difficulties that needed resolution. The evaluations used a variety of qualitative research methods, including individual interviews with Work Package Leaders, surveys of Work Package participants, Secretariat, Steering Committee, Stakeholder Forum and extraction of information from minutes, plans etc. The evaluations concluded that all deliverables were produced in a timely manner, some with delay according to the initial work plan, and effective collaboration between Work Packages was established, but this was time consuming. The large number of participants involved in each Work Package, along with a heavy workload for individuals was challenging and it was noted that sustained participation frequently came from a subset of the whole group. A range of communication methods were used with varying degrees of success and language itself was a challenge. However, the benefits of collaborative working were highly valued, in terms of international experience, knowledge exchange and development of tools.

One organisation left the Project and four joined, resulting in a total of 64 organisations participating at the end. This shows significant commitment of partners and in many cases partners committed additional resources to ensure that outputs were delivered to a high quality and on time. Participants' attitudes towards the new emerging practices improved over the Project period and there was a perception of added value for individual organisations.

2.5 Discussion and recommendations

The EUnetHTA Project

The work of the EUnetHTA Project has involved two clear strands

- delivering tools and information to support HTA in Europe; and
- developing a well-functioning network of national HTA organisations that can share information and undertake joint work.

It has sought to create practical tools and systems that support the development of HTA information to:

- monitor emerging technologies and facilitate new evidence generation;
- enable identification and summarisation of all aspects that impact on the use of a health technology by way of the HTA Core Model; and
- adapt HTA information from one context to another using the HTA Adaptation Toolkit.

It has also provided reference information to support training and development of new and existing HTA organisations.

As presented in Table 2, each Work Package delivered a range of practical tools to improve the quality and timeliness of HTA across Europe. These tools provide high quality information and methodological frameworks for HTA that facilitate sharing of information in and across national or regional systems when health technologies are assessed for new or continued use in health care systems. However, as identified in the internal evaluation, members agree that it will be essential to test all the tools in real life settings, ie for use in everyday HTA work.

A challenge for this Project was that work needed to be undertaken in parallel streams to develop the tools and information systems. Most work was at draft stage in year 2 and finalised at the end of year 3. So given the highly innovative, evolving nature and time consuming work that was required, it was a challenge to have detailed collaboration among sub-projects. This was facilitated by monthly Executive Committee e-meetings, but it was impossible to ensure all details of ongoing work and the terminology being used was consistent across work packages. Hence an important part of the future work will be to consolidate consistency of terminology and structure across tools.

The internal audit found that the dedication and drive of the Project Leadership and Secretariat were instrumental in helping the EUnetHTA Project achieve its objectives; not just the deliverables, but also the well-functioning network. As a result, EUnetHTA members have noted many elements of added value from their collaboration in the Project, including^{xvi}

- advancing methodological developments in the practical application of HTA;
- discussion about the content of HTA;

- providing an arena for increased international collaboration between agencies, institutions, and individuals working with HTA;
- increased international visibility and credibility through participation in the EUnetHTA;
- challenge to thinking about current working processes;
- improved understanding of the role of HTA in relation to other processes in healthcare policy making;
- better connected to HTA colleagues in Europe;
- better informed about HTA processes in Europe; and
- increased attention to stakeholder involvement.

At the EUnetHTA conference in 2008, stakeholders were given the opportunity to comment specifically on the added value of EUnetHTA. An industry representative focused on the value of the HTA Core Model to support collaboration about the required elements of HTA, which will increase the efficiency and quality of the process. Whilst the Director General of the Ministry of Health in Slovenia emphasized the importance of an EU network to build on the work of other countries that have more experience and a colleague of his noted the value of 'gathered expertise' and advice³.

At the end of the Project all Work Packages made recommendations for future work, as summarised in Table 4. Detailed recommendations from each Work Package are presented in the individual Work Package reports later in this document.

Table 4. Working table of recommendations (abridged; see individual WP reports for full recommendation lists)

WP	Key recommendations
1	Build on the effective collaboration established in the EUnetHTA Project to create a permanent, sustainable collaboration for HTA in Europe with robust governance and a practical orientation to good communication, collaborative networks and practical functions.
2	The HTA Information System needs to be continuously developed: web-based tools need to be implemented and members need to be motivated to use tools.
3	The findings of the EUnetHTA Project internal evaluation need to be taken into account when setting up future HTA collaborations.
4	Overlaps in the domains of the HTA Core Model need to be reviewed. Further applications of the model (e.g. for screening, systems that support care, etc) should be considered. An online version of HTA Core Model should be created. HTA organisations should be encouraged to test and apply the HTA Core Model in their work and feedback experiences. The HTA Core Model should be used in education and training.
5	An interactive web-based version of the HTA Adaptation Toolkit should be developed to encourage use of the Toolkit and take suggestions for new terms in the glossary. The Toolkit should be extended to facilitate adaptation of HTA reports on diagnostic screening and screening. The Toolkit should be integrated more closely with other EUnetHTA Project outputs, such as the HTA Core Model.
6	In future collaborations on HTA, efforts should be made to obtain balanced stakeholder representation in a process that will promote legitimacy and which all targeted stakeholders find fair and transparent. The outputs from the EUnetHTA Project (a draft stakeholder policy and associated discussion topic catalogue) should be used as a foundation for continued dialogue and involvement with stakeholders. The links between HTA and policy need to be continually developed, with more focus on regulatory and policy measures (i.e. HTA's relation to management/organisation of health systems). Where evidence is lacking, more primary research needs to be done, especially for context-dependent issues.
7	Methods for disseminating information on new and emerging technologies that satisfy intended

³ http://www.eunetha.eu/News_archive/Whats_the_added_value_of_EUnetHTA/

	<p>audiences need to be developed further, by:</p> <ul style="list-style-type: none"> - using consensus methods to determine the various interests of representatives from EU Member States and creating an electronic information service 'on demand'; and/or - developing a core set of early awareness evidence for some technologies to enable HTA Agencies to develop their own early assessments. <p>EUnetHTA Partners should supply relevant, accurate and up-to-date information to the web-based system collecting structured information about evidence generation for promising health technologies. Develop tools that facilitate joint work to generate evidence in the Access with Evidence Generation framework by agreeing common criteria for data collection and collecting data simultaneously or collaboratively across several countries.</p>
8	<p>The handbook on HTA capacity building should be used as a guide to those wishing to establish a national/regional HTA function, using its approaches to institutional development that learn from experience of existing HTA organisations.</p> <p>An enhanced international coordination strategy for HTA is recommended.</p>

Hence although this Project has been highly successful, there is a need to continue collaboration in HTA across Europe to ensure that all the good work is put into practice, used and developed further. This major recommendation is addressed in the next section.

A sustainable network for HTA across Europe

Policy background

A recent report on the financial sustainability of health care in Europe found that HTA can play a major part in evidence-based decision-making, but it needs to deliver timely and relevant information that reflects the dynamics of technology and the health care systemⁱⁱ. The review notes a number of challenges relating to the use of HTA across Europe:

- many countries have several bodies dedicated to HTA, with unclear roles and responsibilities;
- greater stakeholder involvement is needed to help manage uncertainty (particularly consumers)
- a variety of processes for prioritising technologies for assessment are used that are generally not transparent and focus only on new technologies;
- evidence requirements to support HTA are not uniform and some methodological questions remain; and
- re-assessment must be a key component of the process.

The review concluded that HTA can play a valuable role in health-care decision making but HTA must be *transparent, timely, relevant, and usable*.

Use of EUnetHTA Project tools will ensure that high quality, *relevant* HTAs are produced using a process agreed across Europe, improving *transparency* and *usability*. This harmonisation and standardisation will enable better joint working to gather HTA information and improve the *timeliness* of HTA and its impact. This should also support the Tallinn Charter^{xviii}, agreed in June 2008 by national Ministers of Health in the 52 countries of the WHO European Region. It states that 'health technology assessment should be used to support more informed decision making'. As Sorenson, Kanavos and Drummond indicate^{xvii}, decision-makers should be well equipped to implement decisions that capture the benefits of new technologies, overcome uncertainties and recognise the value of innovation, within the constraints of overall health system resources.

DG SANCO has supported the development of HTA across Europe since the 1990s, as shown by its financial support to previous major projects. Its overall policy aim is to support the development of HTA through collaboration, including the area of pharmaceuticals. This can be achieved by the establishment of a network and development of tools to ensure added value at the EU level. DG SANCO finds that there has been 'very positive' progress on HTA collaboration as a result of the EUnetHTA Project.^{xix}

In July 2008, the European Commission published the proposal for a directive on cross-border health care^{xx}, which provides for the establishment of an EU network for HTA (Article 17). Its intent is to enable Member States to facilitate development and functioning of an HTA network that connects national and regional HTA agencies. This European HTA network will support HTA cooperation and ensure provision of objective, reliable, timely, transparent and transferable information on the short- and long-term effectiveness of health technologies and enable an effective exchange of this information within the network. The European Council, the European Parliament and the European Commission are discussing an EU network for HTA in relation to their handling of the directive proposal as a whole. The process of adopting and implementing a Directive which would include an article on a network of European HTA institutions and its implementation at the Member States level will most likely take several years.

According to the proposed directive, the European Commission will adopt measures to establish and manage the EU network for HTA and define the information to be exchanged^{xviii}. Future developments will be dependent on the interest shown by Member States and the decisions taken on the cross-border health care proposal. If the proposed approach is endorsed, options for the establishment and management of the network will be developed by DG SANCO. Hence a possible communication on HTA could be issued in 2010, but this will depend on the priorities agreed by the new Commission.

Alongside this high-level European policy work, there is a need to ensure the continuity of EUnetHTA and that the work of the Project is used, piloted and developed. So, building on the effective collaboration that has been created in the EUnetHTA Project, the encouragement of the European Commission and the support of Member States that host EUnetHTA members, the Partners have decided to create a sustainable, permanent European HTA collaboration to ensure continuation of communication, collaboration networks and activities. The proposal for this 'EUnetHTA Collaboration' was developed over a 12 month period by the EUnetHTA Project Executive and Steering Committees, which included public consultation and discussions with Member States and DG SANCO. The final version of this proposal was published in June 2008^{xiv}. During the autumn of 2008, a group of 25 organisations in 13 EU Member States, plus Norway and Switzerland worked as 'founding partners' to establish the organisation to create continuity for EUnetHTA beyond 2008. As a result EUnetHTA continues during 2009 as the 'EUnetHTA Collaboration'.

Ultimately the EUnetHTA Collaboration will involve HTA agencies and others involved in the production of HTA information and it is hoped that it will have support of European governments, the European Commission and international health organisations. Its vision is to contribute to the generation of HTAs to inform policy and health care decision making in European countries so that new health technologies can be adopted and obsolete technologies abandoned in a well-informed and robust manner, hence bringing about high quality, safe, accessible, sustainable, ethical and efficient health care for citizens across Europe.

This EUnetHTA Collaboration will develop and implement the work of the EUnetHTA Project aiming to:

- help reduce unnecessary duplication of HTA activities;
- develop and promote good practice in HTA methods and processes;
- share what can be shared; and
- facilitate local adaptation of HTA information.

At the EUnetHTA conference in 2008, a World Health Organisation advisorⁱⁱⁱ stated that a European network of HTA institutions is useful and needed to:

- bridge the know-do gap on all levels of health systems;
- enhance information and knowledge transfer;
- connect global evidence and local decision making;
- enable access to information for all European countries, both rich and poor;
- feed the European research agenda, identifying topics which are relevant for health systems; and
- ultimately strengthen health systems.

The permanent EUnetHTA Collaboration will seek to do this by creating a structure that has robust governance to enable timely and effective decision making and implementation, has a practical orientation to focus on rapid progress that allows cultural and contextual flexibility, supports the functions of the Collaboration and creates long-term viability, utility and value of all activities. Similar to the EUnetHTA Project, the EUnetHTA Collaboration will be driven by a core Executive Committee supported by a coordinating Secretariat and a Plenary Assembly including all Partners.

Its main functions will be to:

- offer a contact point to provide a gateway to the HTA community in Europe;
- provide the European HTA Information and Communication system;
- develop and improve common processes for performing and reporting HTA;
- provide information on emerging/new technologies and facilitate new evidence generation;
- facilitate the establishment and continuous development of HTA institutions; and
- pilot processes for production of HTA core information.

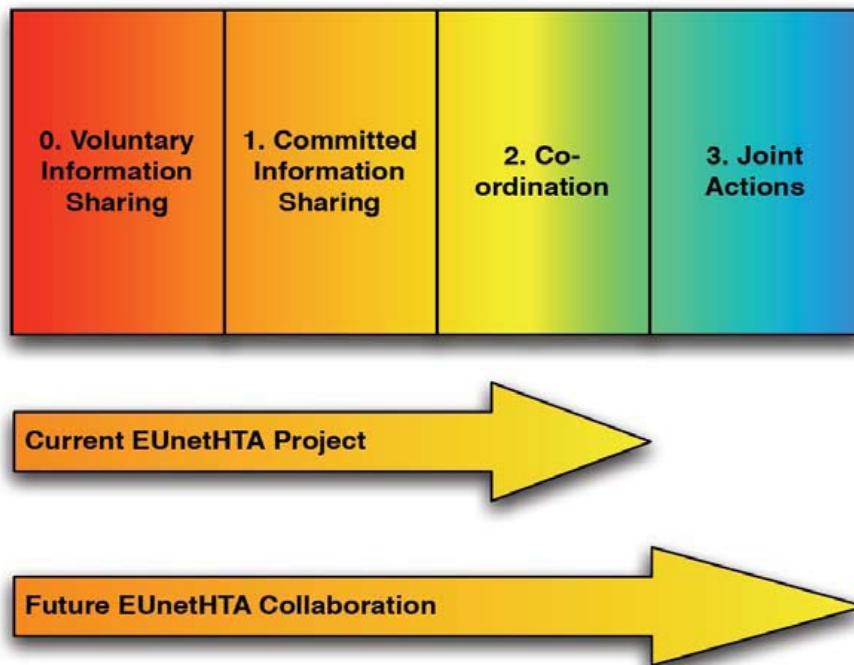
In doing this work, the EUnetHTA Collaboration will take cognisance of the recommendations arising from the internal evaluation of the EUnetHTA Project, namely to:

1. secure funding and maintain a dedicated Secretariat;
2. assure efficiency through an organisational structure made up of well-defined functions (like Work Packages) managed by a core of dedicated partners, with less committed partners taking part as a wider review group;
3. continue developing and evaluating the tools as necessary, and in real settings;

4. involve people in the work to ensure commitment, a high level of knowledge and a broad basis for decision making processes;
5. encourage collaboration and communication among all parties to ensure coherence of work within groups and across EUnetHTA;
6. continue developing the communication platform and clearinghouse functionality to make EUnetHTA the central reference point for HTA in Europe;
7. a face-to-face meeting is important at the start of group work to strengthen social coherence and reach a common understanding of work;
8. evaluate the technical communication platform;
9. continue having English as the main language.

The Collaboration's aim will be to develop the collaborations that have emerged from the EUnetHTA Project so that more coordinated and joint work can be undertaken as shown in Figure 4. This coordinated work on specific HTAs performed in a methodologically sound and transparent way should increase the volume and quality of HTAs.

Figure 4: The “Spectrum of Collaboration”



After this permanent HTA collaboration is fully established it will be important to ensure that it adds value to existing international HTA related networks and is having the desired impact on reducing duplication and improving transparency, efficiency and quality.

2.6 Appendices

2.6.1 Appendix 1

EUnetHTA Project Partners and their participation in Work Packages (WP)

Organisation	Country	WP
EU Member States		
1. Ludwig Boltzman Institute of Health technology Assessment - LBI@HTA (AP)*	Austria	1,5,7
2. Gesundheit Österreich GmbH (CP)*	Austria	4,5
3. Hauptverband der Österreichischen Sozialversicherungsträger (CP)	Austria	5,6,8
4. Health Care Knowledge Centre - KCE (AP)	Belgium	2,4,5,6
5. Ministry of Health (AP)	Cyprus	2,8
6. Centre for Applied Health Services Research and Technology Assessment, University of Southern Denmark - CAST (AP)	Denmark	6,7,8
7. Danish Institute for Health Services Research - DSI (AP)	Denmark	4,5,6
8. Danish Centre for HTA - DACEHTA (Main partner)	Denmark	1,2,4,5,6,7
9. HTA and Health Services Research, Center of Public Health (CP)	Denmark	6
10. University of Tartu, Department of Public Health (AP)	Estonia	4,5,6,7,8
11. Finnish Office for HTA - Finohta (AP)	Finland	1,4,5,6
12. Haute Autorité de Santé – HAS (AP)	France	1,2,5,7
13. Assistance Publique- Hôpitaux de Paris, Direction de la Politique Médicale, Comité d'évaluation et de diffusion des innovations technologiques - CEDIT (CP)	France	6,7
14. German Agency for HTA at the German Institute for Medical Documentation and Information - DAHTA@DIMDI (AP)	Germany	1,2,3,5,6
15. Institute for Social Medicine, Medical University Luebeck (AP)	Germany	4,7
16. Technische Universität Berlin, Department Health Care Management (AP)	Germany	4,5,6
17. Kompetenzzentrum Klinische Studien Bremen, Center of competence for clinical studies Bremen (AP)	Germany	7
18. German HTA Association (CP)	Germany	8
19. Institute for Quality and Efficiency in Health Care - IQWiG (CP)	Germany	6,8
20. Public Health Genetics European Network – PHGEN at German Centre for Public Health Genetics (CP)	Germany	5,6,7,8
21. Health economics and Technology Assessment Unit, Department of Public Policy and Management, Corvinus University of Budapest - HunHTA (AP)	Hungary	2,8
22. Health Information and Quality Authority - HIQA (AP)	Ireland	6,7
23. Agenzia Sanitaria e Sociale Regione Emilia-Romagna (AP)	Italy	2,3,5,7

24. Agenzia Nazionale per i Servizi Sanitari Regionali, Age.n.a.s. (CP from 2007)	Italy	5, 8
25. Università Cattolica del Sacro Cuore, Policlinico universitario "A. Gemelli", Health Technology Assessment Unit and Laboratori of Health Economics (Institute of Hygiene) (AP)	Italy	4,5,6,7,8
26. Regione Veneto (AP)	Italy	2,3,5,7
27. Health Statistics and Medical Technology State Agency - VSMITA (AP)	Latvia	3,8
28. Ministry of Health (AP)	Lithuania	4
29. Central and Eastern European Society for Technology Assessment in Health Care - CEESTAHC (CP)	Poland	8
30. Agency for Health Technology Assessment in Poland - AHTAPol (CP)	Poland	2,4,5,7,8
31. Institute of Molecular Medicine (CP)	Portugal	4,5,6,8
32. National School of Public Health and Health Services Management	Romania	8
33. Institut za varovanje zdravja Republike Slovenije (AP)	Slovenia	5,6,7,8
34. Instituto de Salud Carlos III (ISCIII), Agencia de Evaluación de Tecnologías Sanitarias - AETS (AP)	Spain	3,6,7,8
35. Agencia De Evaluación De Tecnologías Sanitarias De Andalucía - AETSA (AP)	Spain	4,5,7
36. Catalan Agency for HTA - CAHTA (AP)	Spain	1,2,8
37. Galician Agency for HTA (AP)	Spain	4,6,7,8
38. Basque Office for HTA - OSTEBA (AP)	Spain	4,5,7
39. Servicio Canario de la Salud/ Servicio de Evaluación y Planificación / Consejería de Sanidad del Gobierno de Canarias (AP)	Spain	5,6
40. Unidad Evaluación Tecnologías Sanitarias - UETS (AP)	Spain	2,6
41. Swedish Council for Technology Assessment in Health Care - SBU (AP)	Sweden	1,2,3,4,7
42. College voor Zorgverzekeringen - CVZ (AP)	The Netherlands	6,7
43. Netherlands Organisation for Health Research and Development - ZonMw (AP)	The Netherlands	4,5
44. National Coordinating Centre for HTA – NCCHTA (AP)	UK	1,4,5,6
45. Centre for Reviews and Dissemination - CRD (CP)	UK	2
46. National Institute for Health and Clinical Excellence - NICE (CP from 2007)	UK	7
EEA Countries		
47. Directorate of Health (CP)	Iceland	4,5,6,8
48. Norwegian Health Services Research Centre – NOKC (AP)	Norway	1,3,4,5,6,7,8
EFTA Countries		
49. Swiss Network for HTA - SNHTA (CP)	Switzerland	1,2,3,4,5,6,7,8
Other European Countries		
50. Ministry of Health (CP)	Serbia	8

Countries outside Europe

51. Medical services Advisory Committee - MSAC (CP)	Australia	3
52. Canadian Agency for Drugs and Technologies in Health - CADTH (CP)	Canada	2
53. Israelian Centre for technology Assessment in Health Care - ICTAHC (CP)	Israel	7
54. Agency for Healthcare Research and Quality - AHRQ (CP)	USA	2,6
55. Center for Medical Technology Policy – CMTF (CP from 2007)	USA	7

International organisations

56. Health Technology Assessment International - HTAi		6,8
57. European Observatory on Health Systems and Policies (CP)		7,8
58. WHO European Office, Health Evidence Network - HEN (CP)		1,6,8
59. Council of Europe, Directorate General III Social Cohesion (CP)		6,8
60. OECD Biotechnology Division Directorate for Science, Technology and Industry (CP)		3,6,7
61. Guidelines International Network - GIN(CP)		2,4,6
62. International Network of Agencies for HTA - INAHTA (CP)		2,6, 8
63. Cochrane Collaboration, International Secretariat (AP)		2,3,4,5,6,7,8
64. European Information Network on New and Changing Technologies - EuroScan (CP)		2,7,8

Project contacts in other EU Member States

Ministry of Health	Czech Republic	No WP affiliation
Ministry of Health	Greece	No WP affiliation
Ministry of Health	Luxembourg	No WP affiliation
Ministry of Health	Malta	No WP affiliation
Ministry of Health	Poland	No WP affiliation

AP: Associated Partner; CP: Collaborating Partner

2.6.2 Appendix 2

External meetings/presentations of EUnetHTA in 2006-2008

Date	Place	Audience	Content of the presentation	Presenting Institution
01/2006	Trento, Italy	Italian HTA Network Conference	European HTA collaboration, EUnetHTA project	DACEHTA
02/2006	Bielefeld, Germany	PHGEN meeting	EUnetHTA project, organisational aspects in HTA	DACEHTA

02/2006	Brussels, Belgium	Working Group on Relative Effectiveness Meeting	EUnetHTA project	DACEHTA
02/2006	Luxembourg	6 th meeting of the Network of Competent Authorities	EUnetHTA project	DACEHTA
03/2006	Rome, Italy	Meeting the Italian APs in the EUnetHTA project	Regional coordination of HTA in MS	DACEHTA
04/2006	Vienna, Austria	Meeting of Regulatory Bodies on Medical Devices	EUnetHTA project	LBI@HTA
05/2006	Copenhagen, Denmark	Meeting with FIPRA	EUnetHTA project	DACEHTA
05/2006	Copenhagen, Denmark	Meeting with EUCOMED	EUnetHTA project, involving stakeholders in the European HTA process	DACEHTA
05/2006	Paris, France	Senior Management team at HAS	EUnetHTA project, European collaboration on HTA in individual MS	HAS/DACEHTA
06/2006	Brussels, Belgium	High Level Group Meeting	Update on the EUnetHTA project	DACEHTA
06/2006	Manchester, United Kingdom	OECD Expert meeting on "The Evaluation of Clinical Validity and Clinical Utility of Genetic Tests"	EUnetHTA project	HAS
07/2006	Adelaide, Australia	HTAi Annual Conference	EUnetHTA project, Work in Progress	DACEHTA, HAS, LBI@HTA, NCCHTA, FinOHTA
08/2006	Seoul, Korea	World Congress on Medical Physics and Biomedical Engineering 2006 "Imaging the Future Medicine"	EUnetHTA presentation, abstract	MoH of Cyprus (in cooperation with the EUnetHTA Executive)
10/2006	Brussels, Belgium	Working Group on Relative Effectiveness Meeting	Update on the EUnetHTA project progress	DACEHTA
10/2006	Pavia, Italy	Conference "HTA: Evaluazione e Diffusione in Italia"	EunetHTA project, international HTA collaboration	DACEHTA, UCSC
10/2006	Copenhagen, Denmark	ISPOR, 9 th Annual European Congress	EUnetHTA Project: Clearinghouse, emerging technologies and monitoring systems, Core HTA model Development, Adapting HTAs in various contexts	DACEHTA, DAHTA@DIMDI, FinOHTA, NCCHTA (HAS contributed)
10/2006	Bad Gastein, Austria	European Health Forum Gastein	EUnetHTA project, European HTA activities, involvement of the stakeholders in the European HTA process	Diverse group of speakers; organized by DACEHTA (details can be seen on www.eunethta.eu)
11/2006	Montreaux, Switzerland	EUPHA Annual Conference	EUnetHTA project update	DAHTA@DIMDI
11/2006	Seville, Spain	Spanish HTA Network Annual Conference	European HTA collaboration	DACEHTA, AETSA
12/2006	London, United Kingdom	1 st Health Care Winter Symposium, Blenheim Palace	European HTA collaboration	DACEHTA
12/2006	Brussels, Belgium	Meeting with the representatives from DG	Progress of the EUnetHTA project	DACEHTA

		Sanco, Unit C7-Risk Assessment		
12/2006	Luxembourg	7 th meeting of the Working Party on Health Systems	Update on the EUnetHTA project	DACEHTA
12/2006	Brussels, Belgium	Seminar on Health Investments	EUnetHTA project, role of TA in health investment decisions	KCE
12/2006	London, United Kingdom	HTA for Medical Devices across Europe, seminar	Core HTA of the drug eluting stents, EUnetHTA project update	FinOHTA
2007				
03/2007	Vienna, Austria	19 DIA Annual Euromeeting	European cooperation on HTA	DACEHTA
03/2007	Brussels, Belgium	EHMA/Commission's Conference on the Consultation process	Participation in general discussions on the health strategy in Europe	DACEHTA
04/2007	Berne, Switzerland	Annual Meeting of the Swiss HTA Network	EUnetHTA project	DACEHTA
05/2007	Kiel, Germany	ESF-Ifn Conference on the Global Health Economy	EUnetHTA project, international regulation of new medical technology: health technology adoption in the European Union, North America, East Asia, and the developing world	DACEHTA
05/2007	Arlington, USA	ISPOR 12 th Annual International meeting	Participation in the ISPOR HTA Council discussions (EUnetHTA project)	DACEHTA, DIMDI
06/2007	London, UK	Meeting with the Department of Health, NCCHTA	Update on the EUnetHTA project and discussion of plans for the sustainable EUnetHTA collaboration after 2008	DACEHTA/NCCHTA
06/2007	Barcelona, Spain	HTAi Annual Conference	EUnetHTA project, launch of WP4, 5, 7 products; poster presentations from various WPs, and EUnetHTA exhibition (please see detailed description in Chapter 4 of the current report)	FinOHTA, DACEHTA, HAS, LBI/HTA, NCCHTA, DIMDI, University of Bielefeld (details can be found at www.eunethhta.eu)
09/2007	Cartagena, Columbia	ISPOR1st Latin America Conference	EunetHTA project, international HTA collaboration	DACEHTA
09/2007	Prague, Czech Republic	PHGEN project meeting	EUnetHTA project update	DACEHTA
09/2007	Lubeck, Germany	EBM/EBHC course at the University of Lubeck	EUnetHTA project update	DACEHTA, University of Lubeck
10/2007	Helsinki, Finland	EUPHA Conference	EUnetHTA Project, Specifically results from WP4, WP6 and WP8	DACEHTA, CAHTA, FinOHTA
10/2007	Dublin, Ireland	ISPOR European Congress	EUnetHTA project, WP4 Core HTA Model; HTA Council discussions	Diverse group of speakers from EUnetHTA Members organisations
10/2007	Copenhagen, Denmark	EPPOSI Workshop "The reality of Orphan Medicines"	Role of HTA; introduction to EUnetHTA work	DACEHTA

10/2007	Venice, Italy	Medmatic@ Fair	EUnetHTA project (through Regione Veneto exhibition at the Fair)	Regione Veneto
10/2007	Berlin, Germany	Successful Funding and Reimbursement of Medical Devices, HTA workshop	Core HTA of the drug eluting stents, EUnetHTA project update	Technische Universität Berlin
11/2007	Paris, France	Annual Conference of the French Society for Public Health	Oral presentation on sharing information in Europe on health technologies (WP7)	HAS
11/2007	Krakow, Poland	2 nd International Evidence-Based Healthcare Symposium	European HTA collaboration	DACEHTA
11/2007	London, United Kingdom	HTA UK Conference	HTA Adaptation toolkit (WP5); EUnetHTA project	NCCHTA
12/2007	Manchester, United Kingdom	NICE Annual Conference	HTA Adaptation toolkit, EUnetHTA project	NCCHTA
12/2007	Trier, Germany	3 rd European Symposium on pharmaceutical law (organized by Academy of European Law), seminar on HTA	Update on the EUnetHTA project; Core HTA model	Technische Universität Berlin
2008				
01/2008	Rome, Italy	Ministry of Health of Italy	EUnetHTA project results	DACEHTA, UCSC
02/2008	Rome, Italy	HTAi Policy Forum	EUnetHTA project, Preliminary results	NOKC
03/2008	Tel/email contact	EuSANH-ISA F/ project	Potential cooperation with EUnetHTA	DACEHTA, EUnetHTA Executive Committee
03/2008	Tel/email contact	Comparative Effectiveness research/HTA in US, AcademyHealth group, US	European experience in HTA	DACEHTA Project Leader
04/2008	Antalya, Turkey	1 st ISPOR Summer School	HTA Adaptation toolkit translated into Turkish distributed	NCCHTA in collaboration with the Turkish ISPOR Chapter
06/2008	Tallinn, Estonia	WHO European Ministerial Conference on Health Systems	EUnetHTA results; EUnetHTA exhibition	DACEHTA, FinOHTA, HAS, CAHTA
07/2008	Montreal, Canada	HTAi Annual Conference	EUnetHTA project, Preliminary results	DACEHTA, HAS, CAST, CAHTA
09/2008	Seoul, South Korea	ISPOR 3rd Asia-Pacific Conference	EUnetHTA project preliminary results	DACEHTA
11/2008	Paris, France	EUnetHTA Conference "HTA's Future in Europe"	EUnetHTA project results	EUnetHTA partners
11/2008	Athens, Greece	ISPOR 11 Annual European Congress	EUnetHTA project results	DACEHTA, IQWiG
12/2008	London, UK	Health Technology Assessment World Europe 2008	EUnetHTA project results	DACEHTA

Articles on EUnetHTA in 2006

Date	Journal/publication	Article	Author
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03/2006	Bundesgesundheitsblatt - Gesundheitsforschung - Gesundheitsschutz	Toward a sustainable European Network for Health Technology Assessment	DACEHTA
04/2006	Eurohealth	EUnetHTA and health policy-making in Europe	DACEHTA
05/2006	Journal of the European Association for Health Information and Libraries	EUnetHTA - The First European Network to Assess Health Technology	KCE
04/2008	Handbook on HTA, DACEHTA, Denmark	Chapter on EUnetHTA approaches (HTA Core model)	DACEHTA
06/2008	Health Policy, Volume 87	Emerging health technologies: Informing and supporting health policy early	LBI-HTA
06/2008	Policy Brief of the European Observatory on Health Systems and Policies	How can the impact of health technology assessments be enhanced?	Kristensen (DACEHTA) and Busse (TU Berlin) contributed

EUnetHTA WP face-to-face meetings

WP	Location	Number of meetings	Schedule
WP1	Copenhagen, Denmark	3	<ol style="list-style-type: none"> 1. January 27, 2006 2. May 11, 2006 (<i>1st Steering Committee meeting</i>) 3. May 29, 2008 (<i>2nd Steering Committee meeting</i>)
	Barcelona, Spain	1	<ul style="list-style-type: none"> • March 22-23, 2007
	Stockholm, Sweden	1	<ul style="list-style-type: none"> • October 11-12, 2007
	Zürich, Switzerland	1	<ul style="list-style-type: none"> • December 6-7, 2007
	Paris, France	1	<ul style="list-style-type: none"> • April 17-18, 2008
	Vienna, Austria	1	<ul style="list-style-type: none"> • September 25, 2008
	Paris, France	1	<ul style="list-style-type: none"> • November 19, 2008 (WP LPs coordinating meeting in preparation for the EUnetHTA Conference)
WP2	Stockholm, Sweden	1	<ol style="list-style-type: none"> 1. March 17-18, 2006
	Cologne, Germany	2	<ol style="list-style-type: none"> 1. December 8-9, 2006 2. November 26-27, 2007
	Nicosia, Cyprus	1	<ul style="list-style-type: none"> • May 11-12, 2007
WP3	Oslo, Norway	1	<ul style="list-style-type: none"> • February 24, 2006
	Bologna, Italy	1	<ul style="list-style-type: none"> • June 10, 2008
	Venice, Italy	1	<ul style="list-style-type: none"> • October 13-14, 2008
WP4	FinOHTA, Helsinki	3	<ol style="list-style-type: none"> 1. September 19, 2006 2. January 18-19, 2007 (All APs to participate) 3. November 5-6, 2007
	Tartu, Estonia	1	<ul style="list-style-type: none"> • June 5-6, 2008
WP5	London, UK	1	<ul style="list-style-type: none"> • June 4-5, 2006
	Venice, Italy	1	<ul style="list-style-type: none"> • September 27-28, 2007
WP6	Copenhagen, Denmark	1	<ul style="list-style-type: none"> • March 30, 2006
	Berlin, Germany	1	<ul style="list-style-type: none"> • March 15-16, 2007 (workshop with policy makers)
	Rome, Italy	1	<ul style="list-style-type: none"> • June 13, 2008 (meeting with Stakeholders)
WP7	Seville, Spain	1	<ul style="list-style-type: none"> • November 14-15, 2006
	Dublin, Ireland	1	<ul style="list-style-type: none"> • April 12-13, 2007
WP8	Ljubljana, Slovenia	1	<ul style="list-style-type: none"> • March 5-6, 2007
	Barcelona, Spain	1	<ul style="list-style-type: none"> • June 20, 2007
	Santiago di Compostella, Spain	1	<ul style="list-style-type: none"> • October 2, 2008

WPs 4-7	Copenhagen, Denmark	1	<ul style="list-style-type: none"> March 31, 2006
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Other EUnetHTA face-to-face meetings

Dates	Location	Meeting objective
Jan 12, 2006	Stockholm, Sweden	WP1 and WP2 Lead partners meeting to develop the Project Launch strategy
Jan 16, 2006	Stockholm, Sweden	WP2 Lead Partners meeting, SBU and DAHTA (DIMDI)
October 3-6, 2006	Bad Gastein, Austria	WP1/6 LP organised a parallel Forum at the European Health Forum Gastein – launch of the EUnetHTA dialogue with Stakeholders
November 24, 2006	Stockholm, Sweden	EpiServer (EUnetHTA website editing software) Training course for Editors in each Work package
December 5, 2006	Luxembourg	WP1 LP presents EUnetHTA to the Health Systems Working Party (on request from DG SANCO)
December 14, 2006	Southampton, UK	WP5 LP and WP2 Co-Lead Partner met to discuss the needs of WP5 in developing the webbased solution for the Adaptation toolkit
December 15, 2006	Brussels, Belgium	WP1 LP meeting with DG SANCO C7 Unit (C7 took over from Unit C2 the coordination of the EUnetHTA project on the Commission's side)
March 30, 2007	Paris, France	WP7 LP and WP2 Co-Lead Partner met to discuss the needs of WP7 in developing the database prototype
April 25, 2007	Brussels, Belgium	WP1 LP meeting with the DG SANCO C7 coordinators, discussion of the project progress (1 st Interim report)
June 15-20, 2007	Barcelona, Spain	Launch of the WP4, 5, 7 products at the HTAi conference (EUnetHTA workshop); WP1,2,4,5,7 Lead Partners organized the workshop. EUnetHTA exhibition.
September 20, 2007	Brussels, Belgium	WP1 LP meeting with the DG SANCO C7 coordinators, discussion of the project progress
October 11, 2007	Stockholm, Sweden	WP2 Lead Partner coordinating meeting, SBU and DAHTA (DIMDI)
October 30, 2007	Paris, France	WP7 LP and WP2 Co-Lead Partner met to review the solutions presented by the WP2 Co-Lead partner
November 11-12, 2007	Paris, France	WP1, 2 and 7 Lead Partners' (EUnetHTA Conference Organising Committee) meeting in preparation for the EUnetHTA Conference (November 20, 2008). Meeting with the conference bureau and visit to the conference venue.
January 28, 2008	Brussels, Belgium	WP1 LP meeting with the DG SANCO C7 coordinators, discussion of the project progress (2 nd interim report)
February 7, 2008	Helsinki, Finland	WP4 Group on Social Aspect of the core model meeting
July 10, 2008	Brussels, Belgium	WP1 and WP4 Lead partner presentation of the EUnetHTA project progress and EUnetHAT Collaboration proposal to the High Level Group on Medical Services (on request from DG SANCO)
September 3, 2008	Brussels, Belgium	WP1 LP meeting with the DG SANCO, discussion of the project progress and future steps to ensure sustainability of the European network for HTA
October 8, 2008	Stockholm, Sweden	WP1 and WP2 meeting in preparation for the EUnetHTA Conference in Paris (Nov 20, 2008)
October 14, 2008	Paris, France	Project Leader and WP7 Lead Partner meeting to discuss preparations for the EUnetHTA Conference (as part of the French EU Presidency)
October 24, 2008	Brussels, Belgium	WP1 LP meeting with the DG SANCO, discussion of the project progress and future steps to ensure sustainability of the European network for HTA (Relative Effectiveness issues)
November 20, 2008	Paris, France	EUnetHTA Conference "HTA's Future in Europe" (open for attendance by all EUnetHTA partners and other interested parties)

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3 WP1 Tasks and Activities Performed in 2008

Work Package 1	Coordination
Lead Partner (LP)	Main Beneficiary: NBoH Denmark (Danish Centre for HTA (DACEHTA) (<i>LP in WP6</i>)
Partners Involved	Associated Partners: LBI@HTA, Austria (<i>Co-LP in WP7</i>) DAHTA@DIMDI, Germany (<i>Co-LP in WP2</i>) FinOHTA (STAKES), Finland (<i>LP in WP4</i>) HAS, France (<i>LP in WP7</i>) NOKC, Norway (<i>LP in WP3</i>) CAHTA, Spain (<i>LP in WP8</i>) SBU, Sweden (<i>LP in WP2</i>) NCCHTA, United Kingdom (<i>LP in WP5</i>) Collaborating Partners: SNHTA, Switzerland WHO-HEN

3.1 Objectives 2008

According to the 3-year WP1 Work Plan, the activities in 2008 focused on the following objectives:

- Preparation and promotion of the EUnetHTA Conference (to be held on November 20, 2008, Paris, France)
- Timely completion of the project and output deliverance
- Agreements with the European Commission and other possible funders on further steps in EUnetHTA development (after the project completion in 2008)

3.2 Activities

Preparation and promotion of the EUnetHTA Conference (November 20, 2008, Paris, France)

The conference preparation was lead by the conference Organising Committee (reporting to the EUnetHTA Executive Committee) which was comprised of the representatives from WP1,2 and 7 Lead Partner organisations and the hired conference bureau Europa Organisation. The Secretariat and the WP2 Lead Partner (SBU) developed the first conference announcement which the secretariat distributed electronically and with a limited number of paper copies through the EUnetHTA partners and at the relevant conferences. The conference programme was produced later in the year for electronic and paper distribution (eg, the Secretariat has reached an agreement with the European Health Forum Gastein to mutually promote each other's events). The Conference was an official event of the French EU Presidency (July-December 2008).

Please see WP2 report on the details of preparation and outcomes of the conference.

Timely completion of the project and output deliverance

Project Coordination

During 2008 there were no changes in the composition of the Work Package Lead Partners.

The project was coordinated by the main beneficiary National Board of Health of Denmark (Danish Centre for HTA (DACEHTA) located in Copenhagen (Denmark) in cooperation with the nine Associated Partners that act as Lead and Co-Lead Partners in the respective WPs:

WP1 – Coordination: National Board of Health, Copenhagen Denmark

WP2 – Communications: *Lead Partner* - SBU, Swedish Council on Technology Assessment in Health Care, Stockholm, Sweden; *Co-Lead Partner* (Clearinghouse strand) - DAHTA@DIMDI, German Agency for HTA at the German Institute for Medical Documentation and Information, Cologne, Germany

WP3 – Evaluation: NOKC, Norwegian Knowledge Centre for the Health Services, Oslo, Norway

WP4 – Common Core of HTA: Finnish Office for HTA/STAKES, Helsinki, Finland

WP5 – Applying common core information and adapting existing HTAs into local/national settings: NCCHTA, National Coordinating Centre for HTA, Southampton, United Kingdom

WP6 – Transferability of HTA into health policy: National Board of Health, DACEHTA, Copenhagen, Denmark

WP7 – Monitoring emerging/new technology development and prioritization of HTA: *Lead Partner* - HAS, Haute Autorité de santé / French National Authority for Health, Paris, France; *Co-Lead Partner* - LBI@HTA, Ludwig Boltzman Institute of Health Technology Assessment, Vienna, Austria

WP8 – System for support of countries without institutionalized HTA: Catalan Agency for HTA and Research, Barcelona, Spain

Due to reported difficulties in collaborating with one of the partners, the Executive Committee initiated an internal audit that was performed by the WP3 Lead Partner. The Executive Committee and the concerned partner discussed the results of the audit, and the partner made consequential adjustments in their participation in the project.

The main beneficiary acted as the Coordinating Secretariat for the whole of the project. Table 2.1 lists the DACEHTA staff contributed to the EUnetHTA project in 2008.

Table 2.1 Overview – EUnetHTA Coordinating team at DACEHTA 2008

DACEHTA Coordinating team

Finn Børlum Kristensen (Project Leader)

Julia Chamova (Project coordinator)

Marie Louise Bistrup (Research Assistant)

Julie Shea (Assistant Project coordinator)

Camilla Palmhøj Nielsen (coordinator for WP6 – DACEHTA is WP6 Lead Partner)

Note: a number of DACEHTA employees are providing input to the work of various WPs

WP1 coordinating meetings

WP1 held a coordinating face-to-face meeting on April 17-18, 2008 in Paris, France (hosted by Haute Autorité de santé (HAS)). On September 24, 2008, Vienna, Austria a meeting was organised by the Secretariat and LBI-HTA (Austria) to discuss the solutions of the continuing activities in the EUnetHTA Collaboration. A meeting in preparation for the EUnetHTA conference was held on November 19, 2008 in Paris.

In addition, regular monthly e-meetings have been held to monitor the progress of the work within the WPs and coordinating the activities in the project.

The 2nd meeting of the EUnetHTA Steering Committee, May 29, 2008, Copenhagen

The EUnetHTA Steering Committee meeting was convened on May 29, 2008 to discuss and adopt the final version of the EUnetHTA Collaboration proposal. The proposal was endorsed by the Steering Committee and was published on the EUnetHTA website on June 16, 2008.

2nd Interim Technical Implementation Report and Financial Reports

The technical report was prepared in collaboration with the WP Lead Partners and submitted to the Commission on time. Based on the results of the financial reporting the Secretariat performed an extensive analysis of the expenditure per partner and per cost category and in collaboration with the Associated Partners performed the budget adjustments in 2008. These adjustments led to the amendment of the Grant Agreement that was accepted by the Commission.

The instructions for preparation of the Final Technical Implementation and Financial reports were made available to the WP Lead Partners in September 2008, and to the Associated Partners – in November 2008.

Coordination of a common publication of the project results in the International Journal of Technology Assessment in Health Care

As a part of the reporting of the aproject results a Common publication strategy for the EUnetHTA project was adopted in December 2007; the strategy implementation process was coordinated by the Secretariat; WP Lead Partners were developing the individual articles to be included into the publication in the International Journal of Technology Assessment in Health Care.

- Common texts about the EUnetHTA project was developed by WP1 Lead Partner – May 30, 2008
- Work title, estimated number of pages and proposed lead and co-authors for the article were delivered by the WP Lead Partners to the Secretariat in May-June 2008
- Draft article were submitted to the Secretariat (WP1 Lead Partner) in December 2008

- Final articles were submitted to the Journal in February 2009 for review and publication as a Special issue.

Agreements with the European Commission and other possible funders on further steps in EUnetHTA development (after the project completion in 2008)

Following 2 rounds of internal review and a public consultation on the proposal for the EUnetHTA Collaboration an overview of the public consultation feedback was prepared and placed on the EUnetHTA website in February 2008. All original responses were published on the EUnetHTA website on 15 January 2008.

The next version of the proposal based on the results of the internal review and public consultation was developed by the EUnetHTA Executive and presented to the Steering Committee for discussion and adoption (the proposal was endorsed by the Steering Committee at the 2nd Steering Committee meeting in Copenhagen, May 29, 2008). The proposal was made public on the EUnetHTA website on June 16, 2008. The proposal as well as the results of the EUnetHTA project were presented during the EUnetHTA Conference in Paris, November 20, 2009. On July 9, 2008 the Secretariat and the EUnetHTA Executive Committee representatives presented the EUnetHTA project and the proposal to the members of the High Level Group on Medical Services at a meeting in Brussels.

Following the discussions with the Commission's representatives in early September 2008 which indicated apparent lack of immediate appropriate mechanisms of the Commission's support for continuation of the EUnetHTA activities in 2009, a group of the EUnetHTA partners (25 organisations, 13 Member States, Norway and Switzerland) took an initiative in cooperation with their respective Ministries/Departments of Health to support the continuation of activities in EUnetHTA in a framework of the EUnetHTA Collaboration. The budget for the activities was developed and an appropriate formal agreement was put in place by the end of the project period. The EUnetHTA Collaboration has been operational from January 1, 2009.

4 Work Package 2: Communications – Report on results and activities 2006-2008

4.1 Summary

The 3-year EUnetHTA project involved 63 organisations from 29 European countries, as well as Canada, United States, Israel and Australia. As the members were geographically spread, and there were a limited number of face-to-face meetings scheduled, there was a need for different communication tools.

Work Package 2 Communication, has been responsible for internal and external communication within the EUnetHTA project. Work Package 2 had 50 members from 22 organizations and 14 countries. The EUnetHTA effort was organised in 8 Work Packages, each managed by a Lead Partner. SBU, Sweden, was the Lead Partner of Work Package 2, and DAHTA/DIMDI, Germany, was the Co-Lead Partner, responsible for the Clearinghouse project.

The EUnetHTA Information platform and the Secretariat has been the heart of the internal and external communication in EUnetHTA. The work of Work Package 2 depended upon the information, the needs, and the concrete products coming out of the other Work Packages.

Early in the project, a distinct visual identity was developed including a EUnetHTA logotype. An information package was also developed with external and internal e-newsletters, PowerPoint templates, fact sheets and some exhibition material. All information material was web based, and available on the EUnetHTA website. Only a limited number of copies were printed.

The EUnetHTA website included a public website, a Members-only site and 8 extranets, one for each Work Package. The content management system (CMS) EpiServer was used when developing the website. The CMS made it easier to update the website, regardless of programming skills and contained several functions and tools to choose from and to integrate into the website. A number of functions and tools were included in the EUnetHTA website, eg, calendar, search engine, subscription function, discussion forum and group mail function. The website facilitated communication and information exchange among partners, and made the project's products, progress and results easily accessible to external audiences.

A communication strategy formed the base for the communication in the project. The objective was to write a practical strategic document that would serve as a guide in the daily communication effort. The purpose was to identify how to communicate to achieve the goals of EUnetHTA. The Communication strategy was an internal document, published on the Members-only site.

The Clearinghouse project was an effort to develop a single point of access to all HTA relevant information. The Clearinghouse prototype document was delivered in January 2008. The Clearinghouse prototype was evaluated by the Work Package Lead Partners (Executive Committee) and it was decided not to develop the Clearinghouse as it was described in the report. Instead a small-scale, step-wise approach was chosen to develop the EUnetHTA website already in place.

The original task was to develop a prototype of a Clearinghouse, not a running system. That task was completed with the deliverance of the Clearinghouse report. The development of a running HTA Information System was an added project, performed by the Lead Partner SBU, during the last three months of the project. Several new functions and communication tools were added to the EUnetHTA website, for example virtual work rooms, check-in/check-out files, a new contact database, a function to send short messages, a new module for sending e-newsletters, an interactive comment function and a database for proposed, planned and ongoing projects. The HTA Information System needs to be continuously developed. The web-based tools need to be implemented and members need to be motivated to use the tools.

Work Package 2 also supported members of the other Work Packages in communication and web issues, eg, developing web-based forms for Work Package meetings, developing a dedicated part of the website for the Work Package 6 Open Stakeholder Forum, and design and production of the Work Package 7 e-newsletter "On the Horizon".

4.2 Methods

The Communication Group, Work Package 2, was formed by 50 individual members from 22 organisations and 14 countries. There were four face-to-face meetings during the project, and two e-meetings, together with several meetings in smaller sub groups. Work Package 2 was divided in two main subgroups, the Communication group and the Clearinghouse group. The Communication group was lead by SBU, and the

Clearinghouse group by DAHTA/DIMDI. Later a smaller subgroup was formed to develop the Clearinghouse prototype. The last step – the development of the HTA Information system – was performed by the Lead Partner SBU.

The Content Management System, EpiServer, was chosen when developing the EUnetHTA website, and the HTA Information System. All Work Package Lead Partners were offered training in EpiServer to be able to edit their own extranets.

The development of the EUnetHTA website and the HTA Information System followed an iterative model. The development was performed stepwise. Members needs were the starting point of the development. The other Work Packages were represented in the Work Package 2, which was helpful, when analysing user needs.

4.3 Manpower for the Execution of the Activities

The manpower resource used comprised time from SBU and DAHTA/DIMDI staff, time of Partners participating in meetings providing comments, and refining drafts, and time of partners developing the Clearinghouse prototype. There have been a number of Deliverables, Milestones and other activities performed by Work Package 2, during the 3-year project (See Appendix 1 Activity List Work Package 2).

Partners Involved

Work Package 2 was divided into two subgroups, the Communication Group and the Clearinghouse group. SBU (Sweden) was leading the Communication group and DAHTA/DIMDI (Germany) was leading the Clearinghouse group. Later a smaller Clearinghouse subgroup was formed, working with the Clearinghouse prototype document.

Lead Partners

SBU, Sweden (Lead Partner)

DAHTA/DIMDI, Germany (Co-Lead Partner)

Associated Partners

ASR, Italy

CAHTA, Spain

Cochrane Collaboration, United Kingdom

DACEHTA (NBoH Denmark), Denmark

HAS, France

HunHTA, Hungary

IQWIG, Germany

KCE, Belgium

Ministry of Health Cyprus, Cyprus

Regione Veneto, Italy

UETS, Spain

Collaborating Partners

AHRQ, United States

AHTAPol, Poland

CADTH, Canada

CRD, University of York, United Kingdom

EuroScan

G-I-N Executive, Germany

INAHTA (SBU, Sweden)

SNHTA, Switzerland

WIHE, Switzerland

The members of the Communication Group had different professional backgrounds, for example in medicine, health economics, project management, information science and communication. Many members also represented the other Working Groups, with was helpful when analysing user needs.

Many practical tasks were performed by the Lead Partner SBU, with the internal expertise in graphic design, web design, web production, and content management. Besides communication and marketing, Susanna Allgurun Neikter (SBU, Sweden) was responsible for design of the logotype and graphic profile, design and production of printed material, design of the EUnetHTA web site, PowerPoint templates, exhibition material, etc. Susanne Eksell (SBU, Sweden) served as the EUnetHTA Web Content Manager during the project, and was responsible for developing and updating the EUnetHTA website, and helping the other Work Packages. The main team for the practical development of the EUnetHTA Information Platform and the EUnetHTA Information System consisted of Susanne Eksell and Susanna Allgurun Neikter, with help from computer programmers and input from Work Package 2 members and other EUnetHTA members. Julia Chamova, Project Coordinator (DACEHTA, Denmark) was also providing support in EUnetHTA communication and in content development of the EUnetHTA web site. Julia Chamova served as editor of the public EUnetHTA website, and Susanne served as editor of the Members-only site.

The Clearinghouse project was lead by Hans-Peter Dauben and Alric R  ther from DAHTA/DIMDI, Germany. Responsible for the Clearinghouse prototype document were: Hans-Peter Dauben (Lead author), Alric R  ther (DAHTA/DIMDI 2006–2007, IQWIG 2008, Germany), Stelios Christofides (Ministry of Health Cyprus), Charalambos Yiannakkaras (Ministry of Health Cyprus), Patrice Chalon (KCE, Belgium), Christoph K  nzli (SNHTA, Switzerland), and Malene Fabricius Jensen (DACEHTA, Denmark).

The communication strategy was written by Susanna Allgurun Neikter (SBU, Sweden), in collaboration with Nina Rehnqvist (SBU, Sweden) and with input and support from the Work Package 2 members. The section about the Clearinghouse project was written by Hans-Peter Dauben.

The EUnetHTA Conference Organising Committee had the following members: Julia Chamova (DACEHTA, Denmark), Susanna Allgurun Neikter (SBU, Sweden), Susanne Eksell (SBU, Sweden), Sun Hae Lee Robin (HAS, France), Esther Pensado (HAS, France), Fabienne Quentin (HAS, France), C  line Moty-Monnerau, and members from the conference bureau Europa Organisation.

Countries Involved

There were members from 14 countries represented in Work Package 2. Altogether, in the EUnetHTA project, there were 33 countries represented, 25 from EU countries.

The Work Package 2 lead and coordination took place in Sweden. The lead and coordination of the Clearinghouse project took place in Germany.

There were four Work Package 2 face-to-face meetings, one in Sweden (organised by SBU), one in Cyprus (organised by Ministry of Health Cyprus), and two in Germany (organised by DAHTA/DIMDI).

In the Communication Strategy it was clearly stated that EUnetHTA should focus on communication on the European level. EUnetHTA should leave communication, dissemination of information and efforts to change practice at the national and regional levels to the various EUnetHTA Partners.

Twelve European countries were represented in Work Package 2:

- Belgium: KCE
- Cyprus: Ministry of Health
- Denmark: DACEHTA
- France: HAS
- Germany: DAHTA/DIMDI, G-I-N and IQWIG
- Hungary: HunHTA
- Italy: ASR and Regione Veneto
- Poland: AHTAPol
- Spain: CAHTA and UETS
- Sweden: SBU
- Switzerland: SNHTA and WIHE
- United Kingdom: Cochrane Collaboration and CRD

United States and Canada were also represented in the group:

- United States: AHRQ
- Canada: CADTH

The international organisations EuroScan and INAHTA were also members of Work Package 2.

As all EUnetHTA information was published on the Members-only site, all members had access to the information. As soon as the information was made public, the information was published on the public website.

4.4 Achievement of the Aims and Objectives

Milestones and Deliverables

The 3-year project included several Milestones and Deliverables for Work Package 2:

Common logo/graphic profile, 3-year plan & info package

- Milestone April 2006 – *completed on time*

EUnetHTA website/info platform launch

- Milestone June 2006 – *completed on time*

An elaborate communication strategy of the network

- Deliverable December 2006 – *completed on January 20, 2007, delivered*

Seminar/open meeting at the HTAi Conference 2007

- Milestone June 2007 – *completed on time*

A Clearinghouse functionality

- Deliverable December 2007 – *completed on January 29, 2008, delivered*

EUnetHTA Conference (project results and future plans presented)

- Deliverable November 2008 – *completed on time, delivered*

Final report from the project

- Deliverable December 2008 – *due after the completion of the project, preparation work commenced*

HTA Information System

- The last project, the development of the running HTA Information System, was not originally planned. New tools and functions were added to the website already in place.

Work Package 2 Objectives

Work Package 2 was linked to the EUnetHTA objective:

- Effective dissemination and handling of HTA results, information sharing and co-ordination of HTA activities through the development and implementation of elaborate communication strategies and Clearinghouse activities.

The overall objective for the Communication group was:

- Facilitate coherent, effective and sustainable external and internal communication of the project, where its aims, objectives, work in progress, results and final products are known to all Partners, identified stakeholders and target groups on the EU and national/regional levels.

Clearinghouse Objectives

Several of the Work Package 2 Objectives, as stated in the project application, were linked to the Clearinghouse prototype:

- Identify scientific literature databases of relevance to HTA and ways to provide access to support the work of the project members.
- Provide common data structures and common communication interoperability of information systems building on existing systems and databases such as INAHTA's HTA Database.
- Offer structures for semantic interoperability.
- Explore best solutions to providing a contemporary electronic publishing facility for results, methodological and scientific developments and public information of the network.
- Provide structure for assuring the quality of the information produced by the network.
- Development of a model for the future operation of the Clearinghouse (including organisational, management, and financial aspects) in regard to the needs of members and external target groups.
- Development of a Clearinghouse prototype to describe the functionalities in preparation for the future implementation of a running Clearinghouse.

4.5 Results

EUnetHTA Project Launch 2006

External Project Launch January 31, 2006

A press release was sent electronically to selected specialised periodicals/mass media outlets, associations for healthcare professionals, patients, and health care industry, industry associations, as well as patient associations at the EU and international level.

The aim was to create awareness of the project and its aim to:

- Enable effective exchange of information and support to policy decision in the EU member states.
- Invite stakeholder participation in the HTA process in Europe on the EU and international level.

A list of different target groups was compiled in due time before the project launch, for example: professional/scientific associations, patient associations, mass media and specialised periodicals, relevant international organisations, EU contacts and relevant national HTA-related organisations.

A temporary public website was developed within the Main Partner DACEHTA's information platform.

Internal Project Launch February 7, 2006

To facilitate communications within the network a first temporary version of the Members-only-site was opened in time for the internal project launch. The website was developed within the CMS system hosted by SBU.

Template Text

A template text was prepared by the Secretariat for the Ministers of Health and relevant health policy bodies informing about the project aims, objectives, and activities. The EUnetHTA Partners took the responsibility to translate and adjust the text to local context and distribute to relevant healthcare policy bodies.

Paragraph (Short Text)

A paragraph was prepared and sent out for the members to put on their websites, in e-newsletters etc. The aim was to create awareness of the project on the national/regional level. The paragraph informed about the project start and was sent to the Partners for inclusion in their respective communication media.

Competition

To encourage members to visit the EUnetHTA web site, a competition was arranged (sudoku). The aim was to create a positive interest around EUnetHTA and enhance the traffic to the website.

3-year Work Plan

Early in the project, a 3-year work plan was developed for Work Package 2. The work plan included time frames, milestones, deliverables and detailed action lists. The Work Package 2 work plan was included in the overall EUnetHTA work plan.

Visual Identity

Graphic Profile and EUnetHTA Logotype

Early in the project, a clear visual identity for the project was developed, by the Work Package 2 Lead Partner. The EUnetHTA logotype and graphic profile has been used in all communication on the web, in PowerPoint presentations, communication materials, etc. The common graphic profile and symbol made it easier to gain and maintain recognition. The graphic profile included colours, fonts, symbols, illustrations and photographs. A European map was included among the pictures. The logotype was available in different formats to be downloaded from the Members-only site.

The EUnetHTA logo is a symbol of communication, cooperation, networking and energy. The EUnetHTA symbol looks like the sun, projecting a lot of energy. It has a distinct look and is easy to remember. The logotype has a hidden message – HTA, which made it become a discussion item.

A symbol was created for each Work Package be used on the website, in Power Point-presentations, and communication material together with the logotype.

A Graphic Guide was put together so that members could more easily use the graphic profile. The guide explains how and when to use the EUnetHTA logotype, the EU logotype, the Work Package Symbols, the colours, the pictures, etc.

The European Commission co-financing was acknowledged in all publications, on the website and different types of communication (presentations, conferences, seminars, printed material, etc).

Information Package

Electronic and Printed Material

EUnetHTA has been focusing on producing electronic information material to be downloaded from the website. A limited number of copies has been printed and handed out at meetings and conferences, eg, the HTAi Meeting. All design and development of communication material was done in-house. Most of the material was also printed in-house, however, printing offices were used for the conference invitation and conference material.

The aim was to have more electronic than printed material. One overall fact sheet for the EUnetHTA project and one for each Work Package was compiled. The fact sheets were handed out at conferences, exhibitions, and meetings. PDF versions of the fact sheets have been available on the Members-only site so that they could be printed out by each Partner organisation. The different work packages have presented their results in a variety of printed material during the project following the EUnetHTA graphic profile. A bookmark promoting the EUnetHTA Paris Conference was developed and spread on meetings, eg, the HTAi Meetings in Barcelona and Montreal. To be able to identify EUnetHTA members during meetings and conferences, a EUnetHTA pop button was produced.

PowerPoint Presentations

PowerPoint templates with a variety of slides have been put together using the EUnetHTA graphic profile. Intended for external presentations, internal presentations and tables, they incorporate the logos of both EUnetHTA and the EU, together with the Work Package symbols.

Exhibition Material

Exhibition material was produced for the HTAi Meeting 2007 in Barcelona and for the EUnetHTA Paris Conference 2008. A large EUnetHTA exhibition screen (3 times 2 meter) was produced, as well as a floor stand with the EUnetHTA logotype and some additional signs. The material put together for exhibition purposes will also be used at future conferences and meetings. A poster was made from EUnetHTA's overall fact sheet for the European Health Forum Gastein 2006.

Internal e-newsletter – Members Update

The EUnetHTA Members Update has been sent to all EUnetHTA Partners once a month. The Secretariat, with help from Work Package 1, compiled and edited the information. The Work Package 2 Lead Partner (SBU) was responsible for developing the design of the newsletter. The EUnetHTA members were responsible for distributing the newsletter to their colleagues. The Members Update was also published on the Members-only site.

External e-newsletter – The EUnetHTA Newsletter

The EUnetHTA Newsletter has been sent from the Secretariat to the EUnetHTA e-newsletter subscribers (number of current subscribers December 2008: 580). The newsletter is published electronically. The newsletter is a tool to facilitate consistent exposure of news and information about EUnetHTA. It also strives to attract more visitors to the EUnetHTA website. The newsletter includes links to the site and highlights news that appears there (Newsletter archive: www.eunethta.net). The Partner organisations of some countries will translate the newsletter before forwarding it to their e-mail subscribers and contacts.

EUnetHTA Website/Information Platform

EUnetHTA has had a public website for external communication with different target groups and stakeholders and a Members-only site (including a login function) for internal communication between Partners. There have also been 8 extranets, one for each Work Package, for communication within each working group. The Members-only area has had a login function, including a username and password.

When developing the EUnetHTA Information Platform, one of the first tasks was to develop a wish list specifying structure, functions, and information needed together with priority.

The EUnetHTA website was developed using a Content Management System (CMS) called EpiServer. The CMS made the website easy to update for anyone from any computer regardless of programming skills. Development of the EUnetHTA website follows the Web Accessibility Initiative (WAI) Guidelines for universal accessibility. The guidelines have been recommended for all governmental agencies of EU Member States, and the European Commission co-finances the WAI project.

An EpiServer training course was offered to all Lead Partners responsible for editing the extranets. The course was arranged and financed by SBU in Stockholm during the autumn 2006 (travel to the meeting was included into the EUnetHTA budget of individual participating organisations). SBU and the Secretariat also trained relevant personnel from Lead Partner organisations in EpiServer, either through telephone meetings or the e-meeting system, Centra.

The Public Website, www.eunethta.net

The content of the public website expanded during the project as information from the Work Packages was published and transferred from the Members-only site. The website included information about EUnetHTA, its members, the results of the project, links to HTA organisations, important HTA sources, etc. The website was developed continually in accordance with the Communication strategy and the needs of the different Work Packages. EUnetHTA has been focusing on producing electronic communication material to be downloaded from the website. Three domain names have been registered: www.eunethta.net, www.eunethta.org and www.eunethta.eu. During 2007 the domain name www.eunethta.de was registered for the Clearinghouse prototype.

Some practical functions and tools have been available on the EUnetHTA public website:

Subscription function: Visitors could sign up for the EUnetHTA Update, an e-newsletter that was sent to subscribers and specified target groups.

Search engine: The Members-only site included a search engine.

News function: News was listed automatically on the home page.

The Members-Only Site

The Members-only site has been open to all EUnetHTA Members. On the site they could find minutes, work in progress, invitations to meetings, results of the project, calendar, etc.

Some practical functions and tools have been available on the Members-only site:

Members contact database: EUnetHTA Members have been entered into a contact database on the Members-only site. The database includes contact information for all individual members.

Search engine: The Members-only site included a search engine.

Group mail function: The group mail function made it possible to e-mail all members of a Work Package or subgroup, whose addresses were constantly updated by the Secretariat.

Calendar: A calendar has been developed to keep track of conferences, meetings, etc.

Form template: The template made it easy to create forms for surveys and invitations to meetings.

Eight Extranets

Each Work Package had its own dedicated extranet that was accessible through the Members-only site. The extranet contained working documents, minutes, meeting agendas, internal documents, financial information and other features. The extranets was updated by respective Lead Partner or by the EUnetHTA web master, at SBU. Relevant personnel from each Lead Partner have been trained in EpiServer.

Links, Web Portals and Statistics

During 2008 there were 89 646 unique visitors to the EUnetHTA website. During the three year project different ways of optimising the EUnetHTA websites' ranking in Google and other search engines, have been considered. Most EUnetHTA Partners have information about EUnetHTA on their websites and have also established links to the EUnetHTA website (104 links to the public website). We have also registered the website at key web portals as Google and MSN. In December 2008 there were 3 200 links to EUnetHTA.

E-meetings

During the EUnetHTA project an e-meeting system, Centra (www.saba.com/centra) was used frequently (approx 75 e-meetings were held annually). The e-meeting facility was proven valuable for group discussions in between the scheduled face-to face meetings and allowed efficient use of resources and reduced spending on travel (also contributing to the reduction of the carbon emissions from travel). The e-meeting facility provided opportunities for participants to sit at their own computer, discuss live (microphone and speakers needed), chat, watch slides, share files, etc. The meetings have been recorded so that a playback was made available immediately after the meeting to all invited to the e-meeting (even if they did not participate in the meeting itself). All Associated Partners could also use the e-meeting system free of charge for collaboration meetings inside their own organisations. Collaborative Partners could participate in e-meetings, but not set up their own meetings.

Communication Strategy

The Communication Strategy was a project Deliverable and was published on the Members-only site and sent to the Commission on January 23, 2006. The document (55 pages including appendices and an Executive Summary) was for internal use only. The strategy was drawn up for the 3-year project. Once the network has become sustainable and continuous, the strategy will have to be adjusted accordingly.

The purpose of the strategy was to identify how and to whom we must communicate to achieve the goals of EUnetHTA. The strategy included target groups and messages, as well as channels and activities for the internal and external communication. One of the key components was to focus on cooperation and collaboration with

EUnetHTA Partners and with other relevant external target groups and stakeholders. The communication of EUnetHTA has only focused on the European level, the national and regional levels have been left to the Partners.

Publication Guidelines

Communication to various audiences on the objectives, the plans, and the results of the EUnetHTA project are critically important for success in establishing a sustainable network of HTA in Europe. SBU contributed to the development of the publication guidelines that include principles of publication, presentation and other public communication in EUnetHTA. Openness and transparency are the main priorities of the Publication Guidelines. The Publication Guidelines set the terms on which we agree to receive and provide information, striking the balance between transparency and confidentiality. The guidelines were a part of the Standard Operating Procedures (SOP) Manual that was developed at the start of the project and made available to the EUnetHTA partners on the Members-only website.

The Clearinghouse Project

The Clearinghouse could be described as a system offering a single point of access to all HTA related information. The Clearinghouse is a tool to improve coordination and cooperation between HTA institutions and interested persons especially in Europe. The overall aim of the prototype was to identify EUnetHTA partners' needs and to integrate them into an IT infrastructure.

The Clearinghouse prototype identified needs and requirements on how a system could be set up to:

- Explore best solutions to provide an information exchange platform and contemporary electronic publishing facility for results, methodological and scientific developments and public information of the network.
- Provide common data structures and common communication interoperability of information systems building on existing systems and databases. In addition to offer structures for semantic interoperability.
- Make identified scientific literature databases of relevance to HTA accessible.
- Provide structure for assuring the quality of the information produced by the network.
- Provide security to the whole IT infrastructure.
- Find ways to provide all this to the network.

A challenge was to find a common understanding of wordings and methodologies. The Clearinghouse prototype was prepared by a small Clearinghouse subgroup, lead by DAHTA/DIMDI. The Clearinghouse prototype document (99 pages plus appendices) was delivered on January 29, 2008, to the European Commission, and published on the EUnetHTA website.

The deliverable offers a model for the future operation of the Clearinghouse, including considerations of the organisational, management, and financial aspects. It also offers a prototype describing the functionalities of the Clearinghouse in preparation for the future implementation of a running system.

Evaluation of the Clearinghouse Prototype

In spring 2008, the Clearinghouse prototype was reviewed by the Executive Committee, that consisted of the EUnetHTA Lead Partners. The Work Package 3 Lead Partner NOKC (Norway) was responsible for the evaluation process. They carried out an audit of the Clearinghouse strand of the Work Package 2. Included in the report were the results of a survey among the Executive Members and a survey among the authors of the Clearinghouse prototype deliverable. The review was done from different viewpoints – HTA professionals, IT specialists, and coherence with the existing EUnetHTA Information Platform capabilities. In addition a web consultant was asked to review the technical aspects of the prototype.

The Lead Partners agreed not to pursue at present the development of the Clearinghouse prototype as it was described in the document. The Clearinghouse project would have involved a big investment and the state of the understanding of the overall needs for the coherent, user-friendly, understandable (by the majority of users) system was not in place. Instead another approach was chosen – to develop through a step-wise approach the website already in place. It was decided that SBU, as the Work Package 2 Lead Partner, should continue the development of the EUnetHTA HTA Information System.

To develop a running HTA Information System was not originally planned, this was an aim that was added late in the process. The original task was to develop a prototype, not a running system. This task was taken one step further by developing a running HTA Information System, during the last three months of the project.

The EUnetHTA HTA Information System

When developing the HTA Information System, several functions and tools were added to the existing EUnetHTA website, eg, a new contact database, different communication tools, and a database for proposed, planned and ongoing projects. Information and tools from the other Work Packages were also included in the system.

Several web-based tools and functions were included in the HTA Information System:

Contact Database

- Each EUnetHTA member can update information and upload images and documents
- Individual members, expert, organizations, and working groups could be included in the contact database
- The contact database is connected to email and a message system
- The contact database makes it possible to find experts with special backgrounds and knowledge
- You can extract different lists in spreadsheet format from the database

Communication Tools

- **Virtual workrooms including interactive notice board:** Communication tools to facilitate working together, eg, share information and documents, upload images, participate in discussions
- **Check-in/check-out files:** Upload and download document and pictures directly on the website
- **e-newsletter function:** This module makes it possible to send many e-newsletters at the same time
- **Discussion forums:** To discuss different topics and be able to follow the threads in the discussion
- **Search engine:** To find relevant information
- **Database tool, voting tool, survey tool, and a draft appraisal tool:** Tools to set up a database, to vote, to make a survey and to support the appraisal process
- **Interactive tool to submit comments:** To be able to make comments directly on the website
- **Message system (an alternative to email):** To be able to send short messages to other members directly from the Members-only site
- **Subscription on automatic updates:** Be alerted when new information is published on the website by email. A possibility to choose frequency of the updates

Database for Proposed, Planned and Ongoing Projects

- Each member can submit and edit information about their organisation's HTA projects
- If the information is not updated an automatic reminder will be sent
- The database will make it possible to avoid duplication of effort and to collaborate early in the HTA process

Personalization of the Website

- Different members can be given different access rights, eg, to edit information, enter virtual workrooms, and start their own working groups
- Members-only is adapted to each individual with name, photo, contacts, links, etc
- This function enables tailor-made information and services according to individual interests and needs

Tools Developed in Other Work Packages

- **Open stakeholder forum (Work Package 6):** To support communication with stakeholders on the European level
- **Core HTA model (Work Package 4):** To develop a common methodology for HTA to support collaboration and sharing of results
- **Web-based toolkit for adapting core HTA results (Work Package 5):** To facilitate the local adaptation and use of HTA in Europe
- **Glossary of HTA adaptation terms (Work Package 5):** To enhance understanding
- **Set of tools for monitoring new emerging technologies (Work Package 7):** To provide tools to monitor the development of health technologies and to provide information on new and emerging technologies

Information Developed in Other Work Packages

- **EUnetHTA and European Observatory book on HTA and policy-making:** To connect HTA and policy-making in Europe
- **EUnetHTA Handbook on HTA Capacity Building:** To support HTA in countries with limited institutionalization of HTA
- **Newsletter on emerging technologies "On the Horizon".**

The HTA Information System needs to be continuously developed. The web-based tools need to be implemented and members need to be motivated and encouraged to use the tools.

Conferences and Meetings

The Annual HTAi Conference

HTAi Meeting 2006, Adelaide, July 2–5

The annual HTAi Meeting is a major international conference of the global HTA community. Participation in this meeting was already planned in the EUnetHTA project proposal. In June 2006, EUnetHTA arranged a lunch session at the HTAi Conference in Adelaide and presented proceedings from the various Work Packages. There were 70 participants registered for the session. The EUnetHTA factsheet was available at the SBU booth and handed out during the lunch session.

HTAi Meeting 2007, Barcelona, June 17–20

EUnetHTA arranged a pre-conference session at the HTAi Conference in Barcelona in June 2007. The focus was on the proceedings from the Work Packages. It was the public launch of the first results from Work Package 4, 5 and 7. In collaboration with Work Package 2, Work Package 1 was responsible for the session. The session was very successful with 95 participants (instead of projected 70 participants).

EUnetHTA had many active members during the conference. Members from Work Package 2 (Clearinghouse), Work Package 5, Work Package 6 and Work Package 8 presented posters. Members from EUnetHTA also had two oral presentations. As many EUnetHTA members participated in the HTAi conference, it was also an important internal marketing channel and an opportunity to meet colleagues and get updates from the work packages.

In the EUnetHTA booth the results from the Work Packages were presented. Work Package 2 (SBU) was responsible for the design and production of the booth, as well as logistics. The aim was to raise awareness of and interest in EUnetHTA. During the coffee breaks the Lead Partners were invited to the booth to present the results from their Work Packages. They showed PowerPoint presentations on a big plasma screen and answered questions. Between the presentations a slide show run with pictures from EUnetHTA meetings. A competition was arranged in the booth to create interest around EUnetHTA.

Work Package 2, in collaboration with the other Work Packages, was responsible for producing fact sheets and other printed material that was handed out on the pre-conference session and in the EUnetHTA booth. A bookmark promoting the EUnetHTA Paris Conference was also distributed. To be able to identify EUnetHTA members during the conference, a EUnetHTA pop button was produced.

Exhibition material was produced for the conference: a large EUnetHTA exhibition screen (3 times 2 meter), a floor stand with the EUnetHTA logotype and some signs. The material put together for exhibition purposes will also be used at other conferences and meetings.

HTAi Meeting 2008, Montreal, July 6–9

It is important to connect EUnetHTA to running international HTA societies and networks. Duplication of work should be avoided and the connection to international developments, especially in methods, has to be assured.

There was no EUnetHTA booth, as the HTAi conference in Montreal was outside Europe. However, EUnetHTA had an exhibition space in the SBU booth, promoting the EUnetHTA Paris Conference. An Eiffel Tower was displayed and the EUnetHTA conference invitation was handed out together with some give-aways (EUnetHTA pen, pop button and bookmark). Additional printed material was also handed out at the EUnetHTA presentations. The EUnetHTA Conference invitation was included in the HTAi conference bag. Oral and poster presentations of the results from Work Package 7 and Work Package 8 were included in the conference programme.

The HTAi meeting is an important marketing channel, as many EUnetHTA members and other contacts will come to the conference, and it is an opportunity to meet colleagues and have meetings. Special remark will be set on collaboration of EUnetHTA with other international HTA activities. The aim has been to identify pathways for collaboration and exchange.

Health Forum Gastein

The European Health Forum Gastein (EHFG) is an annual event to reach important stakeholder groups like, national healthcare politicians, EU parliament members, patient organizations, administrators, European research organizations, medical device and pharmaceutical industry top management. The meeting is held in Bad Gastein, Austria.

Health Forum Gastein, October 4–7, 2006

EUnetHTA organised a session at the European HTA Parallel Forum at the European Health Forum Gastein. The event was the first step in putting together a mechanism for stakeholder involvement in the European HTA process (The Open EUnetHTA Stakeholder Forum). EUnetHTA representatives made presentations. A poster was made for the conference of the EUnetHTA overall fact sheet.

Health Forum Gastein, October 1–4, 2008

An agreement was reached with the EHFG Organising Committee to mutually promote EHFG conference and EUnetHTA Paris conference: a EUnetHTA Paris Conference flyer was printed for the Health Forum Gastein 2008 and put in the conference bag. A number of EUnetHTA partners attended the conference on their own initiative and participated in the discussions during the EHFG 2008.

The EUnetHTA Conference, Paris 2008

The final results from the 3-year EUnetHTA project and plans for the next steps after the completion of the project were presented at the EUnetHTA Conference “HTA’s Future in Europe” in Paris on November 20, 2008. Work Package 2 organised the conference in collaboration with Work Package 1. The Organising Committee (reporting to the Executive Committee) included representatives from the Secretariat, SBU and HAS. The conference venue was the “The Pasteur Institute” in Paris.

The conference was fully booked (440 people registered for the conference). Approximately 70 VIP guests were invited for free. A dedicated part of the EUnetHTA website was set up (www.eunetha.net/Paris), with updated information on the conference.

The results from the Work Packages were presented in a plenary session. A panel discussion followed with representatives from the work packages together with invited representatives from different stakeholders. There were high level speakers both for the opening and for the closing of the conference. During the breaks there were discussion stations with representatives from the work packages. Work Package 4 had produced a brochure presenting the HTA Core Model. There was also one station for international collaboration, with invited representatives from the international HTA organisation INAHTA, HTAi and EuroScan. After the conference there was a cocktail reception.

A conference portfolio was put together and handed out to conference participants. A EUnetHTA bag contained the Conference program, a participant list, the Work Package 6 book “Health technology assessment and health policy-making in Europe – Current status, challenges and potential”, a EUnetHTA block-of-pads, a EUnetHTA pen, a EUnetHTA bookmark, and a USB stick with the results from the Work Packages 5, 7 and 8.

Planning of the Conference

The professional conference bureau (Europa Organisation, Paris, France) was contracted by the Secretariat already in 2006 to begin practical preparations of the conference (venue search, catering arrangements, social programme, etc). In 2007 Work Package 2, in collaboration with the Secretariat, started to plan the EUnetHTA Conference in Paris November 20. A bookmark was produced to promote the conference. It was handed-out on the HTAi Meeting in Barcelona and distributed to the EUnetHTA partners to be spread at various relevant events in their respective countries. The EUnetHTA conference was promoted on conferences in France, eg, “Société Française de Santé Publique annual meeting”, SFSP in Montpellier 2007 and “First HAS annual meeting” in Paris.

In autumn 2007 the first information about the conference was published on the EUnetHTA website and a dedicated web page was set up. A form was developed for visitors to register to receive information about the EUnetHTA Conference 2008.

The Organising Committee included members from the Secretariat (DACEHTA, Denmark), SBU (Sweden), HAS (France) and the Conference Bureau “Europa Organisation”. The Organising Committee had meetings, visited the Conference venue, and met with the Conference Bureau in Paris.

An electronic invitation for the Paris Conference was produced by SBU, in collaboration with the Secretariat. The 1st Announcement of the EUnetHTA Paris Conference was sent from the Secretariat in February 2008 to EUnetHTA members together with selected target groups on the European and international level, eg, specialised periodicals/mass media outlets, and associations for healthcare professionals, patients, and health care industry. It was also sent to people that had registered on the EUnetHTA website. The EUnetHTA Partners were responsible for promoting the conference on the national and regional level, and were asked to publish information on their websites and to forward the invitation to their own contacts. Web banners in different sizes were produced by SBU to promote the conference. Later a printed conference invitation was produced and distributed to the EUnetHTA members and to selected target groups (March–April 2008). The conference invitation was also distributed on the Health Forum Gastein in October 2008.

Proceedings from the Conference

All presentation and audio files from the EUnetHTA Paris Conference are published on the EUnetHTA website, www.eunetha.net.

The conference attracted a wide variety of target groups’ representatives: conference participants included HTA professionals (38%), industry (25%), health policy makers (15%), health professionals (5%), health administrators (4%), and other (13%). Among the participants that registered as “other” were representatives of

the European Commission (DG SANCO, DG Enterprise), EMEA, various health policy consulting companies, patient organisations, social security institutions, research institutions, universities, other EU-sponsored projects. Information from the conference was published on a number of occasions in newsletters of the organisations participating in the conference (eg, European Patient Forum, HOPE; EUnetHTA partner organisations, eg, DACEHTA, FinOHTA).

An evaluation of the conference was performed. An evaluation form was sent via e-mail by Europa Organisation to all participants (367 individuals). 20 completed forms were received in response. The overall evaluation results (for details please see the report, Appendix 2) and response received by the Secretariat through informal communication, showed good satisfaction with the content and organisation of the conference.

4.6 Additional Activities and Outcomes

Help to Other Work Packages

The Work Package 2 Lead Partner, SBU, has been assisting the EUnetHTA members in communication issues and with practical issues, as web production and graphic design. The Co-Lead Partner DAHTA/DIMDI supported the Work Packages in developing i-tools. During the project several Work Packages has been assisted:

EpiServer Training

- Organising EpiServer training course for Lead Partner representatives, in Stockholm 2006
- Continuous EpiServer training and help for editors.

Registration Forms

- Developing Web-based registration forms for Work Package meetings.

Work Package 4

- Support for the development of an i-tool for integration of the common-core-process into the Clearinghouse (Clearinghouse project).

Work Package 5

- Publishing and developing functions for a web based glossary.
- Developing a form for members to comment on the HTA adaptation glossary.
- Support for the development of an i-tool for facilitating the process of adaptation of HTA products (Clearinghouse project).

Work Package 6

- Developing a dedicated part of the website for the EUnetHTA Open Stakeholder Forum. The first dedicated web pages were published in summer 2007. They include an open forum for stakeholders, FAQ, a discussion forum, and a possibility to vote if interested or not participating in the forum. The Open Forum will be an avenue for stakeholders and HTA doers, where to comment on existing approaches of involvement.

Work Package 7

- Design and production of the e-newsletter "On the Horizon", developed by Work Package 7 in collaboration with the University of Birmingham.
- Support for the development of an i-tool for defining and describing emerging technologies (Clearinghouse project).

Communication to Commissioning Parties and Stakeholders

The EUnetHTA project has been committed to a transparent communication to the commissioning parties (DG Sanco and Associated Partners) and to different stakeholder groups. Regular EUnetHTA Members Updates are issued, the public website news section is updated when appropriate, and EUnetHTA news (electronic newsletter) is sent to a list of subscribers. Contact through regular e-mail, telephone and face-to-face meetings are maintained with the contact persons at the European Commission. The Associated Partners are responsible for the communication about the project developments on the national and regional level.

EUnetHTA Presentations

During the project there have been several presentations of the EUnetHTA project in international conferences (see Appendix 2, Overview Chapter). Individual Associated Partners also gave presentations in their local institutions and briefings at their respective Ministry of Health.

EUnetHTA Articles

Information about the EUnetHTA project has also been published in different articles and journals. The aim has been to create awareness of the project. There have also been several articles about the results coming out of the Work Packages. However, the majority of the publications are planned for the end of the project, when presenting the project results (see Appendix 2, Overview Chapter).

Final report from the Project

Report to the Commission and publication in a scientific journal

The final results from the project including the proceedings will be included in a final report. A common publication strategy for the project developed by the Secretariat was approved by the Executive Committee: the results of the project will be published in the main issue of the International Journal of Technology Assessment in Health Care, in a peer reviewed edition, at the end of 2009. Individual articles presenting the results from each Work package are prepared by the Work Package Lead Partners in collaboration with the relevant EUnetHTA partners. The Secretariat coordinated the submission to the Journal and assistance with editing to ensure consistency between the articles.

A 4 000 word article, presenting some of the Work Package 2 results, has been prepared for the International Journal of Technology Assessment in Health Care. The preliminary title is: "Towards a new information infrastructure in HTA – Communication, Design, Process and Result". The authors are Susanna Allgurun Neikter, Nina Rehnqvist, Måns Rosén and Helena Dahlgren, from SBU in Sweden.

Individual Work Packages are going to seek opportunities to publish individual articles in other relevant journals as well.

Work Package 2 Meetings

Meetings 2006	Location	Date
Meeting with Project Coordinator at SBU	Stockholm, Sweden	January 12, 2006
Work Package 2 Lead Partner Meeting, DAHTA to SBU	Stockholm, Sweden	January 16, 2006
1st Work Package 2 Meeting at SBU,	Stockholm, Sweden	March 17–18, 2006
HTAi Conference, EUnetHTA presentation, and presentation material, Work Package 2 Informal Meeting	Adelaide, Australia	July 3–6, 2006
HTAi Conference, EUnetHTA Lunch Meeting,	Adelaide, Australia	July 3, 2006
EpiServer Training Course for Editors in each Work Package,	Stockholm, Sweden	November 24, 2006
2nd Work Package 2 Meeting at DAHTA@DIMDI	Cologne, Germany	December 8–9, 2006
E-meeting regarding the Clearinghouse	e-meeting	December 20, 2006
Meetings 2007	Location	Date
Communication Strategy	e-meeting	January 10, 2007
3rd Work Package 2 Meeting	Nicosia, Cyprus	May 11–12, 2007
Pre-conference session, HTAi Conference	Barcelona, Spain	June 17, 2007
EUnetHTA Booth PowerPoint-presentations and presentation material, HTAi Conference	Barcelona, Spain	June 17–20, 2007
Work Package 2, Lead Partners Meeting	Stockholm, Sweden	October 11, 2007
EUnetHTA Conference Meetings with Organising Committee and Conference Bureau	Paris, France	November 11–12, 2007
4th Work Package 2 Meeting	Dusseldorf, Germany	November 26–27, 2007
Meetings 2008	Location	Date
HTA Information System meetings between SBU and web programmers, several meetings between September and December	Stockholm, Sweden	Autumn 2008
EUnetHTA Conference Meeting, SBU and Project Coordinator	Stockholm, Sweden	October 8, 2008
EUnetHTA Conference, Organising Committee	Telephone Meetings	October 23, November 4, November 12, 2008

EUnetHTA Conference meetings with Organising Committee and Conference Bureau "Europa Organisation"	Paris, France	November 18, 2008
EUnetHTA Conference preparations with Organising Committee and Conference Bureau	Paris, France	November 19, 2008
EUnetHTA Conference Paris	Paris, France	November 20
5 th Work Package 2 Meeting	Stockholm, Sweden	Cancelled

2006

1st Work Package 2 Meeting, Stockholm, March 17–18, 2006

The main topics on the first Work Package 2 Meeting were the upcoming milestones: the EUnetHTA logotype, the graphic profile, the 3-year work plan and the EUnetHTA website/information platform launch. The Communication strategy and the Clearinghouse project were also discussed.

Present Associated Partners: SBU (Lead Partner, Sweden), DAHTA@DIMDI (Co-Lead Partner, Germany), ASR (Italy), CAHTA (Spain), Ministry of Health (Cyprus), DACEHTA (Denmark), HunHTA (Hungary), HAS (France), KCE (Belgium), Regione Veneto (Italy), and UETS (Spain)

Apologies Associated Partners: Cochrane Collaboration (UK)

Present Collaborating Partners: INAHTA (SBU, Sweden), and WIG (Switzerland)

Apologies Collaborating Partners: AHRQ (USA), CCOHTA (Canada), CRD (UK), EuroScan (UK), and G-I-N (Germany)

2nd Work Package 2 Meeting, Cologne, December 8–9, 2006

The main topic on the second Work Package 2 Meeting was the upcoming deliverable, the Communication strategy. The Clearinghouse project was also discussed.

Present Associated Partners: SBU (Lead Partner, Sweden), DAHTA@DIMDI (Co-Lead Partner, Germany), Cochrane Collaboration (UK), Ministry of Health (Cyprus), DACEHTA (Denmark), HAS (France), KCE (Belgium), and UETS (Spain)

Apologies Associated Partners: ASR (Italy), CAHTA (Spain), and HunHTA (Hungary)

Present Collaborating Partners: AHTA Pol (Poland) and WIG (Switzerland)

Apologies Collaborating Partners: AHRQ (USA), CCOHTA (Canada), CRD (UK), EuroScan (UK), G-I-N (Germany), and INAHTA (SBU, Sweden)

2007

Communication Strategy e-meeting, January 10, 2007

An e-meeting about the Communication strategy was arranged by SBU on January 10. The topic was the Executive Summary.

Present Associated Partners: SBU (Lead Partner, Sweden), DAHTA@DIMDI (Co-Lead Partner, Germany), HAS (France), KCE (Belgium) and Ministry of Health Cyprus.

Apologies Associated Partners: ASR (Italy), Cochrane Collaboration (UK), DACEHTA (Denmark), HunHTA (Hungary), Regione Veneto (Italy) and UETS (Spain).

Present Collaborating Partners: INAHTA (SBU, Sweden) and SNHTA (Switzerland).

Apologies Collaborating Partners: AHRQ (USA), AHTAPol (Poland), CADTH (Canada), CRD (UK), EuroScan (UK), G-I-N Executive (Germany) and WIHE (Switzerland).

3rd Work Package 2 Meeting, Cyprus, May 11–12, 2007

The main topic for the third face-to-face meeting was the Clearinghouse-project. Other topics were the HTAI Meeting in Barcelona and the EUnetHTA Conference in Paris 2008. How to implement the communication strategy was also discussed.

Present Associated Partners: SBU (Lead Partner, Sweden), DAHTA@DIMDI (Co-Lead Partner, Germany), CAHTA (Spain), DACEHTA (Denmark), HAS (France), HunHTA (Hungary), KCE (Belgium), Ministry of Health Cyprus and UETS (Spain).

Apologies Associated Partners: ASR (Italy), Cochrane Collaboration (UK) and Regione Veneto (Italy).

Present Collaborating Partners: INAHTA (SBU, Sweden), SNHTA (Switzerland) and WIHE (Switzerland).

Apologies Collaborating Partners: AHRQ (USA), AHTAPol (Poland), CADTH (Canada), CRD (UK), EuroScan (UK) and G-I-N Executive (Germany).

Work Package 2, Lead Partner Meeting, Stockholm, October 11, 2007

DAHTA@DIMDI and SBU had a meeting in Stockholm about the progress of the Clearinghouse strand in conjunction with the Work Package 1 Meeting.

EUnetHTA Conference Meetings, Paris, November 11–12, 2007

The Organising Committee for the EUnetHTA Conference in Paris 2008 (the Secretariat, SBU and HAS) had meetings in Paris in the beginning of November, 2007. They met the Conference Bureau (Europa Organisation) and visited the conference venue, the Pasteur Institute.

4th Work Package 2 Meeting, Dusseldorf, November 26–27, 2007

The fourth Work Package 2 Meeting focused on the Clearinghouse project. Another topic was the EUnetHTA Conference in Paris 2008.

Present Associated Partners: SBU (Lead Partner, Sweden), DAHTA@DIMDI (Co-Lead Partner, Germany), CAHTA (Spain), DACEHTA (Denmark), HAS (France), HunHTA (Hungary), KCE (Belgium), Ministry of Health Cyprus and UETS (Spain).

Apologies Associated Partners: ASR (Italy), Cochrane Collaboration (UK) and Regione Veneto (Italy).

Present Collaborating Partners: SNHTA (Switzerland).

Apologies Collaborating Partners: AHRQ (USA), AHTAPol (Poland), CADTH (Canada), CRD (UK), EuroScan (UK), G-I-N Executive (Germany), INAHTA (SBU, Sweden) and WIHE (Switzerland).

2008

5th Work Package 2 Meeting, Stockholm, 2008

A 5th face-to-face meeting was planned for Stockholm in autumn 2008. This meeting was cancelled, due to the added Work Package 2 project – the development on a running HTA Information System. The project, that was not originally planned, was prioritised and performed during the last three months of the project, leaving no time for organising this meeting.

EUnetHTA Conference Meetings, Paris, April 17–18 and November 18–20, 2008

There were several meetings in the Organising Committee for the Paris Conference. The first meeting was in conjunction with the Work Package 1 Meeting in Paris, April 17–18, at the Conference Bureau “Europa Organisation”. The Organising Committee visited the conference venue “Pasteur Institute”. The other meetings were in conjunction with the EUnetHTA Conference in Paris, November 18–20. There were also a number of telephone meetings as well as face-to face meetings (October 8, October 23, November 4 and November 12)

Paris, April 17–18, 2008: Present Partners: DACEHTA (Denmark), SBU (Sweden), HAS (France)

Paris, November 18–20, 2008: Present Partners: DACEHTA (Denmark), SBU (Sweden), HAS (France)

4.7 Appendices

4.7.1 Appendix 1. EUnetHTA Work Package 2 Activity List 2006–2008

Organisation/ Name	3-year Work Plan Work Package 2	EUnetHTA logotype and Visual identity, and Info Package 06	EUnetHTA Webb site/Information Platform	Work Package 2 Meeting Stockholm 06	Work Package 2 Meeting Cologne 06	Work Package 2 Meeting Cyprus 07	Work Package 2 Meeting Düsseldorf 07	Clearinghouse e-meetings 07	Commenting Clearinghouse 07	Commenting Stakeholder Policy 07	Commenting Communication strategy 07	Presentations on Meetings 07	Preparation/Working HTAi Barcelona 07	Organising Paris Conference 07 + 08 + Work Package 2 Slideshow	Work Package 2 Article IJTAHC	Comments
Lead Partners:																
SBU	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	Active Partner
Susanna Allgurun Neikter	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	*SAN
Susanne Eksell	X	X	X	X								X	X	X	X	*SE
Helena Dahlgren				X		X	X		X		X	X			X	
Nina Rehnqvist	X		X	X	X					X	X	X			X	
Måns Rosén					X							X			X	
Karin Rydin				X					X							
DAHTA/DIMDI	X				X	X	X		X	X	X	X	X			Active Partner
Alric Rütter (from 2008 IQWiG)	X			X	X		X		X	X	X	X	X			*AR
Hans-Peter Dauben	X			X	X	X	X		X		X	X	X			*HPD
Elisabeth Giesenhausen					X	X	X		X							
Associated Partners:																
ASR				X												Active Partner 2006
Alessandro Liberati																
Roberto Grilli				X												
CAHTA				X		X	X									Active Partner
Toni Parada				X		X	X									
Monica Cortés																
Mireia Espallargus																
Montse Moharra																
Nadine Kubesch							X									
Cochrane Collaboration					X											Active Partner 2006
Gert Antes					X											
Nick Royle																
DACEHTA	X	X	X	X		X	X		X	X	X	X	X	X	X	Active Partner

Malene Fabricius Jensen				X	X	X	X		X			X				
Julia Chamova	X	X	X	X	X		X			X	X	X	X	X	X	
HAS				X	X	X	X				X		X	X		Active Partner
Sun Hae Lee Robin				X	X	X	X				X		X	X		
Cédric Carbonneil														X		
Céline Moty-Monnerau											X			X		
Esther Pensado														X		
Fabienne Quentin											X			X		
HunHTA				X		X	X				X					Active Partner
Valentin Brodsky						X	X									
László Gulácsi											X					
Istvan Majer				X												
IQWIG (New Member 2008)																New Partner
Alric Rüther (2006–2007 DAHTA/DIMDI)																
KCE				X	X	X	X			X	X	X				Active Partner
Patrice Chalon				X	X	X	X			X	X	X				*PC
Irina Clemmput																
Dirk Ramaekers																
Ministry of Cyprus	X			X	X	X	X		X	X	X	X				Active Partner
Stelios Christofides	X			X	X	X	X		X	X	X	X				SC *
Charalambos Yiannakkaras																CY *
Regione Veneto				X												Active Partner 2006
Luigi Bertinato																
Constantino Gallo																
Teresa Gasparetto																
Ilaria Passarani				X												
UETS				X	X	X	X									Active Partner
Juan Antonio Blasco				X	X	X	X									
Sofia Escalona							X									
Elena Andradás																
Assumpta Mausi																

Organisation/ Name	3-year Work Plan Work Package 2	EUnetHTA logotype and Visual identity, and Info Package 06	EUnetHTA Webb site/Information Platform	Work Package 2 Meeting Stockholm 06	Work Package 2 Meeting Cologne 06	Work Package 2 Meeting Cyprus 07	Work Package 2 Meeting Düsseldorf 07	Clearinghouse e-meetings 07	Commenting Clearinghouse 07	Commenting Stakeholder Policy 07	Commenting Communication strategy 07	Presentations on Meetings 07	Preparation/Working HTA Barcelona 07	Organising Paris Conference 07 + 08 + Work Package 2 Slideshow	Work Package 2 Article IJTAHC	Comments
Collaborating Partners:																
AHRQ																Non responding
Jean Slutsky																
CADTH																Non responding
Jill Sander																
Tammy Clifford																
CRD																Non responding
Amanda Sowden																
EuroScan											X					Non responding
Claire Packer																
Sue Simpson											X					
G-I-N																Non responding
Angela Maienborn																
Jako Burgers																
INAHTA				X		X					X					Active Partner
Margareta Nordwall Ghetu				X		X					X					MN*
Elizabeth Adams				X												
Guy Maddern																
Oksana Selezneva																
AHTAPoI					X					X	X					Active Partner
Anna Zawada					X					X	X					
Marcin Trojński																
Norbert Wilk																
Ewa Kierztyn																
Zbigniew J Król																

WIHE				X	X	X			X		X	X				Active Partner
Urs Brügger				X	X	X			X		X	X				
SNHTA						X	X		X		X					Active Partner
Christoph Künzli						X	X		X		X					*CC

Comments:

*SAN: Susanna Allgurin Neikter, SBU: Lead Partner Project Director; Administration, mail contacts, planning, writing documents, etc. Writing 3-year Work Plan Work Package 2; Preparing Project Launch, Making send list with contacts, preparing competition; Organising Work Package 2 Meetings; Giving presentations on Work Package 2 Meetings (Stockholm, Cologne, Cyprus and Dusseldorf) and Work Package 1 Meetings; Preparing slides; Writing Technical Reports 2006, 2007 and 2006–2008; Assisting work packages in communication issues; Writing/adjusting minutes; Design of EUnetHTA logotype and graphic profile; Developing EUnetHTA Graphic Guide; Developing EUnetHTA Information Package; Design of PowerPoint templates; Design and production of fact sheets; Planning, structure and content EUnetHTA web site/Information Platform, web design, choosing CMS (EpiServer), meetings with web consultants; Lead author Communication Strategy (Deliverable), Writing stakeholder policy document; Planning EUnetHTA Booth at HTAi Meeting 2006 in Barcelona; Graphic design and production of printed material, give-aways, exhibition material, PowerPoint slides etc; Design and production of EUnetHTA Exhibition Stand; Preparing exhibitions at SBU booth at HTAi Meetings in Adelaide and Montreal; Design and updates EUnetHTA web site; Design of Newsletter Work Package 7 “On the Horizon”; HTA Information System, planning and developing new functions and tools, new web design, meetings with web consultants; Organising Paris Conference 2008 (Member of Organising Committee); Design and production of Conference Invitation and Conference Program; Design and production of give-aways: EUnetHTA pen, block of pads and USB key; Conference Speaker, Presenting Work Package 2 results; Lead Author Work Package 2 Article IJTAHC.

*SE: Susanne Eksell, SBU: Web Content Manager, Web Master, Editor of EUnetHTA Web site; Web site Updates, Technical implementation in EpiServer, Maintenance and development; Preparing Project Launch, Technical implementation of competition; Organising Work Package 2 Meeting in Stockholm, and giving a presentation; Planning of structure and content of EUnetHTA web site Information Platform, web design, choosing CMS (EpiServer), meetings with web consultants; Production of web forms for registration to different EUnetHTA meetings; Developing Stakeholder Forum Website; Technical Interface Newsletter Work Package 7 “On the Horizon”; Organising EUnetHTA Exhibition HTAi Barcelona, EpiServer training, Design and web production of electronic Christmas card sent to members; Production of Paris Conference Newsletter and banners; HTA Information System, planning and developing new functions and tools, new web design, meetings with web consultants; Organising Paris Conference 2008 (Member of Organising Committee); Preparing conference bag and Work Package 2 Discussion Station.

*MN: Margareta Norwall, INAHTA: Taking minutes Work Package 2 Meeting Cyprus

*AR: Alric Rüther: Co-author Clearinghouse Prototype, Organising Work Package 2 Meetings in Cologne and Dusseldorf

*HPD: Hans-Peter Dauben: Leading Clearinghouse sub-group. Lead Author Clearinghouse Prototype Document, Organising Work Package 2 Meetings in Cologne and Dusseldorf

*PC: Patrice Chalon: Co-author Clearinghouse Prototype

*SC: Stelios Christofides: Co-author Clearinghouse Prototype, Organising Work Package 2 Meeting on Cyprus

*Charalambos Yiannakkaras: Co-author Clearinghouse Prototype

*CC: Chistoph Künsli: Co-author Clearinghouse Prototype

* Organising Committee EUnetHTA Paris Conference 2008: DACEHTA, HAS and SBU

4.7.2 Appendix 2

Evaluation Results

EUnetHTA Conference, November 20, 2008, Paris, France



General Information

<p>Evaluation Form was sent via e-mail by the conference bureau Europa Organisation to all participants (367 individuals) in the EUnetHTA Conference (November 20, 2008, Paris, France) Twenty completed questionnaire forms were received.</p> <p>HTA Professional 9 Health Professional 1 Healthcare administrator 2 Healthcare policy maker 1 Industry representative 1 Other (please indicate): 6</p>
Participant 16 Speaker 1 Journalist 0 Invited Guest 3
female 14 male 6

Questions about the content and organisation of the Conference

Grading scale: **1** (excellent) to **5** (very bad)

Balance between different sessions (plenary, panel discussion)	1.9
The topic of the conference has been presented throughout the conference	1.5
Opportunity to discuss the content of the conference during the day	2
Would you participate again in a EUnetHTA-organised event?	Yes 100%
Communication prior to the event	1.68
Assistance given by the conference staff	1.52
Satisfaction with the Conference portfolio	2.1
Information at the Discussion Stations (relevance, opportunity to discuss the topics)	2.21
Marking of the event's locations	2.15

Duration of the presentations (1 too long, 3 OK, 5 too short)	3
Number of presentations per session (1 too many, 3 OK, 5 too few)	3
Time allocated to discussion (1 too much, 3 OK, 5 too little)	3.4
Length of the breaks (1 too long, 3 OK, 5 too short)	2.6
Number of breaks (1 too many, 3 OK, 5 too few)	2.9

5 Work Package 3: Evaluation – Report on results and activities 2006-2008

5.1 Summary

An internal evaluation of the EUnetHTA project was carried out as requested by the EU Commission for their grant to the project. This report presents the work done to attain information useful for the EU Commission, the project management and the participants.

The prospective work plan was made by the WP3 group at the start of the project period in 2006 building on initial drafts. The internal evaluation was organized as a separate Work Package - WP3 Evaluation. Information about the different aspects of project progress were made by three yearly participant surveys, five biannual WP leader interviews, and from relevant documents produced during the project.

The overall experiences from the network were analyzed according to specified criteria in view of the general aim of the project of establishing an effective and sustainable network:

1. Production of deliverables in a timely manner;
2. Effective working collaboration among WPs;
3. Degree of participation within WPs;
4. Effective communication;
5. Sustained commitment to the project;
6. User and stakeholder satisfaction with new routines and practice;
7. Perceived added value.

In general, the evaluation showed that all the deliverables including new tools were produced as planned by the end of the project with some production delays within the 3-year timeframe of the project. Collaboration between WPs was challenging due to the large number of partners involved. Participation within the WPs varied. Different means of communication were used. The new tools have undergone pilot testing during the project and need to be tested further in real life situations and evaluated. The participants believed in EUnetHTA having an added value for the organisations and the increased use of HTA as a working method.

The results were overall positive with an expressed wish for continuation of an effective and a sustainable EUnetHTA collaboration. Nine recommendations were formulated for the continuation of development of a permanent structure for the network.

5.2 Introduction

The EU Commission made it a prerequisite to perform an internal evaluation of the EUnetHTA project (1). This was the main objective and the working group established prospective plans for this purpose (2). The results are summarized in the report (3). In addition, a framework was made for a possible external evaluation based on overview of available documentary information to aid the facilitation of such a process in the transition of EUnetHTA into a permanent network (4).

The evaluation was carried according to general methods on evaluation (5-8). Additional information was sought in evaluation reports (9-13).

5.3 Objectives

The main objective was to perform an internal evaluation of the EUnetHTA project during the period 2006-2008.

5.4 Methods and Activities

The work towards achieving the established milestones and deliverables followed plans drawn up by the group. The venues were held when it was seen necessary for carrying out the internal evaluation. The main means of communication was E-mails between formal meetings. In the following are presented overview tables reporting milestones, deliverables, and activities/ tasks for each year of the project. The tables of activities /tasks include the dates, type of meeting, host organisation of face-to-face meetings, and lastly the agenda of the meetings. The agenda is included to show the items considered as necessary for the progress of the work as it proceeded. Further information is given specifically for the progress of the surveys and interviews.

Milestones WP3 according to the work plan 2006-2008

Number	Date	Milestone
M4	April 2006	Establishing reporting routines from other work packages
M4	April 2006	Start prospective evaluation
M30	June 2008	Framework for external evaluation completed

Deliverables WP3 according to the work plan 2006-2008

Number	Deliverable title	Deliverable date	Nature	Confidentiality level	Dissemination
D3	An internal evaluation of the project	Month 34	Report	Public	Report sent to partners and relevant stakeholders including DG SANCO and Ministries of Health
D4	The framework for external evaluation of EUnetHTA	Month 30	Report	Restricted	The framework and material will be provided to the DG SANCO

Tasks/Activities Performed in 2006

Date	Type of meeting	Host organisation	Agenda of the meeting
24.02.2006	Face-to-face meeting	Norwegian Knowledge Centre for the Health Service (NOKC), Norway	<p>Welcome:</p> <p>a) Brief presentation of participants</p> <p>b) About evaluation</p> <p>Overall planning:</p> <p>a) General plan of activities: What and when</p> <p>b) Content of activities:</p> <p>Detailed planning:</p> <p>a) Making required questionnaires for evaluation</p> <p>b) Specific content of interim reports and final report</p> <p>1) Discuss the content and outline of the questionnaires 1 and 2 for the evaluation.</p> <p>2) 3-year work plan</p> <p>1) Results of the first round of WP-leader interviews</p> <p>2) Results of the first participant survey 2</p>
27.04.2006	Telephone meeting		
09.10.2006	Telephone meeting		

Minutes of 3 meetings (available on WP3 intranet

http://www.eunetha.eu/Members_only/Workpackages/Workpackage_3/Meetings/)

Participant survey

The first participant survey questionnaire was developed to catch the impression of the participant ideas of domains of interest regarding the development of EUnetHTA and vision for its future. The participants were also asked to give their experience and expectations for the work in the groups they had joined. The questionnaire underwent an iteration process among the WP3-group members on the development of the questionnaire content. The questionnaire was sent out to the EUnetHTA participants as an attachment to an e-mail late in June with a subsequent reminder. The response was slow as the summer holiday period varies across Europe. Lead Partner (LP) Manager for WP3 (Lise Lund Håheim) organized the collection of the questionnaire responses and made the report which the group reviewed. The questionnaires were recorded electronically in house at NOKC. The results of the survey were published on the members only of the EUnetHTA web-site (http://www.eunetha.eu/Members_only/Workpackages/Workpackage_3/)

WP leader interviews

WP3 group sought to register the WP leaders own view on the progress and any deviations to each WP plan every six month. This was planned in order to catch their views and how they may alter as EUnetHTA was developing. It was anticipated that the different stages in the project may pose different challenges to the leaders. This evaluation was not one directed on detailed technical issues but one that should map their impressions of major issues as they saw it.

In 2006 the leaders were interviewed about the first six months of 2006. The interviews were short and were held by the WP3 LP Project Manager. The results were presented on the members only of the EUnetHTA web-site (http://www.eunethta.eu/Members_only/Workpackages/Workpackage_3/)

Separate reporting routines as specified in milestone 4 were not found necessary to establish. Sufficient information from the WPs was received through the Participant surveys and WP leader interviews.

Tasks/Activities Performed in 2007

Date	Type of meeting	Host organisation	Agenda of the meeting
24.10.2007	Telephone meeting		Work plan for the evaluation - <u>main items</u> : 1. First step is to compare 1. and 2. survey. 2. Review questionnaire for changes to 3.survey.
31.10.2007	Telephone meeting		1. The plan for the report 2. Timetable
03.12.2007	Telephone meeting		1.Review of WP-leader interviews 2.Review of Participant survey questionnaire 3.Participant Survey: Status analyses 4.Face-to-face meetings 2008

Minutes of 3 meetings (available on WP3 intranet

http://www.eunethta.eu/Members_only/Workpackages/Workpackage_3/Meetings/)

Participant survey

The second participant survey was carried out in June 2007 with two reminders. The questionnaires were recorded electronically in house at NOKC. Results were made available on the EUnetHTA Members Only (link: http://www.eunethta.eu/Members_only/Workpackages/Workpackage_3/) to the members taking part in EUnetHTA. The results gave an overview of the experience on EUnetHTA among the participants, their views on the future of EUnetHTA and SWOT-analyses. The surveys gave the participants an opportunity to have their voice heard.

WP leader interviews

WP-leader interviews were carried out twice in January/February and August/September. All leaders responded to the call. Results were made available on the EUnetHTA Members Only (http://www.eunethta.eu/Members_only/Workpackages/Workpackage_3/) to give feedback to EUnetHTA members on the experience of the EUnetHTA-project. The WP1 leader commented on these interviews' and surveys' results and gave information on how he dealt with deviations.

Tasks/Activities Performed in 2008

Date	Type of meeting	Host organisation	Agenda of the meeting
25.01.2008	Telephone meeting		1.WP3 Technical report 2.Survey analysis 3.WP-leader interviews 4.Face-to-face meeting 5.Other issues a. Contact with DG SANCO b. Publication c. E-meeting dates
05.03.2008	Telephone meeting		1.External evaluation news 2.New questionnaires to stakeholders, secretariat and steering committee 3.New questions to the participant survey 4.Status WP-leader interviews 5.Status tasks and meeting dates
27.03.2008	Telephone meeting		1.Face-to-face meeting in Bologna 2. Plan of analysis of Participant survey Please see the file "Survey analysis proposal". 3. New questions to the participant survey 4. Status regarding survey of Steering committee, Stakeholder Forum and the Secretariat

			5. Overview of deliverables for the report, external evaluation
			6. WP-leader report no.4 and related events
23.04.2008	Telephone meeting		1. Questionnaire Participant Survey
22.05.2008	Telephone meeting		2. Stakeholder Forum
			1. The Bologna meeting
			a. Practical details
			b. Agenda for the meeting
			c. Preparation for the meeting – written contributions to the report
			2. Manuscript: Title and list of authors
10.06.2008	Face-to-face	Agenzia Sanitaria e Sociale Regionale (ASSR) Regione Emilia-Romagna, Italy	1. Content and structure of the report
			2. Writing/analysis session
			3. Discussion
			4. Deliverable on framework of external evaluation
13.-14. 10.2008	Face-to-face	Direzioni Piani e Programmi Socio Sanitari, Regione Veneto, Italy	1. Review Evaluation report
			2. Plan for Publications

Minutes of all meetings (available on WP3 intranet

http://www.eunethta.eu/Members_only/Workpackages/Workpackage_3/Meetings/)

Participant survey

The third Participant Survey was carried out May/June according to plan. The third survey included separate surveys to the Steering Committee, The Secretariat, and the Stakeholder Forum participants. The main survey questionnaire was modified for the purpose of surveying different groups. The questionnaires were recorded electronically by an independent Norwegian data company as planned as the number of surveys had increased and manpower for this task was not available at NOKC at that time.

WP leader interviews

Interviews no.4 and 5 with Work Package leaders were carried out as planned in February and in August / September 2008 (available on http://www.eunethta.eu/Members_only/Workpackages/Workpackage_3/)

Publications

WP 3 Lead Partner will develop an article for the International Journal of Technology Assessment in Health Care (as a part of the general project results publication strategy for the EUnetHTA project). The deadlines for this work were met:

- Work title, estimated number of pages and proposed lead and co-authors for the article was delivered to the Secretariat by the deadline of May 30, 2008.
- Draft article to be delivered to the Secretariat by the deadline of December 15, 2008.

Abstracts were made for presentations at the HTAi 2009 Conference.

5.5 Manpower for the execution of the activities

Partners involved

The group consisted of one lead partner (LP), seven associated partners (AP) and three collaborating partners (CP).

Lead partner organisation:

Norwegian Knowledge Centre for the Health Service (NOKC), Norway;

Associated partner organisations:

1. Swedish Council on technology Assessment in Health Care (SBU), Sweden;
2. Health Statistics and Medical Technologies State Agency (VSMTVA), Latvia;
3. German Agency for Health Technology Assessment at the German Institute for Medical Documentation and Information (DAHTA@DIMDI), Germany (until June 2008);
4. Direzioni Piani e Programmi Socio Sanitari, Regione Veneto, Italy,
5. Agencia de Evaluación de Tecnologías Sanitarias (AETS), Instituto de Salud Carlos III, Spain
6. Agenzia Sanitaria e Sociale Regionale (ASSR) Regione Emilia-Romagna, Italy,

7. Cochrane Collaboration represented by ASSR Regione Emilia-Romagna, Italy.

Collaborating partner organisations:

1. Swiss Network for Health Technology Assessment (SNHTA), Swiss Federal Office of Public Health, Berne, Switzerland;
2. Medical Services Advisory Committee (MSAC), Canberra, Australia;
3. Organisation for Economic Cooperation and Development OECD), Paris, France.

Members of the evaluation team were:

Lise Lund Håheim, NOKC, project leader;
Berit Mørland, NOKC.
Helene Dahlgren, SBU;
Igor Trofimovs, VSMITVA;
Marlène Läubli, SNHTA*;
Teresa Gasparetto, Direzione Piani e Programmi Socio Sanitari, Regione Veneto, Italy;
Iñaki Imaz Iglesia, AETS;
Jesús González-Enríquez, AETS
Alessandro Liberati, ASSR and Cochrane Collaboration;
Hans-Peter Dauben, DAHTA@DIMDI until June 2008;
Elena Berti, ASSR from January 2008.

Acknowledgement:

Andrew M. Blakely (AETS) is thanked for his contribution in the participant surveys analysis. The level of participation in the WP3 work among the Collaborating Partners varied greatly. Formal contact with MSAC was unsuccessful despite several attempts. Likewise, OECD, did not formalize the contact. However, SNHTA was an important partner in WP3 through the active participation by the SNHTA representative

Countries involved

Lead partner:	Norway
Associated partners:	Spain, Sweden, Italy, Germany, Latvia
Collaborative partners:	Switzerland, Australia, France

5.6 Results

The evaluation was carried out to study if the project reached its main objective of establishing an effective and sustainable network. In pursuing this task the work was carried out according to the plans made early in the project phase. The plan was adhered to through the three year period. The five biannual rounds of interviews with WP-leaders and the three yearly participant surveys were all published on the EUnetHTA intranet to give feedback to the organisation. To inform the leaders and other participants about the project progress and the participant attitudes and views was seen as an important activity by the WP3 group. The first participant survey was seen as a little too early by some participants, but on the other hand it was also intended to provide a baseline registration and make the participants more conscious of the dynamics of the project development. The intranet publications served as a communication channel in a broader sense.

We were pleased to have a third face-to-face meeting after having the suggested four meetings reduced to two. This third meeting was very important in the final stage of collating the evaluation report and making the foundation for the publication and conference abstracts.

The results were presented during the EUnetHTA Conference on November 20, 2008 in Paris (http://www.eunetha.eu/Home/EUnetHTA_Conference_HTAs_Future_in_Europe/Programme/)

We believe that we succeeded through the evaluation to harvest and feed back information into the organisation and to look at trends of the development through the project period. Based on this work WP 3 group developed specific criteria for concluding on the internal evaluation which were as follow:

- Production of deliverables in a timely manner;

With a few exceptions the deliverables were made to the time scheduled – all deliverables were in place by the end of the project in December 2008. The tools that have been developed were designed to facilitate networking in making HTA-reports. There was room for adjustments and development of ideas. However, the HTA tools have not yet been tried in a real working relation. The network will continue piloting these tools. The EUnetHTA has been carried out according to plan maintaining its organisational structure, and the tools were developed within the time frame.

- Effective working collaboration between Work Packages.

* SNHTA (Switzerland) is thanked for their significant contribution throughout the project. MSAC, Australia and OECD did not take part actively, however.

Collaboration between WPs was necessary as development of tools were interconnected. This was seen as a very interesting aspect, but also a demanding one in terms of timing and cooperation between parties involved.

- Degree of participation within Work Packages

The large groups involved in the working groups, coupled with the heavy workload on participants were seen as a cause of delays in deliverables. The benefit of working in the WPs was considered to be great in terms of international experience, exchange of knowledge, and developing the tools.

- Effective communication

Different ways of communication was used. E-mails were most frequently used. Meetings were organized as face-to-face, telephone, and E-meeting. Language is a complicating and challenging factor in such collaboration but people have made the efforts to improve it. The large number of participating organisations represented a challenge in communication. There were reported variations in degree of success in methods of communication.

- Sustained commitment to Project

Only one organisation has left the network (during the first half of 2006) and five have joined during the project period. Commitment was present throughout; the inputs from participants and organisations have, in many instances, been greater than planned. Moreover, the organisations have put extra funding into the project to be able to make the tools.

- Perceived added-value

The participants expressed belief that their agency's involvement in EUnetHTA has a positive outcome. They were resolute, however, that EUnetHTA should remain a network and should not become a centralized organisation, undermining local/national autonomy. Dedicated leaders and the secretariat were considered instrumental in helping EUnetHTA achieve its objectives to date and for supporting its future development as a sustainable network from 2009 and beyond.

Full internal evaluation report was submitted to the Secretariat on October 31st and to the Commission on November 5, 2008 and is available online (<http://www.eunethta.eu/>).

5.7 Recommendations

The WP3 group summarized the information and experience of the project. This was formulated into nine recommendations which were considered to be of use for further establishment of a sustainable network. They are as follows:

1. Secure funding, and maintain a dedicated coordinating secretariat.
2. Organisational structure of WPs should be a core of dedicated partners with a review group of less committed partners to ensure efficiency.
3. Continue developing and evaluating the tools as necessary.
4. Involve people in the work to ensure commitment, a high level of knowledge, and a broad basis for decision making processes.
5. Encourage collaboration and communication among all parties to ensure coherence within groups and EUnetHTA.
6. Continue developing the Communication platform and Clearinghouse functionality to make EUnetHTA that central point for HTA.
7. Arrange face-to-face meetings at start of group or committee work to strengthen social coherence and reach a common understanding of the work.
8. Evaluate the tools used in real setting and the technical communication platform.
9. English has been the main language and should continue to be so.

5.7 References

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6 Work Package 4: Common Core HTA (ie, HTA Core Model) – Report on results and activities 2006-2008

6.1 Summary

WP4 aimed at developing and testing a generic framework to enable international collaboration for producing and sharing results of HTA.

International expert teams constructed a model for undertaking and reporting HTA, the *HTA Core Model*. The Model considers health technologies through nine domains. Two applications of the Model were developed, one for medical and surgical interventions and another for diagnostic technologies.

While constructing the Model, the information contained in an (ideal) HTA was divided into standardized pieces, the *assessment elements*. Each element contains a generic issue that is translated into practical research questions while performing an assessment. Elements were described in detail in *element cards*.

Two pilot HTAs, designated as *Core HTAs* were also produced in parallel with model development. These provided the first real-life testing of the Model and input for further development.

The Model and Core HTAs were both validated by international HTA agencies through using online questionnaires. Public feedback was also sought. The results of formal validation and public feedback were primarily positive. Development needs were also identified and considered. Input from the validation and public feedback was used to refine the documents.

Guidance on the use of the HTA Core Model was collected into a Handbook that is part of a (future) online version of the Model.

The HTA Core Model is a novel approach to HTA. It enables effective international production and sharing of HTA results in a structured format. The face validity of the Model was confirmed during the project but further testing and refinement are needed to ensure optimal usefulness and user-friendliness. Core HTAs are intended to serve as a basis for local HTA reports. Core HTAs do not contain recommendations on technology use.

6.2 Introduction

The organisation of health technology assessment (HTA) and the settings in which HTA agencies operate vary considerably across countries (1). According to a recent study there are also significant differences in the practical application of HTA (2).

Differences in health care systems and in the organisation of HTA probably explain a large part of the variance in international HTA. On the other hand, differences in how HTA is *perceived, understood or used* in various parts of the world may have an important impact on the way it is performed and used. Hence different applications of HTA may exist even in settings where there are no substantial differences in the health care system or in the organisation of HTA.

The varying implementation of HTA internationally and even within Europe makes sharing of information difficult and reduces the applicability of foreign HTA results for one's own purposes. This applies even in cases where use of assessment produced elsewhere would be feasible because of low context-dependency of their results.

Another problem in importing assessment results of HTAs is the non-standardized information structure of reports. An HTA report can be seen as a collection of information which represents the results of an assessment process. In the contemporary style of writing HTA reports, the varying structure makes it rather difficult to extract and analyze information on specific topics – either by humans or computers.

The need for clear structure, transparency, and rigorous handling of information in any HTA leads to a need for standardisation. Steps towards definition of some standards at the international level have been done by INAHTA (checklist) and the previous European Projects (EUR-ASSESS, ECHTA/ECAHI).

WP4 built on earlier work on European HTA, but aimed at constructing a model that would more specifically than earlier a) operationalize the questions that should be asked and answered within an HTA and b) define and standardise the fine structure of the final product, the HTA report. The work led to construction of the HTA Core Model - a novel method for producing and publishing HTAs that enables international collaboration in undertaking assessments and utilization of their results.

6.3 Objectives

The general task of WP4 was defined in the Grant Agreement among the specific objectives of the EUnetHTA project⁴ as: "*tools for producing a common core of HTA evidence on clinical effectiveness, basic economic data and models, and for identifying key social, cultural and ethical issues relevant to assessed technologies.*"

More specifically, the tasks of WP4, as defined in the Grant Agreement, were as follows:

1. To produce examples of context-independent HTA topics (Core HTAs) for two different types of questions (e.g. diagnosis and treatment).
2. Linked to the HTA production to develop a generic methodological HTA framework based on current best practices (Core HTA Structure).
3. To support the adaptability testing of Core HTAs in various national HTA agencies (Adaptation, WP5) and to finalise the Core Structure after the testing.
4. To participate in the development of models for policy transferability of national adaptations based on these Core HTAs (Transferability, WP6).
5. To examine the need for developing additional types of Core Structures.Methods

6.4 Methods and Activities

Overview

WP4 produced two models for producing HTAs, one for medical and surgical interventions and another for diagnostic technologies. The models were jointly designated as the HTA Core Model. Both models were tested through producing two pilot (Core) HTAs. A Handbook on using the Model was also developed.

WP LP set up a *coordinating team* that consisted of employees of the LP. The coordinating team met weekly to plan further steps and resolve problems that had been encountered.

A team of international experts (team on *general design*) focused on developing the general structure of the Model and on providing guidance on issues that would arise during the process.

The practical development work was performed in *domain teams*, each of which consisted of a group of HTA experts focusing on one of the following domains of HTA:

1. Health problem and current use of technology
2. Description and technical characteristics of technology
3. Safety
4. Clinical Effectiveness (including Accuracy of diagnostic tests)
5. Costs and economic evaluation
6. Ethical analysis
7. Organisational aspects
8. Social aspects
9. Legal aspects

The domains were originally identified in the EUR-ASSESS project (3) and only some names were slightly modified for current purposes. A tentative domain for Accuracy was included in the diagnostics model, but its status was reconsidered during the project and it was merged with clinical effectiveness domain.

The teams operated largely through emails and through circulating draft documents. Four WP meetings that covered the project period supported the work. Each team consisted of *investigators* and *reviewers*. One investigator was assigned the role as *primary investigator* for the Model and another for the Core HTA in each team. In some cases the same person was responsible for both the Model and the Core HTA. Other investigators contributed to varying degree in building the Model. Reviewers provided feedback to draft documents within their domains. Additionally, each team had a *coordinator* on behalf of the WP LP.

The development of the Model and Core HTAs took place to a large extent as a parallel and iterative process in which the Model was modified as new needs were discovered while conducting the pilot HTAs. Methods of the development work are explained in more detail in the final WP deliverables available at http://www.eunethta.net/EUnetHTA_Deliverables_project_2006-2008/.

The first draft of the *HTA Core Model for medical and surgical interventions*, as well as the *Core HTA on drug eluting stents* were both published in July 2007. The first draft of the *HTA Core Model for diagnostic technologies*

⁴ Project agreement, page 32.

was published a year later, in July 2008, and the *Core HTA on multi-slice CT coronary angiography* was published in October 2008. These documents were made public through the project web site at http://www.eunetha.net/Work_Packages/WP_4/Activities/.

After publication, each document underwent a validation. Public feedback was also sought. Results of the validation and public feedback were taken into account when preparing the final versions of the documents.

Each of the two model documents and two Core HTAs was subjected to validation by members of EUnetHTA and the International Network of Agencies for Health Technology Assessment (INAHTA). The validation was performed through online questionnaires that contained both general questions regarding the Model and more detailed questions regarding various domains.

Public feedback was sought in a parallel process likewise through online questionnaires. An invitation to provide feedback was placed on the project web site and notifications were sent through emails to relevant stakeholders.

Principles of use of the HTA Core Model were collected in a *Handbook* that is intended to be part of the online version of the Model. The Handbook is available at <https://fio.stakes.fi/htacore/handbook.html>.

Activities during year 2008

During the final project year 2008, the following activities took place within WP4:

- *HTA Core Model for medical and surgical interventions* and *Core HTA on drug eluting stents*: Final refinement based on validation results and public feedback.
- *HTA Core Model for diagnostic technologies* and *Core HTA on multi-slice CT angiography*: Development of first drafts. Validation and public feedback sought. Final refinement based on validation results and public feedback.
- *HTA Core Model Handbook*: Development and internal review within WP.
- WP Meeting in Tartu (see table 1).
- Dissemination of results (see chapter 4.6)

Meetings and workshops organized by WP4

WP4 organized four face-to-face meetings. The first Workshop was held in Helsinki on September 19, 2006. Thirty persons from 13 countries participated representing 12 APs and 2 CPs of WP4.

The Training Meeting, which was held in Helsinki on 18-19 January 2007, was open for all APs. In addition to 13 APs and 1 CP of WP4, 6 APs and 1 CP from other work packages attended. Altogether 37 participants from 14 different countries took part in the meeting.

The Validation and Development Meeting was also organized in Helsinki. It took place on 5-6 November 2007 and gathered 30 participants from 10 countries. They represented 11 APs and 1 CP.

The last Meeting was organized in Estonia by the University of Tartu. 28 participants from 14 countries got together in Tartu on June 5-6, 2008. Twelve APs and two CPs were present.

Table 1. WP4 general meetings and workshops.

WP4 general meetings and workshops				
Time, place	Meeting, discussion topics	Participants/Agencies	Number of participants	Number of countries
19 th Sep 2006 Helsinki	WP4 Workshop: How to decide what belongs to the core?	12 APs: AVALIA-T, DACEHTA, DSI, KCE, NCCHTA, NOKC, OSTEBa, SBU, TU Berlin, UCSC, UT, ZonMW 2 CPs: AHTAPol, SNHTA	30	13 (Finland, Belgium, Denmark, Estonia, Germany, Italy, Netherlands, Norway, Poland, Spain, Sweden, Switzerland, UK)
18 th -19 th Jan 2007 Helsinki	WP4 Training Meeting: Core Model domain descriptions, methodology and topics	13 WP4 APs: AETSA, AVALIA-T, DACEHTA, DSI, KCE, NCCHTA, OSTEBa, SBU, TU Berlin, UCSC, UL, UT, ZonMW 6 other WP APs: ASR, Cyprus	37	14 (Austria, Finland, Belgium, Cyprus, Denmark, Estonia, France, Germany,

		Ministry of Health, HAS, DAHTA/DIMDI, LBI/HTA, UETS 1 WP4 CP: SNHTA 1 other WP CP: HÖS		Italy, Netherlands, Spain, Sweden, Switzerland, UK)
5 th -6 th Nov 2007 Helsinki	WP4 Validation & Development Meeting: Presentation and discussion of the CM1 validation results	11 APs: AVALIA-T, DACEHTA, DSI, KCE, NOKC, OSTEBa, StaHeCCa, TU Berlin, UCSC, UL, UT 1 CP: AHTAPol	30	10 (Finland, Belgium, Denmark, Estonia, Germany, Italy, Lithuania, Norway, Poland, Spain)
5 th -6 th Jun 2008 Tartu	WP4 Meeting: Status and methodology of the Core HTA Models, electronic knowledge base of structured HTA information, handbook development	12 WP4 APs: AETSA, DACEHTA, DSI, KCE, NCCHTA, NOKC, StaHeCCa, TU Berlin, UCSC, UL, UT, ZonMW 1 other WP AP: IPHS 2 CPs: AHTAPol, SNHTA	28	14 (Finland, Belgium, Denmark, Estonia, Germany, Italy, Lithuania, Netherlands, Norway, Poland, Slovenia, Spain, Switzerland, UK)

Three domain teams organized additional team meetings to discuss matters relevant to their domains in Basel , Switzerland (clinical effectiveness), Rome, Italy (ethical analysis) and Helsinki, Finland in February 2008 (social aspects).

6.5 Manpower for the execution of activities

Altogether at least 136 named persons from 23 countries contributed to WP4 either through a) participating in the domain teams as investigators or reviewers, b) through attending WP4 meetings and workshops, or c) through responding to one or more of the four validation questionnaires (one for each Core Model application and one for each Core HTA), d) through providing intellectual and technical support to the WP4 coordinating team, or through a combination of these activities. Appendix 1 lists each person and their role on the general level, followed by two tables (Appendix 2) that indicate more detailed participation in the domain teams.

Partners involved

The following 23 agencies representing 17 countries were members of WP4:

Lead Partner

Finnish Office for Health Technology Assessment, FinOHTA

Associated Partners

AETSA, Spain
OSTEBa, Spain
Cochrane Collaboration, United Kingdom
DACEHTA, Denmark
DSI, Denmark
AVALIA-t, Spain
KCE, Belgium
Ministry of Health, Lithuania,
NCCHTA, United Kingdom
NOKC, Norway
SBU, Sweden
Technische Universität Berlin, Germany
University of Tartu, Estonia
Università Cattolica del Sacro Cuore, HTA Unit, Italy
University Lübeck, Germany
ZonMW, the Netherlands

Collaborating partners

G-I-N, Germany
Institute of Molecular Medicine, Portugal
AHTAPol, Poland
SNHTA, Switzerland
Department of Health (replaced University of Iceland), Iceland
Gesundheit Österreich GmbH, Austria

Countries involved

The WP lead and coordination took place in Finland, as was the case with three of the four WP workshops or meetings. Sixteen other countries participated as WP members, 11 of them through more active Associated Partners.

One meeting was organized by the University of Tartu and WP4 LP in Estonia.

Altogether 23 countries participated in the work through participation in the WP4 teams and workshops or meetings. Making results available in each of these countries has been primarily at the discretion of individual partners. Being main actors in the field of HTA, the members are likely to know appropriate channels for disseminating the results in their respective settings. All the main products of WP4 are freely available on the project web site and can be linked to from national and regional sources.

Coordination and collaboration with other work packages and parties

WP1

WP4 has participated in all meetings and e-meetings organized by WP1 as a member of the Executive Committee and Steering Committee to support coordination of the project.

WP2

WP4 coordinator participated in WP2 workshop in Düsseldorf, Germany, in November 2007 to discuss coordination of work packages, particularly the relation of the Core Model to the WP2 Clearinghouse.

WP3

WP4 Lead Partner has participated in the interviews of WP3 to support the evaluation of the project.

WP5

Coordination with WP5 took place in several occasions through discussions and email. A joint WP4/5 videoconference was organized on the 21 of August 2006 to coordinate activities. WP4 Lead Partner took part in WP5 Toolkit applicability testing (questionnaire and interview) and participated in the WP5 meeting on the 27-28 of September 2007 in Venice, Italy. In addition to contributing to the work of WP5, these tasks have been important in coordinating the terminology and various concepts used in the development of WP4 deliverables so that they match their counterparts in WP5. WP4 LP had a discussion with WP5 LP in HTAi Barcelona to further develop future interoperability of WP deliverables.

WP6

WP4 participated in a WP6 meeting on the 30th of March 2006 in Copenhagen (2 representatives).

WP4 Lead Partner participated in writing a chapter "What is health technology assessment" to the Book produced by WP6 (5).

WP8

WP4 LP reviewed and commented on a draft of the Handbook on HTA Capacity Building.

Other

WP4 participated on the 31st of March 2006 in a coordination meeting for WPs 4-7 in Copenhagen (2 representatives).

WP4 organized on the 7th of August, in collaboration with project lead partner DACEHTA, a meeting in Copenhagen to explore possible collaboration between the project and a major manufacturer of drug eluting stents, Johnson & Johnson and to hear manufacturer's views on assessment.

Nordic HTA agencies have commenced a project to further test the Core Model.

6.6 Results

The HTA Core Model

WP4 developed two models for conducting HTAs, jointly designated as the HTA Core Model. The two models developed during the project period represent applications of the Model. The first of them covers *medical and surgical interventions* and the second *diagnostic technologies*. It is assumed that further applications of the Model may be needed in the future, for instance for technologies used for screening, or for administrative support systems.

Assessment elements and element cards

The HTA Core Model contains an ontology, i.e. a structure that defines the information content of an ideal HTA. Each domain teams considered what kind of information should be produced within an HTA from the viewpoint of their domain in the context of either a) medical and surgical interventions or b) diagnostic technologies.

The vast amount of possible information was split into standardized elements, the "assessment elements". These are defined by a domain and more narrow topics and issues within it. An assessment element is the basic unit of the model. It defines a piece of information that describes the technology or the consequences or implications of its use, or the patients and the disease for which it is applied. In the context of clinical research, an element may describe a clinical outcome (e.g. reduction of symptoms), whereas in social science an element may describe the impact of technology on patient's life (e.g. ability to work). The nature of elements may vary across domains, since the consequences and implications are understood and studied differently within scientific disciplines.

The common denominator for all elements is that they outline a set of *information* that may be useful when deciding on the use or non-use of technology. As the number of possible elements of HTA is very large, perhaps infinite, we chose to focus particularly on

- a) elements that deal with context-independent (i.e. easily transferable) information and
- b) elements that are particularly important from the viewpoint of HTA (even if these would not be easily transferable).

Each assessment elements was given a more tangible format in the form of "element cards". Each element card describes one assessment element in more detail by indicating e.g. suggested research methodologies. The descriptions are generic in nature, i.e. they are not specific to any technology. The cards can be used in relevant tools, e.g. in IT applications. The content of the cards is listed below:

Table 2. Contents of an element card. (Abridged version, for full version see original HTA Core Model documents)

Information	Explanation	Format
Element ID:	An individual code for each element.	
Domain:	The domain within which the element belongs to.	Standard list
Topic:	The topic within which the element belongs to.	Standard list
Issue:	The specific question within the aspect and topic. Should be in the form of a question.	Standard list
Clarification:	A brief clarification that explains what the issue is about. Clarification is not necessarily needed if the issue is self-explanatory.	Free text.
Importance:	Defines how important it is to consider the particular issue when conducting HTA. This importance has to do with significance from the viewpoint of HTA. This is not always the same as "relevance" in a particular policy context.	3 categories: <i>Critical</i> <i>Important</i> <i>Optional</i> Further requirements may be indicated, such as " <i>Critical if the technology is a device.</i> "
Information sources(s):	An explanation of how to find answers to this particular issue. What methodology to use? If there are several possible methodologies, which are preferred? Where to find relevant information?	Free text
Transferability:	An estimate about the transferability of data or other findings from one context to another.	3 Categories: <i>Complete</i> <i>Partially</i> <i>Not</i>
Reference:	Indicates the reference of the issue.	Free text.

Relations:	List of other elements that are related to this element.	Primarily a list of Element IDs Free (explanatory) text allowed as well.
Status:	Indicates whether the element belongs to the HTA core or a wider HTA framework.	3 categories: <i>Core</i> <i>Borderline (used temporarily during the project)</i> <i>Not core</i>

The assessment elements are common for the whole HTA Core Model. Each element can be used in one or more applications of the Model (e.g. model for diagnostic technologies), but all elements are drawn from the same pool. Not all elements, however, belong to all applications.

The element cards, on the other hand, are model-specific. Hence an element that deals with formal approval of technology may contain distinct definitions within different applications of the model. This is because the information that should be looked at or after may be different in the context of different types of technology.

Overlaps between domains

Issues discussed within various domains sometimes sound very similar. The same may apply even to issues that belong to the same domain but under different topics. We allowed similar sounding issues across the domains in the Model, but applied the following rule to them: If two issues look similar at the first glance, but are genuinely different, i.e. they would be analyzed differently within two different domains (or topics), they constitute two separate assessment elements. If on the other hand the issues are largely perceived and analyzed similarly within both domains (or topics), they constitute only one assessment element common to both domains (or topics).

Inclusion in the Core

Not all elements defined in the ontology are equally useful or significant in the international context, i.e. they do not belong in the "core". In the HTA Core Model an element is included in the core based on a simple function of two basic characteristics of each assessment element – their importance and transferability.

Transferability is an obvious factor in such consideration, as the aim is to utilize information beyond its original production point. *Importance* was considered to ensure the robustness of the core, i.e. to avoid a situation in which the core would contain several easily transferable pieces of information that anyhow would not be particularly important from the viewpoint of HTA. It should be emphasized that the importance considered here is not equal to relevance for a particular policy question. Issues perceived important from the viewpoint of HTA are often useful, however, for making policy decisions.

Importance and transferability are independent of each other. The inclusion in the core is defined according the Core Matrix (table 3).

Table 3. The Core Matrix. Combinations that were initially defined as "borderline category" are marked with grey.

CORE MATRIX		Importance		
		<i>Optional</i>	<i>Important</i>	<i>Critical</i>
Transferability	<i>Complete</i>	Not core	Core	Core
	<i>Partially</i>	Not core	Core	Core
	<i>Not</i>	Not core	Not core	Core

Utilization of the HTA Core Model

The primary use of the HTA Core Model is production of Core HTAs. They are comprehensive and multidisciplinary assessments that have been conducted using the HTA Core Model and considering all core elements. Core HTAs also contain a summary of findings in each domain, but refrain from giving recommendations on using the technology.

Through the wide scope, focus on core elements and the summary chapter, a Core HTA gives an overview of a technology that is likely to be useful in the European context. A Core HTA can be used as a basis for producing

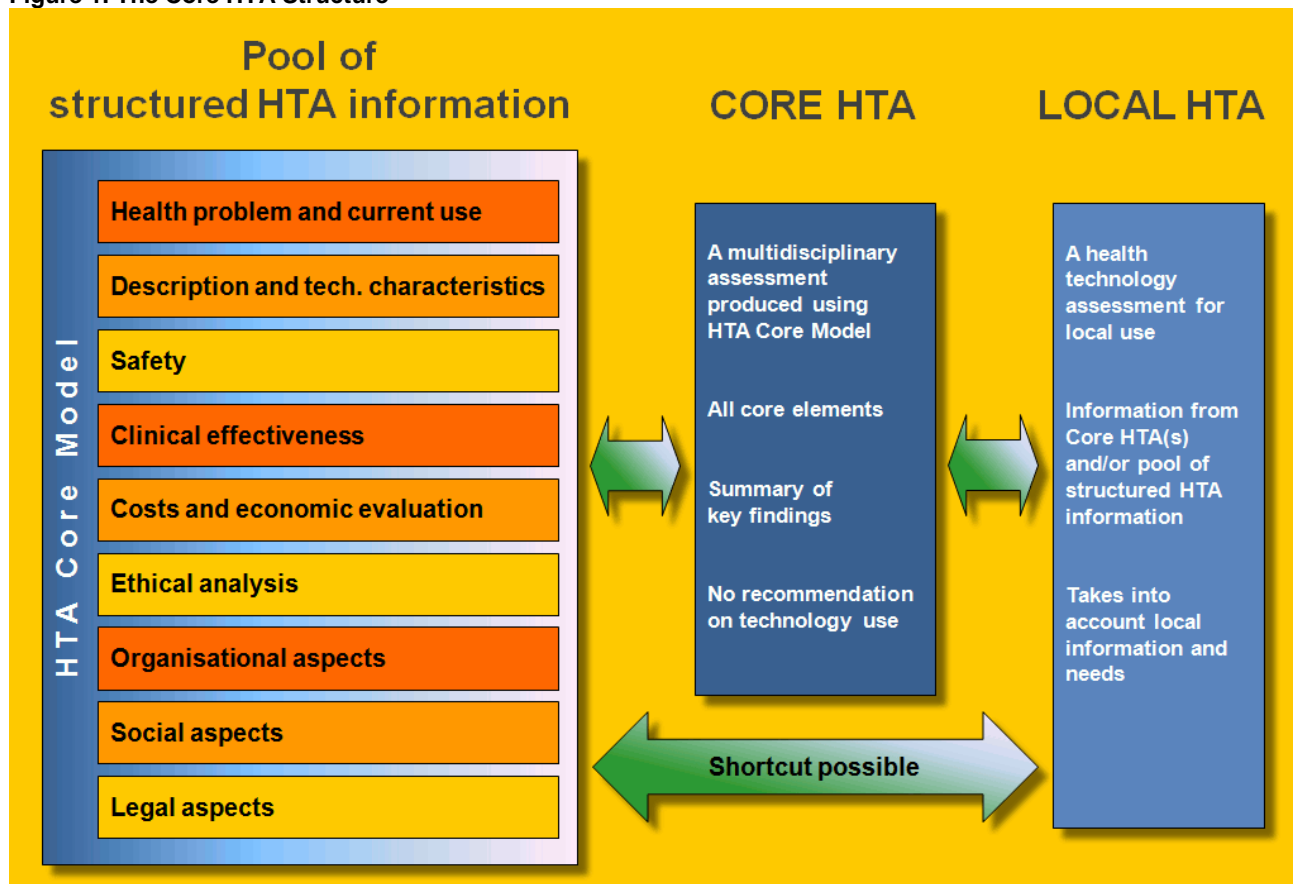
local HTA reports that take into account local circumstances, e.g. epidemiology, organisation, resources and values.

An alternative, secondary use is a more "liberal" selection and use of various assessment elements, perhaps from only one or few of the domains. The needs and interests of the user define the extent of analysis.

Both the Core HTAs and more liberal use of the HTA Core Model result in a pool of *Structured HTA Information* that also can be used for local HTAs. The HTA Core Model and the resulting Core HTAs and local HTAs were collectively designated as the *Core HTA Structure* (Figure 1).

Other uses of the HTA Core Model were presented during the project as well, such as extraction of data from existing HTA reports or educational purposes. These applications are worth considering in the future.

Figure 1. The Core HTA Structure



Core HTAs

The Model was tested through conducting two pilot assessments - Core HTAs - that were designed using the Model.

In the beginning of the project, two surveys were conducted among the WP4 APs and CPs to select topics for the two assessments. Participants of the surveys first proposed topics that would be interesting from their point of view. The proposals were circulated and one most suitable and favoured topic was selected through a voting process. The first survey consisted of two rounds and resulted in selecting *drug eluting stents* to be the topic of the first core HTA. The second survey consisted of three rounds and resulted in selecting *multi-slice CT angiography* for the topic of the second core HTA. Attention was paid in the selection process to selecting topics that would have broad relevance in the European context and would allow extensive testing of the HTA Core Model.

The pilot Core HTAs were intended to test the Model and provide feedback to model development. Hence they were not intended for actual decision-making. Due to the relatively long production process the timeliness of their content at the time of publishing could not be guaranteed.

The following procedure was designed and applied for conducting Core HTAs:

1. The *relevance* of each core assessment element is considered in the context of the technology that is to be assessed
2. The generic issues of relevant elements are *translated* into one or more research questions that the Core HTA should answer.
3. Irrelevant elements are not translated into research questions, but the reason for irrelevance should be recorded in the Core HTA, as it may provide useful information for users of the report.
4. Research questions defined by the relevant elements are studied using typical research methodologies.
5. Answers are recorded in a structured format in which an answer to a particular issue can be found at a standard location (whether published in paper or electronic format).

The model guides researchers in selecting which aspect of technology or its use they could (or should) study. Research tradition and guidelines within each scientific domain define the process in which questions are formulated. The element cards provide guidance on how to conduct research, i.e. how to answer the actual research questions.

Validation and public feedback

The two Core Model documents and two pilot Core HTAs were subjected to validation by members of EUnetHTA and the International Network of Agencies for Health Technology Assessment (INAHTA). Online questionnaires were used to gather results.

The validation aimed at covering the following viewpoints:

The Core Model

- Feasibility of the general concept and structure of the model (assessment elements described as cards)
- Adequate coverage of HTA by the selected 10 domains
- Adequate coverage of the domains by the topics and issues
- Adequate description and definition of assessment elements
- Adequate structure of element cards
- Adequate definition of the "Core"
- Possible conflicts or inconsistencies in the model
- Adequate definition of all terms used in the model

The Core HTA

- Feasibility of the general concept and structure of the Core HTA (research questions defined by generic assessment elements and answered by the assessment)
- Adequate coverage of HTA by the selected 10 domains
- Adequate coverage of the domains by the topics and issues
- Adequate selection of relevant assessment elements
- Adequate translation of relevant assessment elements into research questions
- Adequate methodology used to answer the research questions
- Internationally useful answers to the research questions
- (Potential) usefulness to inform policy questions in respondents' specific contexts
- Possible conflicts or inconsistencies in the Core HTA
- Adequate definition of all terms used in the Core HTA

The questionnaires contained both general questions regarding the Model and more detailed questions regarding various domains and assessment elements. Domains were assigned to EUnetHTA members in such a manner that agencies would not validate parts of the Model (i.e. domains) that they had participated in developing themselves.

Table 4. Number of respondents to the validation questionnaires (only one response from each agency was expected).

Document	Respondents
Model for medical and surgical interventions	25
Model for diagnostic technologies	15
Core HTA on drug eluting stents	23
Core HTA on multi-slice CT angiography	17

The overall feasibility of the HTA Core Model was gauged with eight general questions during validation. Most respondents ($\geq 80\%$) agreed or strongly agreed with seven of these, supportive of the current Model. The agreement was less strong concerning the process for conducting Core HTAs. Even here, most respondents still

supported the design. Strong disagreements were recorded only for three questions regarding the intervention model, representing only 4% of responses to those questions. See table 5 for more details.

Table 5. Results of the general questions of the HTA Core Model validation

Evaluation topic (Exact statements available in Technical Report)	Share of respondents that agreed or strongly agreed with the statement (%)		Share of respondents that disagreed or strongly disagreed with the statement (%)		Share of respondents that neither agreed nor disagreed with the statement or could not say their opinion (%)	
	HTA Core Model for medical and surgical interventions (n = 24)	HTA Core Model for diagnostic technologies (n = 15)	HTA Core Model for medical and surgical interventions (n = 24)	HTA Core Model for diagnostic technologies (n = 15)	HTA Core Model for medical and surgical interventions (n = 24)	HTA Core Model for diagnostic technologies (n = 15)
Feasibility of the general concept	83	93	13	7	4	0
Ability of the domains to represent the main aspects of HTA	92	93	0	0	8	7
Ability of the assessment elements within various domains to cover the domains adequately	88	93	4	0	8	7
Adequate description of the assessment elements in the element cards	92	80	4	13	4	7
Adequacy of the definition of the Core through the importance and transferability of assessment elements (the Core Matrix)	83	80	4	0	13	20
Lack of major conceptual conflicts or inconsistencies in the Model	88	80	4	0	8	20
Adequate description of terms in the Model	88	87	4	0	8	13
Feasibility of the suggested process through which the Model translates into practical research	58	67	17	0	25	33

The validation results of the first Core HTA (on drug eluting stents) suggested strongly that such a report should contain a summary, which was not present in the first report. Including a summary was not straightforward, as concerns were voiced that such a chapter would be a step towards supranational HTAs. After discussions in the Tartu workshop, a summary chapter was finally included in the report structure and implemented in practice in the second Core HTA (on multi-slice CT). It was agreed, however, that the summary should contain only an overview of the results of the assessment – not recommendations on using the technology.

Results of the formal validation were amended through seeking public feedback. An invitation to provide feedback was placed on project web site and notifications were sent through emails to relevant stakeholders.

An online questionnaire was used first in July-October 2007 to gather feedback regarding the Core Model for medical and surgical interventions and Core HTA on drug eluting stents. Ten people responded and an overview

of responses was produced. Additionally, ISPOR (the International Society for Pharmacoeconomics and Outcomes Research) sent feedback through a letter format. A similar online questionnaire was used in November-December 2008 to gather feedback concerning the Core Model for diagnostic technologies and the Core HTA on multi-slice CT angiography. Perhaps due to limited time for responding to the questionnaire, only one response (representing an international organisation) was received to the formal questionnaire. Additionally, two other international organisations provided feedback in a letter format.

Input from both the formal validation and the public feedback was considered and utilized for refining the final documents. It will also provide a basis for further development of the Model and Core HTAs.

Handbook

A Handbook on using the HTA Core Model was developed mostly between May and December 2008. The Handbook is in an online format containing three sections. The *introduction* presents the basic principles of the HTA Core Model. The second section provides *practical guidance on using the Model to produce a Core HTA*, written primarily for users of the online HTA Core Model – an electronic tool that is under construction but not part of official project deliverables. The third section contains *methodological guidance for finding answers to research questions* of the Core HTA.

The relatively brief Handbook connects with more extensive materials that are part of the HTA Core Model. The Handbook e.g. gives an overview of domain descriptions, but users can easily access the more extensive domain descriptions in the Model. This solution was developed after an extensive discussion in the Tartu workshop. The Handbook is available at <https://fio.stakes.fi/htacore/handbook.html>.

Dissemination of results

To support dissemination of project results, the work of WP4 was presented in the following events (most recent first):

- EUnetHTA Conference in Paris on 20 Nov 2008. (Presentation + a leaflet on the HTA Core Model)
- 10th ISPOR Annual European Congress in Dublin, 22-23 October 2007 (ISPOR Forum and Issue Panel).
- 15th European Conference on Public Health (EUPHA) in Helsinki, 12 October 2007.
- 4th EUnetHTA Workshop during the HTAi conference in Barcelona, 17 June 2007.
- Seminar "Funding & reimbursement for Medical Devices" arranged by Informa Life Sciences in Brussels on 6 December 2006.
- 9th ISPOR Annual European Congress in Copenhagen, 29 October 2006.
- 3rd HTAi Conference in Adelaide, 2-5 June 2006
- Additionally as part of multiple presentations by the EUnetHTA Project Leader (see WP1 Coordination).

An article on ethical analysis was published in the Bulletin of the World Health Organisation (4).

Three scientific articles have been written and submitted to a special issue of the International Journal of Technology Assessment in Health Care.

Future development

Several targets for future development have been identified during the process and will be considered to the extent possible with available resources. An online version of the HTA Core Model is under construction and will be available most likely within 2009.

The current Model covers medical and surgical interventions and diagnostic technologies. Other types of technologies may require their own applications of the Model. It is assumed at this point that the number of other applications is relatively low, most likely 3-10 applications are enough to cover most health technologies. One should also notice that the development of new applications does not necessitate starting from scratch. There is a considerable overlap between model applications and the number of truly new assessment elements is likely to be relatively low.

6.7 Recommendations

The HTA Core Model is a tool to support European collaboration in producing and sharing HTAs.

The Model can also be used in education and training, since it makes the definition of HTA tangible.

In piloting the Model, several new challenges were identified. The Core HTAs are consequently not optimal but shall rather be seen as a first test of the Model. The Model must be tested for many technologies, and HTA organisations around the world are encouraged to test and apply the Model in their work and to provide feedback on their experiences. Feedback will be considered by the EUnetHTA Collaboration to improve future versions of the Model.

For full use, an online version of the Model needs to be implemented.

Developing further applications of the Model, for example, screening and other population level interventions, or various systems that support care, would be an interesting step forward.

6.8 References

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6.9 Appendices

6.9.1 Appendix 1. Persons participating in WP4.

Persons participating in WP4						
<p>I = Investigator in one or more domain teams R = Reviewer in one or more domain teams WS = Participated in WP4 meetings or workshops V = Responded to validation questionnaire(s)</p> <p>* Employees of the WP LP that contributed also as members of WP coordinating team.</p>						
Name	Agency	Country	I	R	WS	V
Alun Cameron	ASERNIP-S	Australia				x
Gottfried Endel	Hauptverband der österreichischen Sozialversicherungsträger	Austria			x	
Irmgard Schiller-Fruehwirth	Hauptverband der österreichischen Sozialversicherungsträger	Austria				x
Rosemarie Felder-Puig	LBI@HTA	Austria				x
Philipp Radlberger	LBI@HTA	Austria			x	
Claudia Wild	LBI@HTA	Austria				x
Cecile Camberlin	KCE	Belgium	x			
Chris De Laet	KCE	Belgium	x	x	x	
Hans van Brabandt	KCE	Belgium	x		x	
Irina Cleemput	KCE	Belgium	x	x	x	x

Nancy Thiry	KCE	Belgium				x
Lynda McGahan	CADTH	Canada				x
Stelios Christofides	Cyprus Ministry of Health	Cyprus			x	x
Hindrik Vondeling	CAST	Denmark				x
Marie Louise Bistrup	DACEHTA	Denmark				x
Britta Bjerrum Mortensen	DACEHTA	Denmark	x			
Camilla Palmhøj Nielsen	DACEHTA	Denmark	x		x	
Finn Børlum Kristensen	DACEHTA	Denmark	x	x	x	
Kåre Hansen	DACEHTA	Denmark		x	x	x
Charlotte Bredahl Jacobsen	DSI	Denmark	x			
Henrik Hauschildt-Juhl	DSI	Denmark	x		x	
Betina Højgaard	DSI	Denmark				x
Marie Brandhøj Wiuff	DSI	Denmark	x			
Susanne Rasmussen	DSI	Denmark	x			
Kersti Meiesaar	University of Tartu	Estonia	x	x	x	x
Monika Reesev	University of Tartu	Estonia	x	x	x	
Antti Malmivaara	Finohta	Finland	x		x	
Harri Sintonen	Finohta	Finland	x		x	
Heidi Anttila*	Finohta	Finland	x		x	
Ilona Autti-Rämö*	Finohta	Finland	x	x	x	
Iris Pasternack*	Finohta	Finland	x		x	
Kristian Lampe*	Finohta	Finland	x		x	
Laura Walin	Finohta	Finland	x			
Marjukka Mäkelä*	Finohta	Finland	x	x	x	
Pekka Kuukasjärvi	Finohta	Finland	x			
Pirjo Räsänen*	Finohta	Finland	x		x	
Samuli Saarni	Finohta	Finland	x		x	
Tuija Ikonen	Finohta	Finland	x		x	
Ulla Saalasti-Koskinen*	Finohta	Finland	x		x	
Leena Raustia*	Finohta	Finland			x	
Markku Myllykangas	Finohta	Finland		x		
Martti Kekomäki	Finohta	Finland		x		
Pauliina Savola	Finohta	Finland			x	
Pekka Lampila*	Finohta	Finland			x	
Oskari Saarekas*	Finohta	Finland				
Pia Kärki*	Finohta	Finland			x	
Päivi Reiman-Möttönen*	Finohta	Finland			x	
Sirpa Soini	Finohta	Finland		x		
Juha Koivisto	FinSoc	Finland	x		x	
Ritva Bly	STUK/Finohta	Finland	x	x		
Heikki Ukkonen	TYKS/Finohta	Finland	x	x		
Sami Kajander	TYKS/Finohta	Finland	x			
Dominique Benedittini	HAS	France				x
Sun Hae Lee-Robin	HAS	France			x	x

Hans-Peter Dauben	DAHTA@DIMDI	Germany			x	
Tobias Schulte in den Bäumen	German Center for Public Health Genomics	Germany				x
Marcial Velasco Garrido	Technische Universität Berlin	Germany	x	x	x	x
Dagmar Lühmann	University of Lübeck	Germany	x	x	x	x
Valentin Brodszky	HunHTA	Hungary				x
Sigurdur Helgason	MoH Iceland	Iceland	x	x		x
Vilborg Sigurdardóttir	University Hospital of Iceland	Iceland				x
Mairin Ryan	HIQA	Ireland				x
Elena Berti	ASSR Regione Emilia-Romagna	Italy				x
Elisa Stivanello	ASSR Regione Emilia-Romagna	Italy			x	x
Teresa Gasparetto	Regione Veneto					x
Carmen Furno	Università Cattolica del Sacro Cuore	Italy	x			
Dario Sacchini	Università Cattolica del Sacro Cuore	Italy	x	x		
Lorenzo Leogrande	Università Cattolica del Sacro Cuore	Italy	x			
Marco Marchetti	Università Cattolica del Sacro Cuore	Italy	x	x	x	
Marco Oradei	Università Cattolica del Sacro Cuore	Italy	x			
Matteo Ruggeri	Università Cattolica del Sacro Cuore	Italy	x			
Mirella Corio	Università Cattolica del Sacro Cuore	Italy	x			
Paolo Oppedisano	Università Cattolica del Sacro Cuore	Italy	x			
Pietro Refolo	Università Cattolica del Sacro Cuore	Italy	x	x	x	
Luana Vaikutytė	StaHeCCA	Lithuania		x	x	
Neringa Kuliešiūtė	StaHeCCA	Lithuania		x	x	x
Rasa Terbetienė	StaHeCCA	Lithuania			x	
Izzuna Mudla Mohamed Ghazali	MaHTAS	Malaysia				x
Inger Norderhaug	NOKC	Norway	x	x	x	
Lise Lund Håheim	NOKC	Norway				x
Katrine Bjørnebek Frønsdal	NOKC	Norway	x	x	x	x
Torbjørn Wisløff	NOKC	Norway		x		
Bjørn Hofmann	NOKC/University of Oslo	Norway	x	x	x	
Michał Farkowski	AHTAPol	Poland				x
Bogusława Osińska	AHTAPol	Poland			x	
Kinga Malottki	AHTAPol	Poland			x	x
Norbert Wilk	AHTAPol	Poland			x	
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Cristina Asensio	AETS	Spain				x
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Lucinda Paz	AVALIA-T	Spain				x
Alberto Ruano-Ravina	AVALIA-T	Spain	x	x	x	
Leonor Varela Lema	AVALIA-T	Spain	x	x	x	
Marta Aymerich Martínez	CAHTA	Spain				x
Renata Linertová	Health Service of Canary Islands	Spain				x
Marta Lopez de Argumedo	OSTEBA	Spain	x	x	x	x
Nieves Sobradillo Ruiz	OSTEBA	Spain	x	x	x	x
Juan Antonio Blasco	UETS	Spain			x	x
Assumpta Mauri Mas	UETS	Spain				x
Mercedes Reza Goyanes	UETS	Spain			x	
Bo Freyschuss	SBU	Sweden	x	x	x	
Magnus Nord	SBU	Sweden				x
Måns Rosén	SBU	Sweden	x	x		
Oksana Selezneva	SBU	Sweden				x
Regina Kunz	SNHTA	Switzerland	x		x	x
Felix Gurtner	SNHTA	Switzerland			x	
Matthias Bischof	SNHTA	Switzerland			x	
Wim Goettsch	CVZ	The Netherlands				x
Benien Vingerhoed-van Aken	ZonMw	The Netherlands			x	
Jetty Hoeksema	ZonMw	The Netherlands			x	
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Nick Hicks	NCCHTA	UK	x	x	x	
Jonathan Shepherd	NCCHTA	UK				x
Joyce Craig	NHS QIS	UK				x

The following persons did not participate in WP4 domain teams, international meetings, or as respondents of validation questionnaires, but provided support or feedback for the WP4 Coordinating team in other ways:

National Centre for Welfare and Health, Finland: Linda Akiola, Jaana Isojärvi, Eva Kiura, Esa Läärä, Eeva Mäkinen, Marja Pajukoski, Kerttuli Punkari, Ulla-Maija Rautakorpi, Risto Roine, Olli-Pekka Ryyänen, Maija Saijonkari, Riikka Salonen, Minna Sarelahti,

University of Kuopio: Markku Myllykangas

6.9.2 Appendix 2. Domain teams of WP4

Domain teams HTA Core Model for medical and surgical interventions and Core HTA on drug eluting stents			
DOMAIN	Coordinator	Investigators	Reviewers
	<i>Primary investigators for the Core Model (CM) and Core HTA (CT) in italics</i>		
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Description and technical characteristics of technology	<i>Marjukka Mäkelä (CM)</i>	<i>Hans van Brabandt, KCE (CT)</i> Pekka Kuukasjärvi, FinOHTA Antti Malmivaara, FinOHTA	Leonor Varela Lema, AVALIA-T Marta Lopez de Argumedo, OSTEBA Monika Reesev, U Tartu Marcial Velasco Garrido, TU Berlin
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Effectiveness	Marjukka Mäkelä	<i>Antti Malmivaara (CM)</i> , FinOHTA <i>Regina Kunz (CT)</i> , Basel Institute of Clinical Epidemiology Chris De Laet, KCE Pekka Kuukasjärvi, FinOHTA Susanne Rasmussen, DSI Hans van Brabandt, KCE	Alberto Ruano-Ravina, AVALIA-T Leonor Varela Lema, AVALIA-T Marta Lopez de Argumedo, OSTEBA Bo Freyschuss, SBU Marco Marchetti, UCSC Inger Norderhaug, NOKC Monika Reesev, U Tartu Kersti Meiesaar, U Tartu
Costs, economic evaluation	<i>Pirjo Räsänen (CT)</i>	<i>Kersti Meiesaar (CM)</i> , U Tartu Irina Cleemput, KCE Henrik Hauschildt-Juhl, DSI Monika Reesev, U Tartu Harri Sintonen, FinOHTA	Alberto Ruano-Ravina, AVALIA-T Marco Marchetti, UCSC Inger Norderhaug, NOKC Torbjørn Wisløff, NOKC
Ethical analysis	<i>Ilona Autti-Rämö (CM)</i>	<i>Dagmar Lühmann (CT)</i> , U Lübeck Bjørn Hofmann, NOKC and U Oslo Marta Lopez de Argumedo, OSTEBA Marco Marchetti, UCSC Inger Norderhaug, NOKC Samuli Saarni, FinOHTA Marcial Velasco Garrido, TU Berlin	Pietro Refolo, UCSC Dario Sacchini, UCSC
Organisational aspects	Päivi Reiman-Möttönen	<i>Ulla Saalasti-Koskinen (CM)</i> , FinOHTA <i>Marco Marchetti (CT)</i> , UCSC Finn Børlum Kristensen, DACEHTA Mirella Corio, UCSC Carmen Furno, UCSC Nick Hicks, NCCHTA Juha Koivisto, FinSoc Pekka Kuukasjärvi, FinOHTA	Irina Cleemput, KCE Martti Kekomäki, FinOHTA Dagmar Lühmann, U Lübeck

Domain teams HTA Core Model for medical and surgical interventions and Core HTA on drug eluting stents			
DOMAIN	Coordinator	Investigators	Reviewers
		Marco Oradei, UCSC Camilla Palmhøj Nielsen, DACEHTA Matteo Ruggeri, UCSC Marcial Velasco Garrido, TU Berlin	
Social aspects	Päivi Reiman-Möttönen	<i>Heidi Anttila</i> (CM, CT), FinOHTA Ilona Autti-Rämö, FinOHTA Bjørn Hofmann, NOKC and U Oslo Juha Koivisto, FinSoc Dagmar Lühmann, U Lübeck Marcial Velasco Garrido, TU Berlin	Marco Marchetti, UCSC Markku Myllykangas, FinOHTA Alison Price, NCCHTA
Legal aspects	Kristian Lampe	<i>Laura Walin</i> (CM), FinOHTA <i>Marco Marchetti</i> (CT), UCSC Inger Norderhaug, NOKC Nick Royle, CC Mirella Corio, UCSC Marco Oradei, UCSC Carmen Furno, UCSC	Bjørn Hofmann, NOKC and U Oslo Sirpa Soini, FinOHTA

Domain teams HTA Core Model for diagnostic technologies and Core HTA on multi-slice CT angiography			
DOMAIN	Coordinator	Investigators	Reviewers
	<i>Primary investigators for the Core Model (CM) and Core HTA (CT) in italics</i>		
General design	<i>Kristian Lampe</i> (CM) <i>Iris Pasternack</i> (CT)	Finn Børlum Kristensen, DACEHTA Marjukka Mäkelä, Finohta Katrine Bjørnebek Frønsdal, NOKC Alberto Ruano-Ravina, AVALIA-T Marcial Velasco Garrido, TU Berlin	Irina Cleemput, KCE Måns Rosén, SBU Marco Marchetti, UCSC Dagmar Lühmann, U Lübeck
Current use of the technology (implementation level)	<i>Iris Pasternack</i> (CT)	<i>Marcial Velasco Garrido</i> (CM), TU Berlin Lorenzo Leogrande, UCSC Marta Lopez de Argumedo, OSTEBA Paolo Oppedisano, UCSC Måns Rosén, SBU Nieves Sobradillo, OSTEBA; Heikki Ukkonen, TYKS (through Finohta) Leonor Varela Lema, AVALIA-T	Ritva Bly, STUK (through Finohta) Nick Hicks, NCCHTA Marco Marchetti, UCSC Kersti Meiesaar, U Tartu
Description and technical characteristics of technology	Iris Pasternack	<i>Iris Pasternack</i> (CM, CT), <i>Finohta</i> Sami Kajander, TYKS (through Finohta) Sigurdur Helgason, MoH Iceland Lorenzo Leogrande, UCSC Paolo Oppedisano, UCSC Heikki Ukkonen, TYKS (through Finohta)	Ritva Bly, STUK (through Finohta) Marta Lopez de Argumedo, OSTEBA Leonor Varela Lema, AVALIA-T Monika Reesev, U Tartu Nieves Sobradillo, OSTEBA Marcial Velasco Garrido, TU Berlin
Accuracy and effectiveness	<i>Iris Pasternack</i> (CM)	<i>Tuija Ikonen</i> (CT), <i>Finohta</i> Sigurdur Helgason, MoH Iceland Marjukka Mäkelä, Finohta Heikki Ukkonen, TYKS (through Finohta) Sami Kajander, TYKS (through Finohta)	Alberto Ruano-Ravina, AVALIA-T Marta Lopez de Argumedo, OSTEBA Kåre Hansen, DACEHTA Marco Marchetti, UCSC Kersti Meiesaar, U Tartu Katrine Bjørnebek Frønsdal, NOKC Monika Reesev, U Tartu

Domain teams HTA Core Model for medical and surgical interventions and Core HTA on drug eluting stents			
DOMAIN	Coordinator	Investigators	Reviewers
			Måns Rosén, SBU Nieves Sobradillo, OSTEB Léonor Varela Lema, AVALIA-T Neringa Kuliesuite, StaHeCCA Luana Vaikutyte, StaHeCCA
Safety	Iris Pasternack	<i>Iris Pasternack (CM, CT)</i> Sami Kajander, TYKS (through Finohta) Ritva Bly, STUK (through Finohta) Léonor Varela Lema, AVALIA-T Alberto Ruano-Ravina, AVALIA-T Nick Hicks, NCCHTA	Sigurður Helgason, MoH Iceland Marta Lopez de Argumedo, OSTEB Katrín Björnebek Frønsdal, NOKC Nieves Sobradillo, OSTEB Heikki Ukkonen, TYKS (through Finohta) Luana Vaikutyte, StaHeCCA
Costs, economic evaluation	<i>Pirjo Räsänen</i>	<i>Kersti Meiesaar (CM)</i> , U Tartu <i>Irina Cleemput (CT)</i> , KCE Jose Antonio Navarro, AETSA Cecile Camberlin KCE Belén Corbacho, AETSA Henrik Hauschildt-Juhl, DSI Aurora Llanos Mendez, AETSA Sergio Márquez, AETSA Monika Reesev, U Tartu Victor Sarmiento, AETSA Harri Sintonen, Finohta	Sigurður Helgason, MoH Iceland Marco Marchetti, UCSC Katrín Björnebek Frønsdal, NOKC Heikki Ukkonen, TYKS (through Finohta) Torbjørn Wisløff, NOKC Neringa Kuliesuite, StaHeCCA
Ethical aspects	Ilona Autti-Rämö	<i>Samuli Saarni (CM)</i> , Finohta <i>Pietro Refolo (CT)</i> , UCSC <i>Dario Sacchini (CT)</i> , UCSC Dagmar Lühmann, U Lübeck Bjørn Hofmann, U Oslo Marco Marchetti, UCSC Marcial Velasco Garrido, TU Berlin	Nieves Sobradillo, OSTEB Marta Lopez de Argumedo, OSTEB
Organisational aspects	Päivi Reiman-Möttönen	<i>Ulla Saalasti-Koskinen (CM)</i> , Finohta <i>Marco Marchetti (CT)</i> , UCSC Mirella Corio, UCSC Carmen Furno, UCSC Juha Koivisto, FinSoc Marco Oradei, UCSC Camilla Palmhøj Nielsen, DACEHTA Matteo Ruggeri, UCSC Tuija Ikonen, Finohta Charlotte Bredahl Jacobsen, DSI	Irina Cleemput, KCE Finn Børilum Kristensen, DACEHTA Dagmar Lühmann, U Lübeck Marcial Velasco Garrido, TU Berlin
Societal aspects	Päivi Reiman-Möttönen	<i>Heidi Anttila (CM)</i> , Finohta <i>Dagmar Lühmann (CT)</i> , U Lübeck Juha Koivisto, FinSoc Tuija Ikonen, Finohta Britta Bjerrum Mortensen, DACEHTA Charlotte Bredahl Jacobsen, DSI Marie Brandhøj Wiuff, DSI	Ilona Autti-Rämö, Finohta Marcial Velasco Garrido, TU Berlin Marco Marchetti, UCSC Bjørn Hofmann, U Oslo Pietro Refolo, UCSC Dario Sacchini, UCSC
Legal aspects	Kristian Lampe	<i>Laura Walin (CM)</i> , Finohta <i>Marco Marchetti (CT)</i> , UCSC Katrín Björnebek Frønsdal, NOKC Pietro Refolo, UCSC Dario Sacchini, UCSC Marco Oradei, UCSC Mirella Corio, UCSC Carmen Furno, UCSC Matteo Ruggeri, UCSC	Bjørn Hofmann, U Oslo Nick Royle, CC Sirpa Soini, Finohta Dagmar Lühmann, U Lübeck Marjukka Mäkelä, Finohta

7 Work Package 5: Adapting existing HTAs from one country to other settings – Report on results and activities 2006-2008

7.1 Summary

Background

Health Technology Assessment (HTA) is increasingly used in European countries to inform decision- and policy-making in the health care sector. Several countries have integrated HTA into policy, governance, reimbursement or regulatory processes. Therefore, the EU and Member States in 2004 expressed the need for a sustainable European network for HTA. EUnetHTA was established to respond to this need.

EUnetHTA defined *health technology assessment* (HTA) as “a multidisciplinary process that summarizes information about the medical, social, economic and ethical issues related to the use of a health technology in a systematic, transparent, unbiased, robust manner. Its aim is to inform the formulation of safe effective, health policies that are patient focused and seek to achieve best value”.

The EUnetHTA project was established to create an effective and sustainable network for HTA across Europe that could develop and implement practical tools to provide reliable, timely, transparent and transferable information to contribute to HTAs in Members States.

The scientific work in the EUnetHTA project took place in separately managed Work Packages (WPs), each led by a Lead Partner. NCCHTA was the Lead Partner for Work Package 5, and as such a member of the EUnetHTA Steering Committee and Executive Committee. NCCHTA played a full part in the work of these committees over the three years of the project, by attending face to face and e-meetings, by responding to internal consultations and proposals, and by assisting in the development of the continuing EUnetHTA Collaboration.

NCCHTA: Lead Partner for Work Package 5: ‘Adapting HTAs from one country into other settings’ and Associated Partner within WP1, WP4 and WP6

19 Associated Partners and 7 Collaborating Partners (9 over the three year period) participated in Work Package 5 of the EUnetHTA project, under the leadership of NCCHTA. The objectives and achievements of this partnership are described in full in the following sections of this report and are summarised below.

In addition to leadership of Work Package 5, NCCHTA also played a role as Associated Partner in three other Work Packages: WP1 central governance processes of the EUnetHTA project, WP4 ‘Common Core HTA’ and WP6 ‘Transferability of HTA to Health Policy’. This included attendance at face to face meetings and e-meetings, assisting with the development of products and the drafting of validation reports. The contribution of NCCHTA as Associated Partner is described fully in the reports by the Lead Partners of these work packages.

Objectives and Deliverables of Work Package 5

The objective of Work Package 5 ‘Adapting HTAs from one country into other settings’ was to ensure better use of existing HTA reports by developing a toolkit for adapting the “core” within assessments made for one country into advice appropriate to other contexts within which it may be implemented through policy. The intention was to enable the production of structured products based on work already done that can then be easily utilised in policy making in Member States and the EU. Facilitating the use of existing HTAs in this way would contribute to minimising the duplication of work.

Methods

To this end, the following tasks were undertaken:

1. A survey of current practice in Member States in adapting HTA reports from other countries.
2. The development of a toolkit for adapting core HTA information from existing HTA reports to other contexts.
3. The applicability testing of the adaptation of core information from 2 existing HTA reports in various national HTA environments using the toolkit.

An iterative process involving input from 28 European HTA agencies (all members of the EUnetHTA project). A number of methods were used: literature searching, a survey of adaptation experience, two rounds of a Delphi

survey, e-meetings and email exchange, drawing on the expertise and experience of the partnership, two rounds of review; two rounds of quality assurance testing (termed “applicability testing”), plus two face to face meetings of WP5 partner representatives.

Results

The twin deliverables of an HTA adaptation toolkit tailored for use by EU and Member States and a glossary of HTA adaptation concepts and terms for EU member countries were developed at an early stage in the project, and then further refined through workshops and two rounds of applicability testing. The final deliverable, to make known the results of the applicability testing by the publication of a report, was achieved in the final year of the project.

NCCHTA as Lead Partner for Work Package 5 presented the results of the work of this partnership at the EUnetHTA Conference “HTA’s Future in Europe”, in journal articles and conference presentations. Final versions of both the HTA Adaptation Toolkit and the Glossary of HTA adaptation terms were made available on the EUnetHTA website and to delegates at the closing conference.

Conclusions

Consensus of opinion from 28 European organisations/ networks indicated that the adaptation of HTA reports would be desirable and beneficial, and that there was a need for the development of a toolkit to aid in the adaptation of HTA reports, in order to maximise resources and save costs.

The adaptation toolkit developed by EUnetHTA members is a valuable resource to help with the adaptation of HTA reports produced in other settings and thus avoid duplication. The glossary of adaptation terms is a valuable resource for European HTA agencies when reading HTA reports produced in different contexts and for adapting HTA reports produced in other countries for their own use. The glossary will help improve understanding and help to facilitate the adaptation process.

This collection of resources is available for use by all HTA agencies and can be accessed via <http://www.eunetha.net/>. Interest in the toolkit and glossary has already been expressed from countries working with but not within Europe, such as Turkey.

Recommendations

To make the Toolkit and Glossary truly responsive to user requirements, it is recommended that both resources are further developed into interactive web based resources. It is hoped that this can be taken forward after the end of the funded project through the involvement of NCCHTA and other partners in the activities of the continuing EUnetHTA Collaboration.

The next phase

Through a series of internal and public consultation rounds, the network developed a Proposal for the EUnetHTA Collaboration (published June 16, 2008) detailing the approaches for the future development of the network. A group of founding partners was established after this to implement the proposal for EUnetHTA Collaboration. NCCHTA has been a Founding Partner of the EUnetHTA Collaboration since its establishment and has worked with the Secretariat and other partners to assist the development of this next phase of the European network for Health Technology Assessment.

7.2 Objectives of Work Package 5

The objective of Work Package 5 ‘Adapting HTAs from one country into other settings’ was to ensure better use of existing HTA reports by developing a toolkit for adapting the “core” within assessments made for one country into advice appropriate to other contexts within which it may be implemented through policy. The intention was to enable the production of structured products based on work already done that can then be easily utilised in policy making in Member States and the EU. Facilitating the use of existing HTAs in this way would contribute to minimising the duplication of work.

To this end, the following tasks were undertaken:

1. A survey of current practice in Member States in adapting HTA reports from other countries.
2. The development of a toolkit for adapting core HTA information from existing HTA reports to other contexts.
3. The applicability testing of the adaptation of core information from 2 existing HTA reports in various national HTA environments using the toolkit.

Milestones for Work Package 5

Date	Milestone
M10	Glossary of HTA adaptation concepts completed
M12	HTA adaptation toolkit completed

M21	First applicability testing completed
M30	Second applicability testing completed

Deliverables for Work Package 5

Deliverable	Description
D8	An HTA adaptation toolkit tailored for use by EU and Member States Development of a glossary of HTA adaptation concepts and terms for EU member countries
D9	EUnetHTA Applicability testing of the adaptation of two Core HTAs, from WP4 or existing HTA reports, in various national settings using the toolkit.

WP5 required close input and coordination with WP4 and WP6. Together with WP7 (prioritisation of HTA topics), they covered the HTA side of the Policy - HTA - Policy loop. The links between them were analysed in WP6. For ease of reporting, the methods employed and results achieved WP5 will be dealt with in three stages, covering the tasks and deliverables above. These are:

1. A survey of current practice in Member States in adapting HTA reports from other countries, identifying the need for a toolkit to aid the process.
2. The development of a toolkit for adapting core HTA information from existing HTA reports to other contexts, including two rounds of applicability testing.
3. The development of a glossary of HTA adaptation concepts and terms for EU member countries, developed in parallel with the adaptation toolkit.

7.3 Methods and Activities

NCCHTA: Lead Partner for Work Package 5: ‘Adapting HTAs from one country into other settings’ and Associated Partner within WP1, WP4 and WP6.

NCCHTA was the Lead Partner for Work Package 5, Adapting HTAs from one country to other settings, and as such a member of the EUnetHTA Steering Committee and Executive Committee. NCCHTA played a full part in the work of these committees over the three years of the project, by attending face to face and e-meetings, by responding to internal consultations and proposals, and by assisting in the development of the continuing EUnetHTA Collaboration .

19 Associated Partners and 7 Collaborating Partners (9 over the three year period) participated in Work Package 5 of the EUnetHTA project, under the leadership of NCCHTA. The objectives and achievements of this partnership are described in full in the following sections of this report.

In addition to leadership of Work Package 5 and participation, as an Associated Partner, in the WP1 central governance processes of the EUnetHTA project, internal evaluations and consultations, NCCHTA also played a role as Associated Partner in two other Work Packages: WP4 ‘Common Core HTA’ and WP6 ‘Transferability of HTA to Health Policy’. This included attendance at face to face meetings and e-meetings, assisting with the development of products and the drafting of validation reports. The contribution of NCCHTA as Associated Partner is described fully in the reports by the Lead Partners of these work packages.

A survey of current practice in Member States in adapting HTA reports from other countries, identifying the need for a toolkit to aid the process.

Objectives

There are numerous Health Technology Assessment (HTA) agencies across Europe, each producing their own HTA reports. Reports on the same HTA are often required by a number of agencies around the same time. The preparation of these reports is both time consuming and costly; if HTA reports prepared for different contexts could be adapted, this could reduce the need for multiple reports on the same health technology with resultant saving of time, and resource.

The aims of the survey were to examine and understand the process of adaptation, to investigate whether the adaptation of HTA reports could be useful to agencies across Europe, and how this might be achieved in practice.

Methods

The methods employed were (in chronological order):

a review of the literature; a survey of 28 European HTA partners, round 1 of a Delphi survey, a face to face meeting of 21 EUnetHTA representatives and a second round of the Delphi survey.

The process of developing the toolkit is shown in Figure 1 below.

The face to face meeting are reported in appendix C.

Manpower

The manpower resource used comprised time from NCCHTA staff, attendance at a meeting in London by 21 EUnetHTA representatives (see appendix C), and time of participating partners in completing and discussing two rounds of a Delphi survey.

Partners Involved

The partners involved are listed in appendix A

Countries Involved

The countries involved are listed in appendix A

The development of a toolkit for adapting core HTA information from existing HTA reports to other contexts.

Objectives

To develop an HTA adaptation toolkit for use by EU Member States and to undertake quality assurance testing of this toolkit.

Methods

An iterative process involving input from 28 European HTA agencies (all members of the EUnetHTA project). A number of methods were used: literature searching, a survey of adaptation experience, two rounds of a Delphi survey, meetings, drawing on the expertise and experience of the partnership, two rounds of review; two rounds of quality assurance testing (termed “applicability testing”).

The face to face meeting is reported in appendix B.

Manpower

The manpower resource used comprised time from NCCHTA staff, time of partners in completing further Delphi survey rounds, time of partners in drafting domains in the toolkit, time of partners in reviewing domains, and time of partners in delivering two rounds of applicability testing.

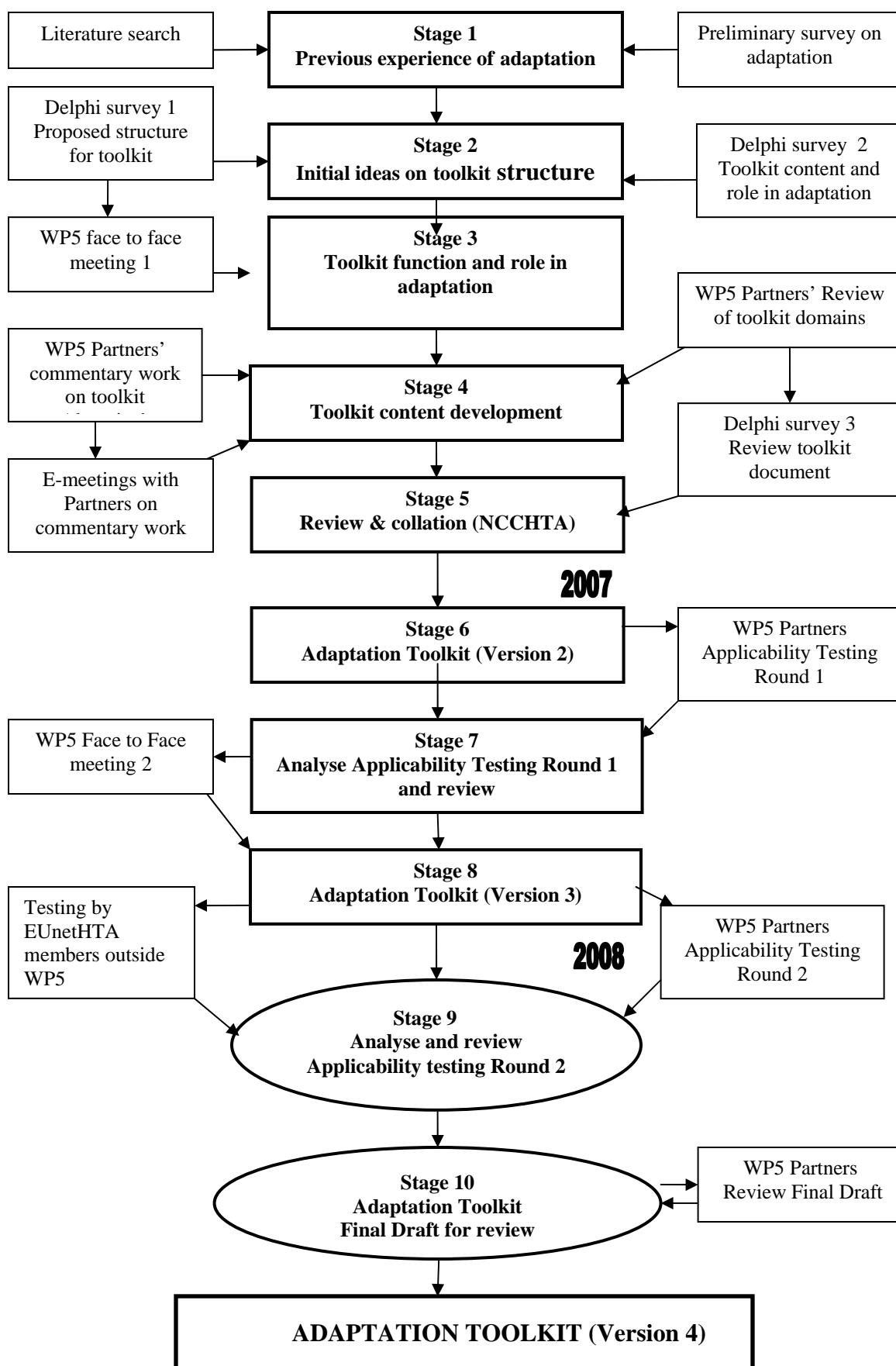
Partners Involved

The partners involved are listed in appendix B

Countries Involved

The countries involved are listed in appendix B

Figure 1 - Flowchart of the development of the HTA Adaptation Toolkit



The development of a glossary of HTA adaptation concepts and terms for EU member countries

Objective

To develop a glossary of HTA adaptation terms to help reduce misunderstanding of terms used in HTA reports from contexts other than the reader's own.

Methods

Several existing HTA glossaries were examined in order to identify ways in which an additional glossary could offer readers something new and to identify adaptation terms for inclusion. 28 European HTA organisations provided terms for the glossary and then drafted descriptions and examples of how each specific term was used in their particular setting. The organisations then commented on the descriptions provided by the other groups and worked together to draft a single description for certain terms.

The process of developing the glossary is shown in Figure 2 below.

Manpower

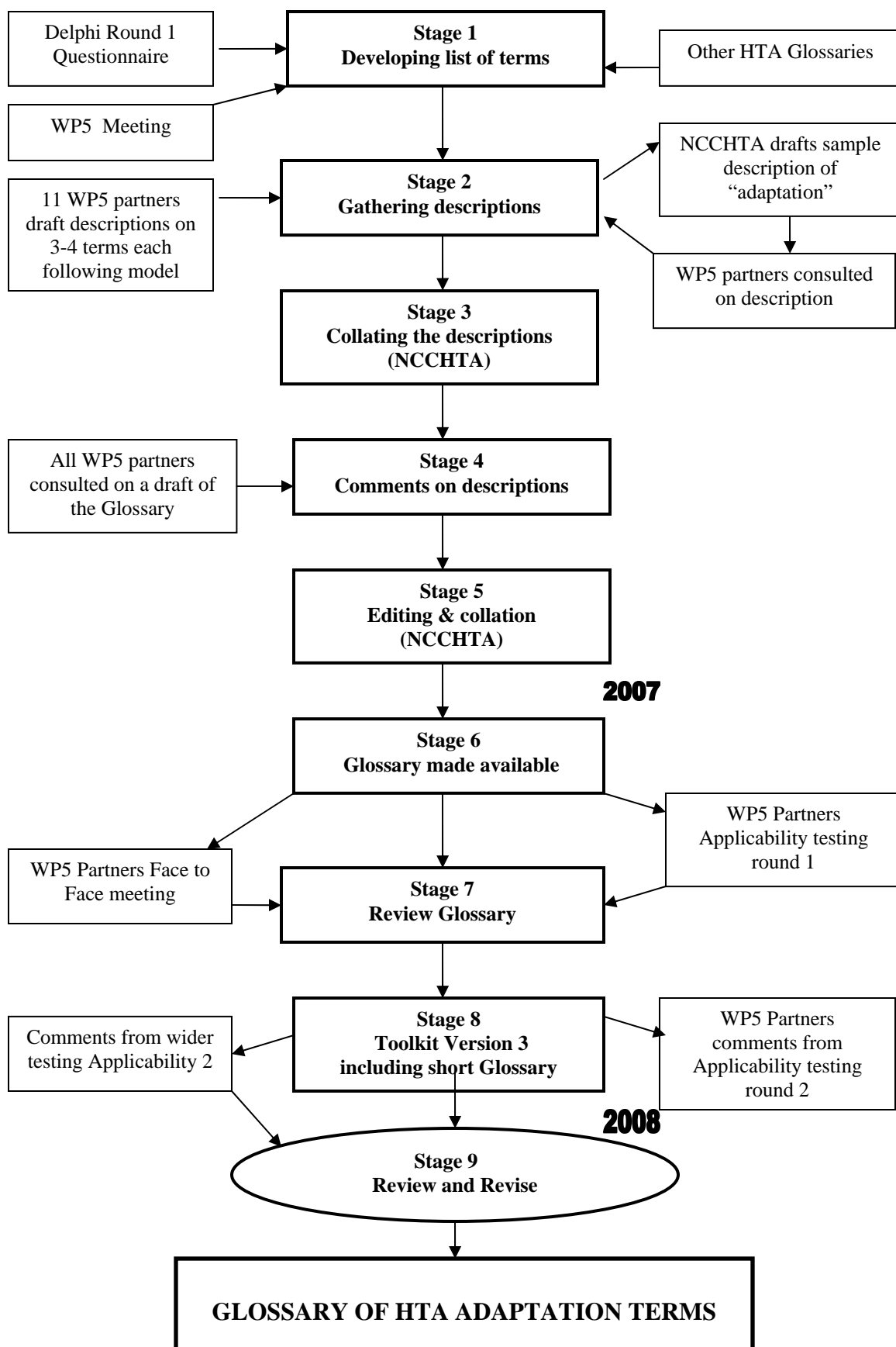
The manpower resource used comprised time from NCCHTA staff, time of partners in drafting and providing definitions for HTA terms, time of partners in commenting on and refining draft versions of the glossary.

Partners and Countries Involved

The partners and countries involved are listed below

1 Lead Partner	19 Associated Partners	8 Collaborative Partners
NCCHTA , United Kingdom	AETSA Spain Agenzia Sanitaria Regionale Italy Basque Office for HTA, OSTEBA Spain Cochrane Collaboration United Kingdom DACEHTA Denmark DAHTA/DIMDI Germany DSI Denmark FinOHTA Finland Galician Agency for HTA Spain HAS France Institut za varovanje zdravja Republike Slovenije Slovenia KCA Belgium LBI (former ITA) Austria NOKC Norway Regione Veneto Italy Servicio Canario de la Salud/ Gobierno de Canarias Spain Technische Universität Berlin, Dep Health Care Management Germany University of Tartu, Department of Public Health Estonia Universita Cattolica del Sacro Cuore, HTA Unit Italy ZonMW Netherlands	DZPHG Germany Hauptverband der Österreichischen Sozialversicherungsträger Austria Institute of Molecular Medicine Portugal Polish Agency for HTA Poland SNHTA Switzerland University of Iceland Iceland Gesundheit Österreich GmbH Austria

Figure 2 - HTA Glossary Development Flowchart



Activities in 2008

There were no meetings organised by WP5 in 2008. All communication was by email exchange. The major activities were:

Glossary

- Drafting and revision of articles for IJTAHC

Toolkit

- Applicability Testing, Delphi Round 2.
- Report of this Applicability Testing round in June 2008
- Update of Toolkit following from this October 2008
- Presentation of WP5 at EUnetHTA conference Paris Nov 2008
- Drafting and revision of three articles for IJTAHC
- Preparation of Final Technical report and Financial report

Other Activities

We were involved in regular monthly updates to members on WP5 activities, and updating / uploading to EUnetHTA WP5 web pages Regular participation at WP1 e-meetings and later Founding Partner e-meetings. We contributed to the consultation and development of future EUnetHTA collaboration proposals. Attendance by Dr Ruairidh Milne and Dr Andrew Cook to EUnetHTA Executive Committee meetings and Steering Committee meetings; Paris in April, Copenhagen in May and a number of e-meetings. Dr Cook and Dr Milne also attended the Paris EUnetHTA conference, in November, as part of their specific work.

Support of Other Work Packages

- Dr Nick Hicks contributed to WP4 (contribution to and review of products Core HTA and Core Model, attendance at meetings/workshops in Tartu, Helsinki)
- Submission (by Debbie Chase) to WP6 book, attendance by Eleanor Bell and presentation to WP6 Stakeholder workshop Rome June 2008
- Response to WP3 Evaluation project (Dr Ruairidh Milne) and WP2 Clearinghouse/IT Platform project (Dr Andrew Cook)

7.4 Results

A survey of current practice in Member States in adapting HTA reports from other countries, identifying the need for a toolkit to aid the process

Descriptions of previous examples of adaptation in the literature are sparse. The majority of respondents had previous experience of adapting reports and all felt that adaptation was useful. There was strong support for the development of an adaptation toolkit.

Consensus of opinion from 28 European organisations/ networks indicated that the adaptation of HTA reports would be desirable and beneficial, and that there was a need for the development of a toolkit to aid in the adaptation of HTA reports, in order to maximize resources and save costs.

Following the completion of the Delphi survey and face to face meeting, the EUnetHTA partners decided that a toolkit for HTA adaptation would be a useful and valuable tool, and commenced work on it.

A paper titled, "The development of a toolkit to aid in the adaptation of HTA reports", has been submitted for publication to the International Journal of Technology Assessment in Health Care.

The development of a toolkit for adapting core HTA information from existing HTA reports to other contexts

The toolkit has moved through multiple versions as further revision and applicability testing has occurred. Version 4 was launched at the EUnetHTA conference in Paris in November 2008. The ongoing EUnetHTA collaboration has recognized the importance of the toolkit, and it will continue to be a significant product in the future.

An adaptation toolkit was developed and tested by EUnetHTA members. This toolkit is composed of a series of checklists and resources which identify or clarify the relevance, reliability and transferability of data and information from existing reports.

A toolkit has been developed by EUnetHTA members to help with the adaptation of HTA reports produced in other settings. This collection of resources is available for use by all HTA agencies and can be accessed via <http://www.eunetha.net/>. The HTA Adaptation Toolkit document is included as an electronic document in the Final Technical Implementation Report CD-ROM.

While NCCHTA has produced the toolkit in English, at least one country (Turkey) has translated it into a local language.

The development of a glossary of HTA adaptation concepts and terms for EU member countries.

A glossary of HTA adaptation terms was developed. It provides a comprehensive range of descriptions, examples and comments for 42 potentially confusing HTA terms related to adaptation. Partners participating in the development of the glossary felt that an accurate version had been produced by the end of 2007.

The current version of the glossary was made available to partners at the end of 2007, and launched publicly at the EUnetHTA conference in Paris in November 2008. It can be accessed via <http://www.eunetha.net/>. The Glossary of HTA Adaptation concepts and terms document is included as an electronic document in the Final Technical Implementation Report CD-ROM.

This glossary will be a valuable resource for European HTA agencies when reading HTA reports produced in different contexts and for adapting HTA reports produced in other countries for their own use. The glossary will help improve understanding and help to facilitate the adaptation process.

7.5 Summary

Consensus of opinion from 28 European organisations/ networks indicated that the adaptation of HTA reports would be desirable and beneficial, and that there was a need for the development of a toolkit to aid in the adaptation of HTA reports, in order to maximize resources and save costs.

A toolkit, composed of a series of checklists and resources which identify or clarify the relevance, reliability and transferability of data and information from existing reports, has been developed by EUnetHTA members to help with the adaptation of HTA reports produced in other settings. This collection of resources is available for use by all HTA agencies and can be accessed via <http://www.eunetha.net/>.

A glossary of HTA adaptation terms was also developed by EUnetHTA members. It provides a comprehensive range of descriptions, examples and comments for 42 potentially confusing HTA terms related to adaptation. This glossary will be a valuable resource for European HTA agencies when reading HTA reports produced in different contexts and for adapting HTA reports produced in other countries for their own use. The glossary will help improve understanding and help to facilitate the adaptation process.

7.6 Recommendations

These products are available in electronic form (PDF), but are in essence paper based resources. Their usefulness resides in their simplicity, and they can be downloaded and used offline where continued internet connection is not available. To add to the Toolkit or Glossary content in this form will reduce their effectiveness. However, the two rounds of applicability testing have produced a rich complexity of suggestions for the toolkit, each of which is relevant to a specific context or domain. They have produced series of questions with decision trees which are not able to be accommodated in a 'flat' file. At several stages in the development of the toolkit, the usefulness of an interactive version was considered, and the decision taken that this would be a useful further development, but requiring more resource than the current project provided.

The recommended next stage is therefore to develop a fully interactive web based version of the toolkit, to be developed by NCCHTA Southampton drawing on the expertise of colleagues from FinOHTA Finland and HAS France, who have also been working on interactive tools.

Similarly, the glossary will benefit from an interactive version which will allow users random access to terms and also the ability to add comments or further explanations without distorting the core glossary.

Both of these developments will be taken forward as an Activity in 2009 within the continuing EUnetHTA Collaboration, so that the wealth of experience already gained is not lost and that of new members incorporated.

7.6 Appendices

7.6.1 Appendix A : WP5 Meeting reports 2006

a. WP5 June 2006 Meeting

Notes from Work Package 5 meeting June 5th and 6th 2006

Melia White House Hotel,
Regents Park,
London



Participants

Finn Børllum Kristensen, Camilla Palmhøj Nielsen (DACEHTA), Elena Berti (ASR), Eduardo Briones (AETSA), Bernard Burnand (IUMSP), Marina Cerbo (Italian HTA network), Mike Clarke (UK Cochrane Collaboration), Hans-Peter Dauben (DAHTA@DIMDI), Teresa Gasparetto (Region Veneto), Jessika van Kammen (ZonMw), Jakob Kjellberg (DSI), Sun Hae Lee Robin, Céline Moty Monnereau (HAS), Mark Leys (KCE), Julio López Bastida (Servicio Canario de la Salud), Marjukka Mäkelä (FinOHTA), Kersti Meiesaar (University of Tartu), Ruairidh Milne, Nick Hicks, Debbie Chase (NCCHTA), Rosa Rico (OSTEBA), Tobias Schulte in den Bäumen (PHGEN), Marcial Velasco Garrido (TU Berlin), Norbert Wilk, Jadwiga Czeżot (AHTAPol), Ingrid Zechmeister (LBI@HTA)

Slides and papers

P-P slides and papers detailing the methods and results of the WP5 preliminary survey and round 1 Delphi survey will be made available on the WP5 extranet at the end of June.

EUnethTA overview

The structure of the sustainable network will be proposed by DACEHTA in August 2006 in a process paper for further discussion.

WP5 and adaptation

Distinction between adaptation and adoption. There is a spectrum ranging from the creation of a completely new report, adaptation to varying degrees and complete adoption of another country's report (with possible language translation).

A description of the stages of adaptation is required. There is no formalised process of adaptation.

There are different types of HTA reports e.g. mini HTA reports. What types of HTA reports are members producing? An understanding of the needs of agencies and users is required.

There was consensus that applicability testing will not produce 'adapted reports' but 'adaptation material'.

WP5 should always start from an existing HTA. Coordination (architecture) is the realm of WP4

Thoughts on toolkit

Toolkit should consider relevance, reliability (quality assessment) and transferability. It should include a checklist of prompts to local context issues for consideration.

It should be very practical and useable.

We must be aware of different types of users e.g. those who haven't adapted a report before, no agency/large agency, information for specialists and generalists.

Should consider issue of dealing with multiple HTA reports

May need more than 5 headings.

Not all sub-headings are relevant for the 5 headings.

Toolkit will develop and change over years 2 and 3 of this project. It will start simple and become more sophisticated over time. Guidance on use will be developed but the toolkit will, eventually, be software based.

A practical exercise would be useful. Using an HTA report as a template and using the toolkit on this i.e. applicability testing.

Thoughts on glossary

Ensure close working with developers of the INAHTA glossary to inform them of our work and for future links.

Issues raised at the meeting for other work packages?

Development of a Clearing House meta-search engine for searching for HTA reports. This facility would search the INAHTA database and agencies' websites for reports.

Provide a standard data extraction sheet and format for an HTA report.

Have a meta-database of literature within HTA reports e.g. efficacy data

Attendees felt there was a need for contact information in future HTA reports to identify additional information and provide access to economic models

Need for instructions to agencies on how to write HTA reports in ways that make these reports easier to use/adapt

Actions

Mini round of e-mails to enable convergence on definition of adaptation. To send out **19/06/06** for comments by **26/06/06**.

E-mail members who did not attend meeting. Suggest e-meeting to help understanding of our objectives, work plan, their input.

Revisions of toolkit and glossary descriptions.

Second round of Delphi – further developed toolkit. **Proposed send out beginning of July. Two week deadline.**

Full results from preliminary survey and 1st round Delphi survey to be made available on Episerver. **End of June/early July.**

Allocation of commentaries to members. **Early July. Deadline early September.**

Allocation of glossary terms and definitions. **Early July. Deadline early September.**

b. E-meetings on toolkit domains

Transcript type notes from Safety Toolkit Commentary Work E-Meeting, 10am Thursday 21st September 2006

Lead:

Nick Hicks, Debbie Chase, Celia Davidson, NCCHTA, England

Participants:

Celine Moty-Monnereau and Najoua MLIKA-CABANNE, HAS, France

Rosa Rico and Nieves Sobradillo, OSTEBA, Spain

Assistance:

Julia Chamova, DACEHTA, Denmark

Slide 6-10 Reliability questions

Rosa: Need to integrate the issues suggested by all commentary workers.

Nick: Will integrate responses after the e-meeting.

Rosa: In my proposal we talked about data coming from contextual database. Data are heavily linked to contextual setting.

Celine's co-worker: Our proposals are based on in house experience. We have lots of experience of adapting guidelines. These are produced for stakeholders and decision makers.

The proposals are in-depth questions used for adapting guidelines. We may not wish to utilise all these questions in the WP5 toolkit.

Debbie: The safety domain within the toolkit could have two sections. The first would include key safety reliability and transferability questions. The second would include more comprehensive questions that could be utilised when necessary.

It is important that we assess reliability before transferability.

What is your experience of using these questions to assess reliability?

Celine's co-worker: Experienced for 3 topics in guidelines area. Have used in depth. Examples are: Initiating labour for women. Syncope, stroke. Propose that these examples are sent to Debbie for consideration.

Rosa: Happy to use HAS checklist in WP5 toolkit with integration of OSTEBA questions.

Slides 11 – 15 Transferability questions and conclusions

Nick: Looking at the HAS checklist, there is a match between the points and those suggested by Rome Group: 1+2 HAS. 2nd point from Rome also in HAS.

Rosa: I agree that they are complementary.

Rosa: Important to add the training aspect to the HAS transferability checklist. Also important to consider evidence from medical incident report systems/ questionnaires in the health services.

Nick: This isn't always emphasised enough in reports or guidance in writing HTA reports.

Debbie: Which methods are better for reporting safety? How could we address this in the toolkit?

Rosa: Don't know about incident report systems. In HTA, usually work with local context with this kind of data because usually no conducted trials re safety but difficult for transferability. Need to know how to read and use other countries' context specific data. It is a necessity.

Celine's co-worker: Need to talk to ADAPTE group: <http://www.adapte.org/index.html> (Bernard Burnand a member). Criteria already there for adaptation: consistent, but no validation undertaken. They are comfortable with it, but not tested.

Debbie: Bernard will be part of the group reviewing these safety checklists.

Are there any specific questions relating to certain types of health technologies that we should include in the toolkit?

Nick: Let's talk internally about this.

Slide 16: Speedy sifting

Debbie: Speedy sifting. Reminder of questions. Can you think of any relevant questions in relation to safety? Now/later?

Rosa: Descriptive questions. Safety [is connected to?] effectiveness question, too. So – perhaps better to do it later?

Celine's co-worker: 5. Be aware that if author is from a well-known organisation still need to check reliability. Be careful with authorship.

Slide 17: Future work.

Debbie: Next stage - review by members who have not worked on this domain, then on WP5 extranet for comments from all WP5 members

Julia: Important to record methods used for development of toolkit – choice of members for work etc.

Debbie: There has been no recording for this e-meeting session. Notes/transcript will be sent to all participants.

**Transcript type notes: Effectiveness domain e-meeting
12.00-13.00 Thursday 21st September 2006**

Lead:

Nick Hicks, Debbie Chase, Celia Davidson, NCCHTA, England

Participants:

Kristian Lampe FinOHTA, Finland

Inger Natvig Norderhaug NOKC, Norway

Assistance:

Julia Chamova, DACEHTA, Denmark

Apologies: Mike Clarke, Cochrane UK

Comments on Mike's commentary work suggestions (12 reliability and one transferability questions):

Kristian: Questions 1 and 2 are from the Overview Quality Assessment Questionnaire (OQAQ) checklist and therefore fine. Question 3 is a new question, and a good idea.

Should we be specific that the search should include the HTA database?

Inger: Good ideas – agree with Kristian: relevance for filtering as not only the quality dimension: consider early or late in the toolkit? Need to consider if intervention is relevant in local context.

Inger, Kristian, Debbie: Questions 5-8. Agreed, should be included in the toolkit.

Inger: Questions 9-13. Need to reconsider the wording of question 12 i.e. relevance.

Inger: These are all important questions to include in the toolkit. It is important that we consider relevance.

Kristian: Important that our standards are connected to some international standards. All questions in toolkit should relate to existing work. Oxman and Guyatt checklist developed to assess the quality of systematic reviews.

Debbie: Do you think that this checklist adequately deals with effectiveness issues – as much as efficacy? Are there further questions we need to add to this checklist relating to effectiveness issues?

Inger: Thinking on quality assessment of effectiveness data is too premature yet to include in the toolkit. We could add this in the future.

Comments on Kristian's commentary work suggestions regarding transferability:

List of factors

Kristian: Proposed list of factors for consideration comes from a colleague and was published recently.

Inger: Some of the items listed relate to validity of the study rather than transferability. Transferability issues – regarding population, intervention and comparator. Analysis part – more on reliability.

Kristian: Agree, some of these issues would fit within the reliability checklist.

Transferability questions

Inger: Agree with the transferability questions proposed by Kristian. Would like to test the toolkit in-house using the agreed checklists.

Economic evaluation e-meeting

October 2, 2006

Lead:

Debbie Chase, Hilary Bunce, Ruairidh Mine, Andrew Cook, NCCHTA, England

Participants:

Jakob Kjellberg, DSI, Denmark

Slide 6 - OBIG (Ingrid Rosian-Schikuta)

Drummond checklist should be used for assessing economic evaluation data reliability

Ingrid: Reference 4 from slide 6, used same for our commentary. This is a German publication. Useful for assessing reliability, quality and transferability. All other references considered for this commentary apart from reference 5.

Slide 7 - Servicio Canario de la Salud, Spain (Julio Lopez Bastida)

Aspects to be followed up later

Supports use of Drummond checklist for assessment of reliability

Jakob: Checklist questions proposed for transferability very similar to questions proposed in the other commentaries.

Slides 8, 9 - Region Veneto (Teresa)

Reliability – though no definition of what reliability means in this context

Possibly benefits from report -> source of bias

So much benefit -> Bias. When should the report be excluded?

Slides 10, 11, 12 – LBI@HTA (Ingrid Zechmeister)

Information from personal experience

Reliability -> Drummond, but possibly leave out some questions (would be dealt with in speedy sifting part of toolkit)

Transferability -> Welte & Leidl checklist for transferability translated into English

W&L have published in English themselves. These criteria are easy to operationalise when dealing with transferability. The checklist has been validated.

Exel based algorithm needs more consideration/investigation. Ingrid has not used this algorithm. It is linked to table 1. However, Ingrid has used the list of factors in table 2 to help with adapting reports from other settings.

Slides 13, 14 - Danish Institute for Health Service Research (Jakob)

All guidelines develop from Drummond & Canadian guidelines, ?Philips

Little to choose between them – unless there is an advanced decision-analytic model in which case Philips may be superior. Some guidelines have better structure. No special preference as to which we chose to include in the toolkit.

Questions must guide assessor where to look in a model – which may have hidden depths in spreadsheets or a computer programme. These are easy to miss for assessors lacking health economics experience -> checklist must be very detailed and comprehensive to guide inexperienced assessors. Drummond therefore will not be detailed enough. The CCOHTA checklist is a more practical tool, more detailed and helpful for inexperienced assessors.

Issue regarding whether an economic evaluation violates national/regional guidelines on economic evaluation. Important to take account of national economic guidance. For example, in Denmark, equity issues are very important. There are specific guidelines for dealing with cost and CBAs.

In relation to transferability, there are organisational issues here. For example, the English health system is not that different from the Danish health system but, in transferring information from a NICE report, we need to be aware of differences in treatment patterns. The way the treatment is organised is very important and has a big impact on cost.

Proposed way forward

Participants agreed that we should include the Drummond checklist (plus additional questions from CCOHTA) in the toolkit and also include the transferability questions and issues raised by all participants (including the list of factors highlighted in Ingrid's commentary). It was agreed that flagging the issue of national economic guidance would be an important addition to the checklists.

Questions and issues regarding reliability and transferability will be collated in-house and e-mailed to members who produced economic evaluation commentaries. Once agreed, these will be sent for review by other WP5 members.

Organisational aspects e-meeting

October 2, 2006

Lead:

Nick Hicks, Debbie Chase, Hilary Bunce, NCCHTA, England

Participants:

Mark Leys, KCE, Belgium

Camilla Palmhøj Nielsen, DACEHTA, Denmark

Finn Børlum Kristensen, DACEHTA, Denmark

Hans-Peter Dauben, DAHTA@DIMDI, Germany

Agreement from participants that 'organisational impact' should be changed to 'organisational aspects'.

Slide 6 – KCE (Mark Leys)

Has a background in Sociology.

Technology not an external factor to organisation. Need to understand how it is shaping the organisation. Specific context is important – legal/political/cultural. For example, in Sweden there is a stronger focus on primary care than in Germany or France.

Need to take account of inter-organisational issues or relationships between organisations. We focus too much on intra-.

In assessing organisational issues, qualitative research, changes/processes important.

There are different approaches but no one checklist to assess reliability. Ideas from system theory.

Slide 7 – DACEHTA (Camilla)

Very brief descriptions on organisational aspects in previous European projects.

WP4 already have ideas on how to take this forward.

Qualitative data important. Checklists already mentioned, however these only look at transparency of data and not theoretical basis of data.

What do we mean by transfer of data on organisational aspects? Is this the conclusions?

Hans-Peter: From German experience, problem is, what do you want to do with these data from another context?

Slide 8 – TU Berlin (presented by Debbie)

Consideration of dimensions and how HTs can induce changes in dimensions.

This domain one of the most context dependent aspects in HTA.

Results unlikely to be transferable, the methods used in the assessment might be transferred to other situations.

Slide 9 – ZonMW (presented by Debbie)

Important that organisational aspects are dealt with as a distinct subject and also implicit in other toolkit domains. Organisational aspects not routinely incorporated into HTA reports - likely reason why there are no checklists or tools for assessing reliability.

Transfer sensible for the kind of issues on organisational aspects and the kind of data, but not the data themselves. Methodologies might also be transferable.

Camilla: Use of different methods, relates to Mark's comment on organisational aspects. Important to consider at different organisational levels.

General discussion

Mark: Need to clearly distinguish all levels of organisational issues – department, direct user.... With a focus on inter-departmental issues.

Nick: Need for a matrix/3-D table that takes account of the different levels and impact on organisations?

Debbie: Does anyone have any examples of adapting information/methods etc. relating to organisational aspects from one report to another?

Hans-Peter: Tried to adapt some HTA reports to different settings. Have tried to develop a model for transferring information into the German setting. For the C-virus HTA report, this was adapted into the Canadian setting. To accomplish this, the author, was part of a Working Group that adapted the report to the new setting. (*Hans-Peter please could you check that I have understood this correctly*)

Camilla: In Denmark, we often adapt more local, Danish, reports. Therefore, not from one country to another. Always include organisational aspects, but don't usually find this in other reports.

Mark: At the descriptive level, HTA reports should include information on organisational aspects. What is the impact on personnel? On relationship? No examples exist.

Hans-Peter: There is a need for more organisational aspects information within the report to be adapted to help transfer information.

Finn: We should look to the WP4 handbook for assistance.

Way forward

Debbie: What should we include in the toolkit? (1) A high-level checklist dealing with issues and methods in this area, (2) nothing – given that few reports include this domain and assessment ideas are at an early stage of development or (3) something else?

Camilla: Try to go with checklist, co-ordinate closely with WP4 and take time to describe issues and problems.

Mark: Thinking in this area has not moved on since 1990s. We need to include this in toolkit. But keep it at a basic level at the moment.

Hans-Peter: Toolkit needs to include information in general about organisational aspects (less checklist). INAHTA working group have been in discussions regarding checklists – difficult, too many different types of topics. Not practicable.

Mark: We are not writing a HIT report. A basic classification is needed. Not too complex. Basic matrix, can locate which level we are dealing with.

Matrix: Content (human resources/logistics...) against levels of analysis.

We don't need to understand other contexts to do this. Look at transferring issues for certain levels/settings.

Notes from technology use and background e-meeting

September 28, 2006

Lead:

Debbie Chase, Hilary Bunce, Andrew Cook, NCCHTA, England

Participants:

Kersti Meiesaar Uni of Tartu, Estonia,

Elena Berti ASR, Italy

Eva Turk, Slovenia

University of Tartu (Kersti)

Technology background information

Should this stuff be at the beginning of the toolkit? – assessment of relevance rather than reliability
(Important to relate to WP4 work – recent meeting in Helsinki)

Were conditions appropriately defined?

Paper from ?? *international journal* ?? in 2002

Technology use

Need to tackle reliability? (of the technology?) (of a report to be converted?)

ASR, Italy (Elena)

Information taken from Valesco Textbook?? Professional Journal of HTA

Background

Definition of policy and research question

No need to be strict about method of evaluation

Institute of Public Health, Slovenia (Eva)

Based on commentary from other partners

Why has the assessment been made – who ordered the work?

Mainly the 'political thing'

General Discussion

Does information on technology use and development affect adaptation? Just a feeling from participants that it is important to include reliability questions on background information,.

Do we need a small section to consider the quality of the information in an HTA? Might this fit under question 4 or 7 of Debbie's 8 relevance questions i.e. speedy sifting questions? Relevance questions deal with most of the questions/issues proposed on technology use and development.

Do we need a separate section in the toolkit that addresses technology use and background information? Or can all the issues be addressed in the speedy sifting part and under each of the other sections e.g. issues relating technology use and development to safety outcomes would be dealt with in the safety section of the toolkit.

CE-meeting on the interactive toolkit

Web-based toolkit E-meeting **21st November 2006**

Attendees:

Representing WP5

Ruairidh Milne (Chair)
Neil Adams
Hilary Bunce
Debbie Chase

Representing WP2

Alric Rütger, DAHTA@DIMDI, Germany
Hans-Peter Dauben, DAHTA@DIMDI,

Purpose of meeting

1. To understand what WP2 and WP5 are doing
2. To agree on possible collaboration

WP2 plans for the Clearinghouse

Purpose of Clearinghouse: to bring together information from different areas to help users prepare or read an HTA report.

The Clearinghouse will include a database of information. Its aim is to reduce duplication of effort. It will have a 'public' and 'closed' area. EUnetHTA and INAHTA toolkits can be brought together within the Clearinghouse.

Clearinghouse facility will not be completely 'up and running' by the end of the EUnetHTA project period. However, prototypes will be developed using WP4 and WP5 products by the end of 2008.

The facility will be a 'portal'. Users would be led through this portal by the questions. It will have an electronic format, linking to websites and a main database. There will be input boxes for data and tables. It is likely to be a Java based system.

WP2 are also setting up a communications strategy for EUnetHTA. The next WP2 meeting in December

WP5 update on the Toolkit

The first version of the toolkit is currently out for review (by WP5 members). It is in the form of a guidance document.

We would like the toolkit to be available both as a guidance document and a user-friendly practical tool.

WP5 members provided their thoughts on what a user-friendly toolkit would look like through the Delphi round 2 survey. A summary of their responses was presented at the meeting.

Mike Clarke, Cochrane Collaboration, made a useful distinction at the WP5 June meeting, that a handbook is a static resource e.g. a pdf file and a toolkit is more like a series of web pages with possible link to a database.

At NCCHTA, we are considering the spectrum of what this user-friendly toolkit would look like and achieve i.e. from a simple set of web-pages to a series of web-forms linked to a database. We need to consider the costs and benefits of different approaches, and decide on what we can achieve within the project period, given the available resources.

Possibilities for Collaboration

What could be achieved in 2007?

An interactive tool could be developed within 6 months after the toolkit is finalised. A less sophisticated tool i.e. not linked to a database, could be achieved in 2 to 3 months.

The content, questions and language of the toolkit will be continually developed over the next couple of years through applicability testing rounds and review from EUnetHTA members.

It would be difficult to integrate the toolkit into the Clearinghouse at a much later date. We will need to develop the interactive toolkit alongside the development of toolkit contents. There is a need for flexibility to make changes to the interactive version.

Initially, we need to consider the graphical user interface and principles for development. Then, determine a 'freezing point' i.e. timepoint in the project period when the interactive toolkit structure is finalised and not developed further.

Next steps

Goal for WP5 would be to test the interactive toolkit in the 2nd round of our applicability testing (September 2007). However, if feasible, e-meeting participants were keen to test the interactive version in our first round (March 2007).

1. Schedule a workshop to agree on a graphical user interface, development of the toolkit and planning workload. *Date fixed for 14th December 2006, Southampton, England*
2. Inform WP2 of our initial plans regarding an interactive toolkit at the WP2 meeting
3. Include information about collaboration with WP2 and initial planning ideas for the interactive toolkit within the WP5 technical report

WP4 and WP5 Lead Partners Videoconference

WP4 and WP5 videoconference 21 st August 2006
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Attendees

NCCHTA: Ruairidh Milne, Nick Hicks and Debbie Chase

FinOHTA: Kristian Lampe and Ilona Autti-Rämö

Key points

(i) WP4 are defining 'core' as some part of the product of importance and transferability (rather than the intersection of importance and transferability); and will describe their process for agreeing on core before doing the work

(ii) WP5 will decide on whether to call them domains/aspects/facets; WP4 and WP5 will then use the same term

For future reference – it was discussed that in using this structure we may miss important issues relating to parameters that fall across domains e.g. quality of life

Final decision after much consideration(!): Domains

(iii) It will be very useful for WP5 to reflect more closely on the overlaps between WP5 and WP4 processes, once their processes are more clearly defined.

For example – information on quality assessment and transferability issues on WP4 cards (each one is about a critical issue relating to the core) will be directly relevant to guidance in the WP5 toolkit

(iv) WP4 will involve WP5 in some yet to be defined way in deciding on the transferability (but not perhaps the importance) of the domains (eg effectiveness) and/or the topics (eg mortality)

(v) WP4 will also involve WP5 in some yet to be defined way in deciding on final status of particular domains and sub-domains. (final status meaning whether something is in the core or not)

(vi) WP4 will call their testing 'validation/validity testing' (and not 'applicability testing')

(vii) WP4 and WP5 need to ensure that we are using the same terms to describe the same things (as in ii). This will be done by ensuring that we each have access to each others reports as early as possible.

After meeting thought – most importantly, WP5 will provide WP4 with the draft glossary (at the same time as WP5 members) before M10 deadline

7.6.2 Appendix B: WP5 Meeting reports 2007

Interactive toolkit emeeting – 30 January 2007

Present

Alric Ruthers, Hans-Peter Dauben, Ruairidh Milne, Andrew Cook, Debbie Chase and Hilary Bunce

Background

This emeeting was convened to confirm what was agreed at the last emeeting, to review progress on the interactive toolkit development to date, to discuss the resource and time implications for developing the toolkit and to agree a plan for implementing the interactive toolkit.

Discussions

- HPD outlined progress to date.
 - There is a URL available for the toolkit.
 - An excel spreadsheet has been set up to input the data
 - They are investigating getting external IT resources, because DAHTA do not have the resources. There have been discussions with the University of Cologne regarding whether a student could take on the work as a project (this would be a less expensive option). Currently they have received an amber-green light. HPD estimated that to develop a first version of the complete webbased interactive toolkit would take 3-months. For developing an excel version for the first round applicability testing in March 2007 would take 40 hours.
- HPD explained that now a number of other work packages had been approached asking for IT support. He highlighted that the DAHTA does not have the facilities and resources to provide all the assistance and that this needs to be discussed in relation to the whole EUnetHTA project. It was agreed that this would be a good example of working collaboratively and should be discussed in Barcelona. In addition, HPD will raise it at the WP1 emeeting in February.

Action – HPD to discuss resources at WP1 meeting in Feb.

- HPD outlined that for the March 2007 round one applicability testing he could prepare an excel questionnaire, which he could have ready in 2-weeks.
 - It would incorporate the questions, guidance and explanations. In addition the evaluation form would have to be incorporated.
 - Excel is the preferred format because the form can be more easily manipulated and will aid the development of the main web based toolkit.
 - It will be made into a user friendly document.
 - It will be possible to make changes to the March toolkit until quite late in the day.

Action – DC and HPD to correspond by email to finalise the arrangements

WP4/WP5 Lead Partners' e-meeting 14th February 2007

Brief notes and actions from meeting

WP4

Core Model (CM) ready January 2007

1st draft of Core Topic (CT) will be ready in next couple of weeks – FinOHTA will send to NCCHTA for comments
Validation of CM and CT to be undertaken in June 2007

Validation results will be discussed at a meeting in the Autumn (currently scheduled for June)

Consideration of whether CT developed enough for applicability testing round 1 – will we be able to distinguish clearly comments on CT and comments on toolkit?

Action: CT not to be included in WP5 applicability testing round 1. But, consider inclusion in applicability testing round 2.

Validity testing

CM validation

Want members to apply the CM questions to their own (their agency's) project. Plan to start in June.
Want members to take one of their own recent reports. Look at all the questions/issues in the core model and identify whether the agency's own HTA considers or answers these questions? Is there anything that isn't covered?

CT validation

Package that partners will use as the basis of their report. Is it useful? Can they apply to their own report?
How useful are sections of the CT report to decision making?

CT will be very different to existing HTA reports (?card system). Information in the report will be structured very differently.

NCCHTA contribution to WP4

NH asked if more detailed timetable for the future years work could be given within the large milestones currently identified. This would help planning and because of the difficulty in working as small groups electronically whether consideration had been given to reviewing this approach. NH suggested perhaps groups could be enlarged and given the timeline and issues they needed to address and could then organise their own work accordingly?

MM noted that in future work – emphasis on including members that have not contributed yet.

NH noted that he needed to re-attach the references in the Safety Core Model and asked if there was any specific work with the Safety Core Model that needed to be undertaken at present.

KL said that the main issue to remember was that the Core Model needed to be finalised for public launch at HTAi in Barcelona in June and that the team needed to be entirely happy with its content at that point. He also said that he would send out further instructions in the next few weeks.

WP5

First round of applicability testing to be undertaken from March – June 2007. Details available on WP5 extranet for comment:

http://www.eunethta.net/Members_only/Workpackages/Workpackage_5/WP5_applicability_testing_round_1/

Second round to start in October 2007.

Should include INAHTA glossary as a resource in the toolkit. Need to re-label our glossary an 'adaptation glossary'

FINOHTA feedback on applicability testing ideas – recommend take a small number of hot topic reports and ask members to adapt using toolkit. Then several units will be evaluating usefulness of toolkit on same report.

General discussion

Timing of WP4 and WP5 testing rounds good – no overlap.

Toolkit and CM should be complimentary rather than overlapping. Metaphor – toolkit like archaeology and CM like architecture! NH felt that this explanation would be very useful for EUnetHTA to explain the work of WP4 and WP5 and should be expanded. MM said that it could be possible to do a piece of work comparing the outputs of the WP5 Toolkit on a WP4 Core Topic and this would identify how they overlapped or supported each other. NH felt this would be quite informative.

We need to consider the overlaps between CM/CT and the toolkit and be clear on these - then present to EUnetHTA. What are the similarities and overlaps between CT and the toolkit?

Action: NCCHTA and FinOHTA to draw up a one page document on similarities and differences between CM/CT and toolkit and take to EUnetHTA

Notes from Work Package 5 meeting September 27th and 28th 2007

Palazzo Cavalli Franchetti,
San Marco,
Venice



Participants

Organisers / Hosts

Ruairidh Milne, Debbie Chase, Claire Rosten, Eleanor Bell (NCCHTA)
Teresa Gasparetto, Luigi Bertinato, Giampietro Rupolo (Regione Veneto)

Associated Partners

Victor Sarmiento-Gonzales (AETSA), Elena Berti, Roberto Grilli (ASR), Finn Børlum Kristensen, Camilla Palmhøj Nielsen (DACEHTA), Hans-Peter Dauben (DAHTA@DIMDI), Iris Pasternack (FinOHTA), Fabienne Quentin (HAS), Eva Turk (IPH), Philipp Radlberger (LBI-HTA), Lise Lund Håheim (NOKC), Nieves Sobradillo (OSTEBA), Marcial Velasco Garrido (TU Berlin), Marina Cerbo (UCSC), Kersti Meiesaar (U Tartu), Jessika van Kammen (ZonMW)

Collaborating Partners

Tobias Schulte in den Bäumen (PHGEN), Zbigniew Krol, Jadwiga Cieczot (HTA Poland), Irmgard Schiller-Fruewirth (Hauptverband ...)

We would like to thank our hosts Regione Veneto for their warm welcome and delightful venue.

Slides and papers

PPT slides of presentations made at the meeting have been made available on the EUnethta website.

[EUnetHTA startpage / Work Packages / WP5 - Adapting HTA / Activities / September 2007](#)

Notes and outcomes of workshop sessions will be made available on the WP5 extranet by the end of October 2007.

Objectives and overview

1. to learn about and celebrate what EUnetHTA and WP5 have achieved so far
2. to agree a plan for the remaining 15 months of the project
3. to consider in detail how we will further test and develop the toolkit (incorporating the glossary)
4. to agree how we will communicate with others about the work of WP5
5. to plan for the post-EUnetHTA sustainable European HTA collaboration

Day 1: 27 September 2007

Members were welcomed to Venice and to the WP5 Members' meeting. After an outline of the meeting programme, Debbie Chase reviewed the year's achievements, and members provided their own reflections on the development of the Toolkit and Glossary. Debbie then provided a report and feedback on Applicability Testing Round 1, completed during the summer, and the meeting then moved into active workshop mode for a facilitated session on the Glossary. Finally Finn B-K provided a useful summary of discussions to date on the Future of the EUnetHTA programme 2009 and beyond.

Our Venetian hosts provided an 'aperitivo' before we left the Palazzo, and later organised a delicious group meal in a local restaurant.

Day 2: 28 September 2007

On the second day, members worked in groups on proposals for Applicability Testing Round 2, and contributed actively to the planning for the final stage of the WP5 work package.

Ruairidh Milne summarised the outcomes of the very positive and productive two days, and members were able to continue networking over lunch, before making their way home.

Local HTA event

The venue and timing of the WP5 event also allowed the opportunity for Regione Veneto to organise their own HTA seminar immediately beforehand for local Venetian healthcare staff, and Finn B-K and Ruairidh were invited to make presentations. This was felt to be of great assistance to Regione Veneto in raising the profile of HTA and the EUnetHTA project with local decision makers.

Review of 2006-7 and Applicability Testing Round 1 (M21)

Please see the presentation slides on the EUnetHTA website

[EUnetHTA startpage / Work Packages / WP5 - Adapting HTA / Activities / September 2007](#)

Glossary Workshop

Please see presentation slides by Claire Rosten and the group feedback report prepared by CR (on WP5 extranet).

In summary, the glossary was found to be a very useful, indeed essential, tool to accompany the toolkit. The web based presentation of the glossary needs to be improved, and there needs to be greater clarity on its purpose, i.e. 'a resource for identifying issues related to different uses and meanings of various HTA terms with a view to aiding the adaptation of HTA reports between settings'. The EUnetHTA glossary uses some definitions from, but does not seek to duplicate, the INAHTA glossary. Although providing a range of explanations from different settings could be confusing, it was also seen as useful in providing insight into different approaches and ways of thinking.

It was agreed that for those who had not worked on the development of the Toolkit and Glossary, Claire would produce a short version, including only terms used in the Toolkit and only the agreed EUnetHTA or INAHTA definitions.

Future of EUnetHTA 2009+ - Finn Børllum Kristensen

WP5 members found the overview provided by Finn B-K of discussions with EU and the prognosis for continued network activity after the end of the current project very illuminating. These discussions, the consultation document, and the public consultation phase, are amply covered on the EUnetHTA website.

Applicability Testing Round 2 (M30 D9)

After an introduction by Debbie Chase (see presentation slides), members selected themselves into five groups to work on the following topic areas:

- Diagnostic testing & screening
- Interactive version of the Toolkit
- Cost effectiveness modelling
- Transferability
- Organisational aspects

This was a very productive active session, and members developed clear views about ways of working with the Toolkit. It was agreed that the five groups as set up in Venice, together with additional members from those APs and CPs not present, would continue to work on these topics through to March 2008, liaising amongst themselves by email and teleconference, and coming together group by group in five eMeetings in March.

A parallel work stream was the use of the Toolkit to adapt a Core Topic, and members saw a clear link here with WP4. Meanwhile, NCCHTA will develop a more comprehensive Toolkit version 3. This will be placed on the EUnetHTA website and members not previously involved with WP5 invited to use the revised toolkit to adapt an existing HTA report.

The outcomes from the series of five work groups, the Core Topic, and those using the Toolkit version 3, will be reported in the spring 2008 as deliverable D9.

Issues raised at the meeting for other work packages

There are identified links between WP5 and WP4 Core Topic and WP2 Clearing House.

However, it was noted that there was no dependency from WP2 Clearing House information system (December 2007) on work undertaken around the Interactive version of the Toolkit, and progress on WP2 would not be delayed by this work group activity.

Actions

Full programme and presentation slides to be placed on EUnetHTA web pages – both public and members only – **by early October.**

Notes of workshop sessions and feedback from members to be placed on the WP5 Members only pages, together with photos of the event – **by mid October.**

Formal note of the Venice meeting to be sent to DACEHTA secretariat – **by end October.**

Round of email instructions to members of five work groups to progress work commenced on Applicability Testing Round 2 – **by early November.**

Invitations to other AP members to join these groups – each AP to contribute to the work of at least one work stream – **by mid November.**

Short version of Glossary to be developed and placed on the EUnetHTA website – **by mid November.**

Toolkit version 3 to be developed and placed on the website. Invitations to those not previously involved in WP5 to use this version to adapt an HTA report – **by early December.**

Report author:

Eleanor Bell, EUnetHTA project manager, NCCHTA, Southampton UK

October 2007

8 Work Package 6: Transferability of HTA into Health Policy – Report on results and activities 2006-2008

8.1 Summary

In this field of 'Transferability of HTA to health policy' the EUnetHTA WP6 worked on two different types of activities.

One activity was focused on obtaining overview over and knowledge about the links between Health Technology Assessment (HTA) and health policy-making in Europe. This activity creating overview over existing research and contributed with new data collection and analyses related to the complex links between HTA and policy. The work is published in a book (1), which addresses the field by:

- examining how HTA contributes to policy processes
- summarising the crucial components of good HTA
- analysing HTA-policy links and processes in different health systems, and classifying common characteristics of the relations
- exploring the impact of HTA on health care and health policy; and
- focusing on needs and demands for HTA as well as challenges and potentials for improving the role of HTA at different policy levels.

The book seeks to transmit the value and potential of HTA to a wider audience beyond the decision-making and health care management arena and, by doing so, aims to increase the role of HTA at different policy levels.

Another activity focused on supporting dialogue with HTA stakeholders in Europe and ensuring exchange of views, expectations and feedback on HTA with the purpose of:

- improving responsiveness of HTA to stakeholders; and
- proposing a framework for stakeholder involvement in the EUnetHTA Collaboration.

The stakeholder activities were multi-faceted and included development of a website for stakeholders, development of a draft stakeholder policy and convening a stakeholder meeting.

8.2 Introduction

Health care policy-makers throughout Europe seek to improve the health status of their citizens through the delivery of health services. Health policy thus aims at improving the performance and health outcomes within sustainable health systems. Health Technology Assessment (HTA) contributes to the formulation of such health policy by providing evidence-based information to those who make policies and decide on coverage and usage of health technologies. However, establishing links between HTA and policy-making poses challenges to both producers and users of HTA – and there is a potential to improve the responsiveness of HTA to the needs of policy-makers to achieve the desired goal for HTA of a larger policy input role.

Obtaining knowledge about the transferability of HTA to policymaking in Europe is important since it is a success criteria that HTA is used in policy-making processes and has an impact on the delivery of health services. Therefore, it was an explicit objective of the EUnetHTA WP6 to get an overview and expand the existing knowledge base concerning the links between HTA and health policy-making in Europe in order to improve the use of HTA.

Also the policy links surrounding the production of HTA is important for the use of HTA and therefore the links to stakeholders are extremely important. The establishment of the EUnetHTA Project with an aim of transformation into a sustainable collaboration on HTA in Europe demanded special attention to the HTA stakeholders in Europe, and it was the responsibility of the EUnetHTA WP6 to support improved responsiveness to stakeholders through exchange of views, expectations and feedback on HTA with HTA stakeholders.

8.3 Objectives

The general task of WP6 was defined in the Grant Agreement among the specific objectives of the EUnetHTA project as producing a book which analyses links and relations between HTA and health care policy making in selected Member States and the EU and to establish a sustainable open EUnetHTA Forum with participation of main stakeholders.

More specifically, the tasks of WP6, as defined in the Grant Agreement, were as follows:

1. To get a systematic overview of the relations between HTA and healthcare policy making in selected Member States and the EU representing different health systems, remuneration systems, etc, and to classify and analyse common characteristics of the relations.
2. To improve the responsiveness of HTA to the demands of the HTA consumers with the purpose of promoting HTA as policy input.
3. To show concrete use of HTAs in policy making in Member States and the EU.
4. To position HTA in relation to other relevant sources of input to health policy making and to regulatory processes.
5. To support improved responsiveness by building a sustainable open forum for EUnetHTA to exchange views, expectations and feedback on HTA with HTA stakeholders.

8.4 Methods and Activities

Overview

WP6 produced:

1. Policy study, published as a book. The quality of the studies was ensured through peer review and editing of the book.
2. Stakeholder activities ultimately aimed at creating a framework for stakeholder involvement in the EUnetHTA Collaboration. The stakeholder activities and plans for future stakeholder involvement in the EUnetHTA Collaboration were discussed with stakeholders at a meeting where the present stakeholders endorsed the future plans. A web-based Open Stakeholder Forum was developed.

WP LP set up a team that consisted of employees of the LP. The team met continuously to plan further steps and resolve problems that had been encountered.

Policy study – the book

Teams of international experts were set up to collect data, analyse identified questions, and write chapters for the WP6 book.

The following questions were analysed and included in the book:

1. How has transnational collaboration on HTA developed with a special focus on Europe?
2. What is the role of HTA in general policy processes and what are the barriers for and factors that facilitate the use of HTA at a societal level?
3. What is HTA and how does the EUnetHTA project contribute to a development of HTA?
4. What different levels of decision-making exist in relation to decisions on the use of technologies, which decision-makers are involved, and what different types of decisions are made with a particular focus on coverage decisions?
5. Who produces HTA in Europe and what are their activity portfolios, formal links to decision-making processes and locations in the health-care systems?
6. What are the effects of HTA reports on the health system?
7. What are the needs and demands of policy-makers?
8. What are the future challenges for HTA in Europe?

These questions were identified early in the project and discussed at the first WP6 meeting in March 2006. The questions were selected to address the WP6 objectives 1-4.

During the 3 years the teams operated largely through emails, e-meetings and developed content through circulating draft documents. A workshop (March 15-16, 2007) with policymakers which discussed draft chapters provided valuable input to the further development of analysis and final chapters. The book is available online: <http://www.euro.who.int/Document/E91922.pdf> (1).

Activities during year 2008

During the final project year 2008, the following activities took place within WP6:

The policy study was finalised. Chapters were finalised by the authors and the editing of the book took place in dialogue with the lead authors of each chapter. The book was printed and a pdf-version was placed on the website of European Observatory and EUnetHTA. The book was distributed to all participants at the EUnetHTA Conference in Paris, November 20, 2008.

- *EUnetHTA Stakeholder Open Forum website* was developed and updated with information from EUnetHTA of special interest to stakeholders and from stakeholders regarding their views on HTA/EUnetHTA.
- *Stakeholder organisations were identified.* They were asked to provide input to the consultation on the Proposal for EUnetHTA 2009+ and were invited for a stakeholder meeting.
- *A discussion topic catalogue was developed.* It contains a synthesis of stakeholder inputs received by EUnetHTA.
- A draft stakeholder policy was developed to set the framework for involvement of stakeholders in the EUnetHTA Collaboration.
- Stakeholder meeting in Rome (see table 1).
- Dissemination of results (see chapter 4.6)

Stakeholder activities

The stakeholder activities which took part in 2008 were multi-faceted:

1. The EUnetHTA Stakeholder Open Forum website was developed and updated. The content of the website primarily include: a) activities/products in EUnetHTA of special interest to stakeholders, b) stakeholder opinions on HTA and EUnetHTA and c) EUnetHTA reply to selected issues raised by stakeholder (FAQ)
2. Relevant stakeholder organisations were identified with the objective of: a) providing input to the consultation on the Proposal for EUnetHTA 2009+, and b) inviting them to a stakeholder meeting. Twenty-nine organisations were identified. The WP6 partners decided to focus on European umbrella organisations operating at the European level. This decision was intended to ensure that EUnetHTA did not interfere with national/regional stakeholder processes – the aim was to focus on EUnetHTA and HTA at a European level. It was also decided to focus on generic rather than disease-specific groups (patient organisations) and healthcare professionals in the areas of medicine, nursing, and dentistry. Further, it was decided that national policymakers should be reached through the EUnetHTA Partners and not through umbrella organisations. Since there was no tradition of formalized stakeholder activities in relation to HTA at a European level, it was necessary to identify specific European umbrella organisations to communicate with. Although it was easy to identify relevant umbrella organisations in some of the stakeholder categories (e.g., industry), organisations in other categories were more difficult to identify (e.g., regional government). They were identified through personal knowledge or contacts among the involved EUnetHTA Partners, Internet searches, lists of stakeholder organisations from other European organisations, and declarations of interest from umbrella organisations
3. A discussion topic catalogue was developed by a WP6 subgroup, which analysed input from different stakeholders. The catalogue mainly builds on comments to the EUnetHTA Proposal of November 2007, but also on other sources (see 5.2.2). The catalogue contains a synthesis of stakeholder opinions and questions raised by stakeholder in relation to HTA in general and EUnetHTA specifically. The catalogue was developed to promote dialog between EUnetHTA and stakeholders and to provide an overview of issues which has to be addressed in future. The aim was to build a platform for qualified discussion with stakeholders regarding the further development of the EUnetHTA Collaboration and European HTA processes. The catalogue functioned as background material for the stakeholder meeting.
4. A draft stakeholder policy was developed. To set the framework for future stakeholder involvement in The EUnetHTA Collaboration the draft policy was developed in line with discussions in the EUnetHTA Steering Committee about the next steps in EUnetHTA development after the project period 2006-2008 is over and was taking the stakeholder input (from the consultation and the discussion topic catalogue) into account. The draft policy was discussed and endorsed at the stakeholder meeting.
5. A stakeholder meeting was held to discuss the progress of EUnetHTA and the future plans for stakeholder involvement with identified stakeholders (for a list of invited organisations see appendix 2)

The activities were selected to address the WP6 objective 5.

Meetings and workshops organized by WP6 2006-2008

WP6 organized one face-to-face meeting for the partners. The workshop was held in Copenhagen on March 30, 2006. Thirty-three persons from 17 countries participated representing 20 APs and 8 CPs of WP6.

The Secretariat in cooperation with WP6 planned an HTA parallel forum at the European Health Forum Gastein on October 4-5 2006. The purpose of this activity was: 1) to increase the knowledge of EUnetHTA in a forum engaging a broad range of stakeholders in the field of public health and health care and 2) to seek stakeholder involvement in the development of EUnetHTA in order to increase the responsiveness of HTA processes to stakeholder needs and expectations. App. 70 policy-makers attended the workshop where 6 WP6 partners and 8 policymakers presented their view on EUnetHTA.

A workshop with policymakers, which was held in Berlin on 15-16 March 2007, was arranged by Technische Universität Berlin. At the workshop the WP6 authors of the policy study met with a group of invited policymakers to discuss the draft chapters of the book. At the meeting 18 APs representing 8 countries met with 13 invited policymakers from 9 countries.

A Stakeholder Meeting was organized in Rome by Università Cattolica del Sacro Cuore and DACEHTA. Ten EUnetHTA partners and 7 representatives from stakeholder organisations met in Rome on June 13, 2008.

Table 1. WP6 general meetings and workshops.

WP6 general meetings and workshops				
Time, place	Meeting, discussion topics	Participants/Agencies	Number of participants	Number of countries (EUnetHTA)
30 th March 2006 Copenhagen	WP6 Workshop: How to carry through the policy study, how to divide the workload, initial discussions of how to establish a stakeholder form.	20 APs: DACEHTA, TU Berlin, AETS, CAST, Cochrane Collaboration, CVZ, DAHTA@DIMDI, DSI, FinOHTA, AVALIA-T, HIQA, Università Cattolica del Sacro Cuore, KCE, NCCHTA, NOKC, Institute of Public Health Slovenia, Servicio Canario de la Salud, UETS, University of Bielefeld, University of Tartu 7 CPs: CEDIT, HTAi, INAHTA, SNHTA, WHO-HEN, Centre for Public Health Genetics, Hauptverband der Österreichischen Sozialversicherungsträger, HTA-unit at Aarhus University Hospital.	33	17 (Denmark, Germany, Spain, UK, Netherlands, Finland, Ireland, Italy, Belgium, Norway, Slovenia, Estonia, France, Canada, Sweden, Switzerland, Austria)
4 th -5 th October 2007 Gastein	Parallel panel session at the European Health Forum Gastein. Presentation from EUnetHTA partners and policymakers.	3 WP6 APs: Università Cattolica del Sacro Cuore, DACEHTA, Institute of Public Health Slovenia 2 WP6 CPs: IQWIG, Hauptverband der Österreichischen Sozialversicherungsträger 2 other WP APs: AHTAPol, HAS.	7 EUnetHTA partners (app. 70 attendees)	7 (Italy, Denmark, Slovenia, Germany, Austria, Poland, France)
15 th -16 th March 2007 Berlin	WP6 workshop with selected policymakers to present draft chapters from the policy study with the aim of getting input to the further development of the study.	12 APs: TU Berlin, DACEHTA, NOKC, University of Bielefeld, AVALIA-T, University of Tartu, HIQA, UETS, CAST, DSI, Institute of Public Health Slovenia, AETS 1 CP: SNHTA.	31 including invited policymakers	8 (Germany, Denmark, Norway, Spain, Estonia, Ireland, Slovenia, Switzerland)
13 th June 2008 Rome	Stakeholder meeting to present current status and future plans for the EUnetHTA collaboration, and to discuss the formulation of a stakeholder policy for the EUnetHTA Collaboration.	6 WP APs: Università Cattolica del Sacro Cuore, DACEHTA, FinOHTA, KCE, NCCHTA, HIQA.	17 including invited stakeholders	6 (Italy, Denmark, Finland, Belgium, UK, Ireland)

In addition e-meetings, phone meetings, and e-mails were used to ensure coordination of the policy study and the stakeholder activities.

8.5 Manpower for the execution of activities

Altogether at least 60 named persons from 17 countries contributed to WP6 either through contributing to: 1) policy study (data collection and/or analysis and writing 2) stakeholder activities or 3) attending WP6 meetings and workshops. Most partners contributed to more than one of the above mentioned activities. Appendix 1 lists each person and their role in general.

Partners involved

The following 35 agencies/international organisations representing 20 countries were partners in WP6:

Lead Partner

Danish Centre for HTA - DACEHTA, Denmark

Associated Partners

Technische Universität Berlin, Germany

AETS, Spain

CAST, Denmark

Cochrane Collaboration, UK

CVZ, the Netherlands

German HTA Agency at DIMDI, Germany

DSI, Denmark

FinOHTA, Finland

Galician HTA Agency, Spain

iHIQA, Ireland

Università Cattolica del Sacro Cuore, Italy

KCE, Belgium

NCCHTA, UK

Public Health Institute, Slovenia

Servicio Casnario de la Salud (Canary Islands), Spain

Norwegian Health Services Research Centre, Norway

UETS, Spain

University of Bielefeld, Germany

University of Tartu, Estonia.

Collaborating partners

AHRQ, USA

CEDIT, France

Council of Europe, France

GIN Executive, Germany

HTAi, Canada

IQWiG, Germany

INAHTA, Sweden

Institute of Molecular Medicine, Portugal

OECD, France

SNHTA, Switzerland

WHO Europe – Hen, Denmark

University of Iceland, Iceland

German Centre for Public Health Genetics – DZPHG, Germany

Hauptverband der Österreichischen Sozialversicherungsträger, Austria

HTA Unit - Aarhus University Hospital, Denmark

Countries involved

The WP lead and coordination took place in Denmark (DACEHTA), while Germany (Technische Universität, Berlin) co-led the work with the policy study. Fifteen other countries participated actively as WP members in the work.

Altogether 17 countries participated in the work through participation in WP6 teams and workshops or meetings. Making results available in each of these countries has been primarily at the discretion of individual partners. Being main actors in the field of HTA, the members are the best positioned to identify and use appropriate channels for disseminating the results in their respective settings. All the main products of WP6 are freely available on the project web site and can be linked to from national and regional websites.

Coordination and collaboration with other work packages and parties

WP1

WP6 has participated in all meetings and e-meetings organized by WP1 as a member of the Executive Committee and Steering Committee to support coordination of the project. The WP6 stakeholder activities have been developed in coordination with the WP1 activities to ensure a close coherence between the overall aim of The EUnetHTA project and the stakeholder activities.

WP2

WP6 have worked with WP2 on the technical side of development of the EUnetHTA Stakeholder Open Forum website

WP3

WP6 Lead Partner has participated in the interviews of WP3 to support the evaluation of the project.

WP4

The WP4 Lead Partner participated in writing a chapter "What is health technology assessment" to the policy study produced by WP6 (1).

WP6 used the WP4 experience of collaboration with stakeholders as basis for discussions with stakeholders at the WP6 stakeholder meeting in Rome.

WP5

The WP5 Lead Partner participated in writing a chapter "What is health technology assessment" to the policy study produced by WP6 (1).

WP6 used the WP4 experience of collaboration with stakeholders as basis for discussions with stakeholders at the WP6 stakeholder meeting in Rome.

WP8

WP6 used the experience and output from the WP8 stakeholder meeting (March 5-6, 2007) in the further development of the EUnetHTA stakeholder activities.

Other

WP6 participated on the 31st of March 2006 in a coordination meeting for WPs 4-7 in Copenhagen.

8.6 Results

The policy study

The policy study was aimed at addressing the WP6 objectives 1-4, and generally focused on describing the 'policy-HTA-policy' loop in EU member states. The work took its starting point in the previous European HTA projects. The book was produced as a collaboration between the EUnetHTA Project and the European Observatory on Health Systems and Policies with the aim of reviewing the relationship between HTA and policy-making from different perspectives, with a special focus on Europe. The purpose of the cooperation was to transmit the value of HTA to a wide public in decision-making and healthcare management in order to increase their awareness of HTA activities and evidence-based decision-making.

The book chapters conclude the following on the different questions that were addressed:

- *How has transnational collaboration on HTA developed with a special focus on Europe?*
Articulate political commitment to and European collaboration on HTA has made it possible to obtain extensive political support from national and regional governments for the EUnetHTA Collaboration. Based on this support it is possible for a group of founding partners to develop a sustainable collaboration based on the proposal endorsed by the EUnetHTA Project Steering Committee in 2008.
- *What is the role of HTA in general policy processes and what are the barriers for and factors that facilitate the use of HTA at a societal level?*
HTA has a unique potential to contribute to policy-making, strategic planning, management, and the implementation of technologies in health care. It can be used as a strategic tool to overcome the disconnect between policy and research but it cannot be guaranteed that fulfilling a number of preconditions ensures that HTA is used as intended. Nevertheless, it may still have the potential to be useful in strategic planning, management, and the implementation of technologies. Also, HTA has a general function in democratic processes since it creates transparency and can help ensure accountability for government decisions and performance. This function is evidently linked to policy-making within the health-care field, but developments towards a more general knowledge society cause other sectors to use research as an input to decision-making and thereby promote transparency and accountability in government performance. Finally it is shown that global trends and societal developments potentially facilitate the demand for HTA. All in all HTA has a great potential to contribute to policy-making if it is performed wisely; in line with user needs and demands; and if the producers work to overcome the barriers between research and policy.
- *What is HTA and how does the EUnetHTA project contribute to a development of HTA?*

HTA is developed with contributions from different methodological streams – policy analysis, evidence-based medicine, health economic evaluation, and social and humanistic sciences. These streams have helped to shape HTA (which is by definition eclectic) and enable it to function as a bridge between decision-making and research domains. Best practice for performing HTA has developed over the years through contributions from HTA producers all over the world. In particular, the EUR-ASSESS and ECHTA projects have contributed to describing frameworks for conducting and reporting HTA. The EUnetHTA Project aimed to build on these and the work of other international networks to build practical collaboration based on development of practical tools. This includes the development of a model for common core information, and adaptation toolkit, and a system for monitoring the diffusion of new health technologies.

- *What different levels of decision-making exist in relation to decisions on the use of technologies, which decision-makers are involved, and what different types of decisions are made with a particular focus on coverage decisions?*

In the chapter there is drawn on a broad understanding of the term health technology to provide an overview of technology related decision-making in the health-care system. The chapter shows different types of decisions within which HTA has the potential to provide valuable input to policymaking (because of its multifaceted and multidisciplinary approach), at least from a theoretical point of view. A broad spectrum of decisions range from those dictating which technologies should be included in the health-care system, and how they should be used, to those related to the organisation and management of the health-care system. HTA has a higher profile in coverage decision and several factors contribute to this greater visibility. The policy processes related to coverage are highly explicit and formalised in many countries. Such formal policy processes establish clear decision-making paths in which HTA is clearly integrated and enforced by law as an input to decision-making. In addition, decision-making on coverage presents the characteristics of a deliberative process in many cases. Deliberative processes stress the integration of scientific research on context-free and context-dependent issues with the views of stakeholder and the public elicited through consultation and participation. Thus, these deliberative processes may add to the visibility of HTA by engaging the public in the process. Finally, decision-making processes for coverage show an increasing degree of transparency through explicit sets of decision-making criteria, public reports that summarise the evidence and the publication, at least to some extent, of the rationale for specific decisions. The acknowledgement that formal deliberative processes may increase not only the visibility of HTA but also its impact does not imply that the role of HTA is of less value in decision-making processes that are less explicit than those on coverage. The value of HTA as an input for policy-making does not depend on its integration in formal appraisal and decision-making processes, rather it is rooted in its methodological approach.

- *Who produces HTA in Europe and what are their activity portfolios, formal links to decision-making processes and locations in the health-care systems?*

It has to be acknowledged that no two approaches to HTA in Europe follow an identical organisational model. This is unsurprising since these institutions are part of the respective health systems they serve, which in turn show great differences in most of their organisational aspects across Europe. The institutional diversity is documented by describing some of the key characteristics of HTA organisations in Europe. This descriptive exercise does not claim that some models are better at achieving HTA's ultimate goal of improved health systems. Furthermore, information on why a particular country has chosen a particular model is not available in an analytical form. A stakeholder analysis would most likely be required to understand these choices at the national level. Nevertheless, this exercise has allowed identification of some tendencies that may be relevant for the continued development of existing and future institutions and indicates that the landscape of HTA in Europe is in changing. The scope of institutions involved seems to be expanding beyond the sole production of HTA reports. Newly created agencies have been mandated with tasks in health services research and quality standards development upon their inception. In addition, a growing tendency to concentrate HTA, health services research and quality assessment related activities under the same institutional roof can be observed in some countries. These developments reflect the recognition that the knowledge needed to manage the health-care system in an evidence-based manner transcends the classic HTA reports - i.e. assessments on the consequences of technology introduction. Researchers argue that classic HTA reports are vital for the improvement of health services but evidence from research on the organisation and delivery of health services (health services research) is at least as relevant. This includes surveying the quality of care and conducting primary research on the needs and demands of patients and providers. The institutional proximity of these tasks to the culture of HTA may lead to a more rigorous approach in this field. An increasing number of European countries have established institutions which mandate to perform or coordinate HTA activities in the past decade. These agencies and units have been created at national, regional and local levels. The establishment of HTA units in regional or local health authorities, as well as their integration within the structure of health-care organisations such as hospitals, represents a process of decentralisation. This emphasises the need to contextualise evidence produced elsewhere in order to make it useful for local decision-making. Central HTA agencies have been quite successful in assessing the clinical effects and macroeconomic consequences of health technologies. However, they have been less effective in producing answers to other questions relevant to local decision-makers concerning impacts on their own organisations. With the increasing economic pressure on purchasers and providers, especially on hospitals (e.g. through DRG- payment systems), it may be an

option for hospital trusts or large hospital facilities such as university hospitals to establish HTA intelligence within their own organisational structures. The issues of cooperation and information sharing have been prominent since the early days of HTA and the need to formalise collaboration among a growing number of European institutions were recognised early. Since the 1990s, efforts to establish such a formal collaboration have led slowly but consistently to the formulation of a serious proposal for the longer-term institutionalisation of a European network. Thus, one of the next steps in the evolution of European HTA will be the establishment of a permanent highly committed cross-national collaboration in a sustainable structure, to act upon the areas of HTA which would profit from a higher degree of centralisation. Tasks could include the coordination of cross-boarder assessment projects; the facilitation of structured information exchange among partner institutions; and the transfer of know-how to nations, regions, or settings wishing to build local capacity for evidence-based policy-making. Such a European HTA coordinating institution would not compete with local institutions, but would complement national HTA efforts, allowing them to direct their resources to increase responsiveness to local decision-maker's needs and demands, for example by emphasising the assessment of aspects that are highly dependent on local context.

- *What are the effects of HTA reports on the health system?*

Many studies documented the considerable impact of HTA reports. Reports were known by a high percentage of their target groups although acceptance varied. The same applied to the ascribed impact on policy decisions. However, the vast majority of the included studies were carried out in countries with national health systems and a strong, often institutionalised, position for HTA, e.g. England, Wales, Sweden or Canada. Thus, it cannot be taken for granted that the same applies to other health systems. The location of the studies might also partly explain why the influence on practice seemed so much lower than on health policy. In these health systems HTA agencies and decision-makers at the policy level interact closely. It is equally interesting to note the type of impact that was discovered. Too often HTA's impact is assessed exclusively on its influence on reimbursement decisions. The review showed a much more heterogeneous contribution. HTA reports also inform stakeholders, structure dialogue and sensitise recipients to outcome parameters. The contribution of HTA reports needs to be managed at different levels. The health systems need to institutionalise the role of HTA by integrating it within the decision-making process. Reports that are only informative are very likely to be overlooked. However, it is shown that many recommendations were accepted at the policy level but never implemented. This requires shifts in the culture of decision-making at the clinical level. Collaborative approaches have been found to be successful in enabling ownership and minimising the risk that relevant aspects were overlooked. Clearly, explicit impact objectives are important for the production of targeted HTA reports. The methodology for assessing the impact of HTA has evolved enormously over the past years. The scope of what are considered to be its impact has broadened and the methodology and indicators of impact have been refined. The basis for successful management is information. Valid feedback on their impact is necessary in order to manage the contribution of HTA reports. Therefore monitoring the impact of HTA reports should become a standard element of the quality assurance portfolio of any commissioning agency.

So far, HTA reports have been written without explicit statements about what they aim to achieve. Prior descriptions of these goals allows for targeted and efficient planning from the outset. In general further research is necessary to consider how to develop and test theoretical frameworks. Successful HTA impact assessment requires the involvement of different disciplines and will face the continuing challenge of optimising the compilation and integration of their results.

- *What are the needs and demands of policy-makers?*

The findings reaffirm the existence of the gap between researchers and decision-makers. The review also identifies several strategies for improving the transfer of knowledge and communication between these two communities. There appears to be higher probability that decision-makers will use scientific when it is of high quality; deals with questions that they consider relevant; involves them in the generating process – from the formulation of questions to presentation of results. Most of the research in this field is carried out in North America. Research on the factors that enhance or limit the use of scientific information (such as HTA) to inform public policy-making among European decision-makers is sparse and involves only a few countries of Western Europe. Although it is likely that decision-maker's pressures and constraints are similar in countries with comparable socioeconomic situations, it is well-known that decision-making environments are context sensitive. Thus, there is a need for research to elucidate whether there are specific barriers and/or facilitators for the transfer of scientific knowledge to decision-makers in the European context and in general around the world. A research-based framework and more research would help the policy-HTA-policy loop to work better. Further European Union projects could focus on this topic and support direct country assessments (including country maps of decision-making bodies, description of the processes, identification and interviews of policy-makers, identification of best practice examples for the transfer of information between the two communities). In summary there is a need for an ongoing dialogue between researchers and policy-makers in order to consolidate mutual trust. This will improve the use of scientific evidence in the decision-making process.

- *What are the future challenges for HTA in Europe?*

This last chapter takes a bird's-eye view and debates the future role of HTA. HTA is described as a tool for knowledge management and as a part of the knowledge value chain in the health sector. It is described how HTA is – or should – be linked to clinical decision making processes, and how mechanisms for monitoring and evaluation are needed to complete the value chain. In sum, HTA should be an integral part of the health system. The settings and roles of the different organisational structures should determine how this should be done. Building on earlier chapters it is discussed how HTA reports increasingly are produced within organisations with a broader mandate than HTA alone. Many institutions that conduct HTA have broad mandates to inform and support decisions within the health services and improve the quality of care. Their main role is to act as knowledge brokers within the health system, supporting the health services by collecting, analysing and disseminating useful knowledge. This is achieved by synthesising and presenting evidence (push efforts); making policy-makers aware of this information and enabling them to utilise it by responding to their needs (pull efforts); and by establishing relationships and partnerships with policy-makers, including professional organisations (exchange efforts). By serving the link between the research community and health and clinical policy-makers, HTA agencies may also have an important role not only in retrospectively assessing evidence but also in identifying what evidence is needed. Prospective HTAs may be an important way forward – focusing on what evidence will be required to make decisions, what exists and what is lacking, and describing the types of evaluative studies required. This answers critique that label HTA as backward looking and a barrier to innovation. It will certainly be necessary to collaborate across countries in order to set up systems that plan and initiate such important and necessary evaluative studies in a coordinated manner and therefore this is also included in the plans for the EUnetHTA Collaboration.

The study of transferability of HTA to policy has in general evolved considerably during the last ten years. However as shown above there still is a considerable lack of knowledge in this area, and research from different scientific disciplines working together is needed into the many areas emphasised above is needed to make progress in the field of transferability of HTA to policy.

The stakeholder activities

Stakeholders are important groups to involve in HTA processes since they have a legitimate interest in the outcome of HTA projects and the decisions made with HTA as an input. Hence, the need for EUnetHTA to initiate activities ensuring stakeholder involvement was obvious. The main challenge was to initiate appropriate activities reflecting that EUnetHTA is a European network aimed at producing practical tools – not a network that produces HTAs directly for utilization in decision making. Therefore, it was not possible to imitate stakeholder involvement strategies known from national HTA agencies since their positions and relationships with stakeholders are of a different kind. Activities had to be tailored to fit the EUnetHTA aims and the position at a European level.

Results of the work with stakeholder activities in relation to EUnetHTA show first and foremost that initiatives were taken to start exchanging views with stakeholders and voicing expectations on HTA processes and the future development of EUnetHTA (its framework for activities after 2006-2008 project years). The first steps were taken to ensure representation of interests in relation to the EUnetHTA Collaboration. WP6 addressed ensuring legitimacy of EUnetHTA and its products to promote its potential for facilitating the use of HTA in making national/regional policies. Tangible results were the EUnetHTA Stakeholder Open Forum website, the discussion topic catalogue, the draft stakeholder policy, and the results of the stakeholder meeting.

EUnetHTA Stakeholder Open Forum website

The website was targeted at providing targeted information from EUnetHTA to stakeholders and at providing a platform for stakeholder opinions on HTA/EUnetHTA. The website was intended to facilitate a dialogue with stakeholders through supporting information sharing of the specific results. Through informal communication, we know that several of the identified stakeholder organisations have used the website to obtain relevant information, and that a few stakeholder organisations have taken the opportunity to provide EUnetHTA with position papers for publication at the website: http://www.eunetha.net/Stakeholder_Forum/

Discussion topic catalogue

The discussion topic catalogue was intended as a synthesis of stakeholder opinions on HTA/EUnetHTA and as a platform for further discussions with stakeholders since it represents some of the issues that stakeholders find important, problematic, or vaguely described.

The catalogue mainly builds upon comments to the EUnetHTA Proposal of November 2007. Comments have been received mainly from the industry, but EUnetHTA has also received responses from patient organisations, national ministries of health, national HTA agencies, the International Network of Agencies for Health Technology Assessment (INAHTA) and Center for Medical Technology Policy (CMTP), which cover interests of both patients, clinicians, payers, manufacturers and researchers. Further sources of information contain position papers on HTA from the industry, an article discussing key conceptual and policy issues related to Coverage with Evidence Development (CED) brought up at an Health Technology Assessment International (HTAi) Policy Forum Meeting, a summary report of a workshop on rare diseases held by the European Platform for Patients' Organisations, Science and Industry (EPPOSI), a visionary book on future health care from Health First Europe (HFE), which is an alliance of patients, doctors, nurses, academics, experts and industry. The sources of

information have been obtained via direct communication from stakeholders to EUnetHTA and via search for position papers and the like on websites, which have been considered relevant.

Viewpoints presented in the paper may not cover opinions of all HTA stakeholders, but they do nevertheless reflect the material available to the authors.

During the EUnetHTA project the catalogue was used as the starting point for the FAQ section at the website – a reply to selected issues from the catalogue can be found on the website. Also the catalogue functioned as a background document for the stakeholder meeting. The stakeholders who attended the meeting acknowledged that the catalogue is a fair synthesis of the input they have provided, and agreed that the catalogue contains topics which should be discussed in future dialogue between stakeholders and the EUnetHTA Collaboration.

The discussion topic catalogue is available at: http://www.eunetha.net/upload/Stakeholder_Forum/June 13 Stakeholder meeting/Annex 8. Discussion Topic Catalogue.pdf

Draft stakeholder policy

A WP6 subgroup formulated a draft stakeholder policy for the EUnetHTA Collaboration which:

- reflects the agreements made in the EUnetHTA Steering Committee concerning involvement of stakeholders, and
- takes into account the need for transparency and fair processes in relation to production of EUnetHTA products
- allows for expertise from stakeholders to be included in the work of EUnetHTA

The draft policy includes considerations on stakeholder definition and criteria, and transparency in stakeholder involvement, financing and EUnetHTA working methods.

Two major points in the draft policy is the establishment of an Advisory Council and the possibility for individual experts from stakeholder organisations to participate in working groups under the conditions that they do not represent a stakeholder organisation, cannot constitute a majority in any working group, and they disclose conflicts of interest.

After the stakeholder meeting the policy is now proposed to the founding partners of the EUnetHTA Collaboration. They are expected to make a final decision concerning a conclusive endorsement of the policy.

The draft stakeholder policy is available at:

http://www.eunetha.net/upload/Stakeholder_Forum/June 13 Stakeholder meeting/Annex 7. Draft Stakeholder Policy.pdf

Results of the stakeholder meeting

A EUnetHTA stakeholder meeting took place in Rome June 13, 2008. The meeting was organised by Università Cattolica del Sacre Cuore, Rome, Italy, and the Danish Centre for Health Technology Assessment (DACEHTA). The meeting was an opportunity for face-to-face contact between WP6 members and stakeholders and among HTA stakeholders. The meeting focused on the current status and future plans for the EUnetHTA collaboration, which stakeholder activities to initiate and the formulation of a stakeholder policy for the EUnetHTA Collaboration. The 29 stakeholder organisations which were identified were all invited to the meeting (see appendix 2). The discussion topic catalogue and the draft stakeholder policy were thoroughly discussed at the meeting in order to move forward with the plans for stakeholder involvement in the EUnetHTA Collaboration.

The discussions resulted in an endorsement of the draft stakeholder policy by the stakeholders under the conditions that the endorsement of the policy was forwarded to the founding partners of the EUnetHTA Collaboration together with the discussion topic catalogue and the summary notes from the meeting. These two documents present questions and concerns of the stakeholders and raises issues which should be clarified in future.

Industry was heavily overrepresented in the stakeholder meeting. The original goal was to obtain a balanced representation of different stakeholder categories at the meeting and in the continued stakeholder involvement. However, it was obvious that the industry umbrella organisations had a tradition of working with HTA and were comfortable about being involved. Some of the other stakeholder categories (patient organisations, health care professionals, policymakers at regional level, and policymakers at institutional level) were interested, but were either not used to working with HTA at a European level, and therefore hesitant to participate, or they were unable to participate at the specific date of the meeting. Hence, it is an ongoing challenge to ensure balanced stakeholder representation in relation to EUnetHTA and HTA in Europe.

Dissemination of results

To support dissemination of project results, the work of WP6 was presented in the following events (most recent first):

- Planned – 6th HTAi Annual Meeting in Singapore, 21-24 June 2009.
- EUnetHTA Conference in Paris, 20 November 2008 (Presentation + distribution of policy study and material on stakeholder activities).
- 3rd European Symposium on Pharmaceutical Law, Pricing and Reimbursement of Medicines, in Brussels, 13-14 December 2007.
- 15th European Conference on Public Health (EUPHA) in Helsinki, 12 October 2007.
- 5th HTAi Annual Meeting in Barcelona, 17-20 June 2007 (Poster presentation of part of the policy study).
- 9th ISPOR Annual European Congress in Copenhagen, 29 October 2006.
- 3rd HTAi Annual Meeting in Adelaide, 2-5 June 2006.
- Additionally as part of multiple presentations by the EUnetHTA Project Leader (see WP1 Coordination).
- European Observatory on Health Care Systems distributed the book to the relevant target groups (policy makers, etc) using their own distribution lists.

One scientific article have been written and submitted to a special issue of the International Journal of Technology Assessment in Health Care. The Policy study is reported in a book (1). The EUnetHTA Stakeholder Open Forum website has been a platform for dissemination of information to stakeholder.

The work performed in WP6 has given impetus to further studies by a group of individuals who collaborated through the EUnetHTA WP6. In an article they expand the discussion in the last chapter of the policy study and discuss the relations between HTA and research on health systems within a health services research framework.

8.7 Recommendations

In relation to the policy study the following is recommended:

- to ensure more research into the field of transferability of HTA to policy. The research should include different scientific disciplines to develop useful frameworks for understanding and working in practice with the large number of issues raised in the policy study.

In relation to the stakeholder activities the following is recommended:

- to continue the work ensuring transparency of interests and processes, legitimacy, and utilization of EUnetHTA and its products through dialogue with stakeholders.
- to adopt and implement the proposed stakeholder policy as the future policy for stakeholder involvement in the European network for HTA (the EUnetHTA Collaboration).
- to recognize that the processes for involvement described in the draft stakeholder policy need to be specified in greater detail, and this work should take place in dialogue with stakeholders.
- to obtain a more balanced stakeholder representation through encouraging the stakeholder groups other than industry to take a more active part in the stakeholder activities.

8.8 References

1. Velasco Garrido M, Kristensen FB, Palmhøj Nielsen C, Busse R. Health technology assessment and health policy-making in Europe – Current status, challenges and potential. Observatory studies series no 14. European Observatory on Health Systems and Policies 2008. <http://www.euro.who.int/Document/E91922.pdf>

8.9 Appendices

8.9.1 Appendix 1 - Persons participating in WP6

Persons participating in WP6

The list contains persons who are not partners in WP6. They have in particular contributed to the stakeholder activities.

P = Participated in policy study (authors or contributing to data collection)

S = Participated in stakeholder activities

WS = Participated in WP6 meetings or workshops

* Participants which took part in coordination of the activities.

Name	Agency	Country	P	S	WS
Finn Børllum Kristensen*	DACEHTA	Denmark	x	x	x
Camilla Palmhøj Nielsen*	DACEHTA	Denmark	x	x	x
Marie Louise Bistrup*	DACEHTA	Denmark	x	x	x
Sarah Wadmann Lauritsen*	DACEHTA	Denmark		x	x
Niels Würigler Hansen*	DACEHTA	Denmark	x		x
Reinhard Busse*	TU Berlin	Germany	x		x
Marcial Velasco Garrido*	TU Berlin	Germany	x		x
Annette Zentner	TU Berlin	Germany	x		
Antonio Sarría-Santamera	AETS	Spain	x		x
Hindrik Vondeling	CAST	Denmark	x		x
Lotty Hooft	Cochrane Collaboration	Netherlands			x
Lydia de Heij	CVZ	Netherlands	x		x
Albert Boer	CVZ	Netherlands	x		
Hans-Peter Dauben*	DAHTA@DIMDI	Germany	x	x	x
Henrik Hauschildt Juhl	DSI	Denmark			x
Ilona Autti-Rämö	FinOHTA	Finland	x		x
Pirjo Räsänen	FinOHTA	Finland	x		x
Kristian Lampe	FinOHTA	Finland	x		
Marjukka Mäkelä	FinOHTA	Finland	x		
Iris Pasternak	FinOHTA	Finland		x	x
Gerado Aienza Merino	Galician Agency for HTA	Spain	x		x
Leonor Varela Lema	Galician Agency for HTA	Spain	x		x
Lesley Tilson	HIQA	Ireland	x		x
Mairin Ryan	HIQA	Ireland	x		x
Caroline Waldron	HIQA	Ireland		x	x
Americo Cicchetti*	Università Cattolica del Sacro Cuore	Italy	x	x	x
Marco Marchetti*	Università Cattolica del Sacro Cuore	Italy		x	x
Mirella Corio*	Università Cattolica del Sacro Cuore	Italy		x	x
Davide Integlia	Università Cattolica del Sacro Cuore	Italy	x		
Dirk Ramaekers	KCE	Belgium	x		x
Chris De Laet	KCE	Belgium	x		x
Ruairidh Milne	NCCHTA	UK	x		x
Debbie Chase	NCCHTA	UK	x		
Eleanor Bell	NCCHTA	UK		x	x
John-Arne Røttingen	NOKC	Norway	x		x
Inger Natvig Norderhaug	NOKC	Norway	x		
Claire Glenton	NOKC	Norway		x	
EvaTurk	Institute of Public Health	Slovenia	x	x	x
Tit Albreht	Institute of Public Health	Slovenia		x	
Julio López Bastida	Servicio Canario de la Salud	Spain			x
Elena Andradadas	UETS	Spain			x
Juan Antonio Blasco	UETS	Spain	x		x
Beatriz Valentin	UETS	Spain	x		

Ansgar Gerhardus	University of Bielsfeld	Germany	x		x
Evelyn Dorendorf	University of Bielsfeld	Germany	x		
Kersti Meiesaar	Univeristy of Tartu	Estonia	x		x
Margus Lember	University of Tartu	Estonia	x		
Anne-Florence Fay	CEDIT	France			x
Helena Dahlgren	INAHTA	Sweden			x
Maya Züllig	SNHTA	Switzerland			x
Christoph Künzli	SNHTA	Switzerland	x		x
Leena Eklund	WHO-HEN	Denmark			x
Angela Brand	German Centre for Public Health Genetics – DZPHG	Germany			x
Gottfried Endel	Hauptverband der österreichischen Sozialversicherungsträger	Austria	x	x	x
Mette Kjølby	HTA-unit at Aarhus University Hospital	Denmark	x		x
Ulla Væggemose	HTA-unit at Aarhus University Hospital	Denmark	x		
Peter Sawicki	IQWIG	Germany		x	
Sun Hae Lee-Robin	HAS	France	x	x	
Lise Rochaix	HAS	France		x	
Norbert Wilk	AHTAPol	Poland		x	

8.9.2 Appendix 2 – Identified stakeholder organisations

Policymakers at regional level:

CCRE The Council of European Municipalities and Regions

Policymakers at institutional level:

AEMH European Association of Senior Hospital Physicians

EAHM European Association of Hospital managers

EHMA European Health Management Association

HOPE European Hospital and Healthcare Federation

Patient organisations:

BEUC European Consumers' Organisation

CIPAST Citizen Participation in Science and Technology

EDF European Disability Forum

EPF European Patients' Forum

EPTA European Parliamentary Technology Assessment

HFE Health First Europe

EPHA European Public Health Alliance

HAI Health Action International – Europe

IAPO International Alliance of Patients' Organisations

Healthcare professionals:

CED Council of European Dentists

CPME Standing Committee of European Doctors

EFN European Federation of Nurses Associations

UEMO European Union of General Practitioners

UEMS European Union of Medical Specialists

Industry:

AESGP Association of the European Self-Medication Industry

ADVAMED Advanced Medical Technology Association

EAEP The European Association of Euro-Pharmaceutical Companies

EBE European Biopharmaceutical Enterprise Products

EDMA European Diagnostic Manufacturers Association

EGA European Generic Medicines Association

EFPIA European Federation of Pharmaceutical Industries and Associations

ECHAMP European Coalition of Homeopathic and Anthroposophic Medicinal Products

EUCOMED EUCOMED

EuropaBio EuropaBio

9 Work Package 7: Monitoring development for emerging/new technologies and prioritisation for HTA

9.1 Summary

Introduction: There is an increasing need for reliable and timely information on emerging/new technologies to input health policy decision making. Once a promising technology is identified, a major obstacle to ensuring timely access is lack of sufficient evidence to make robust decisions on marketing authorizations or coverage. Several countries have therefore developed “access with evidence generation” (AEG) mechanism that allow temporary access to promising technologies whilst at the same time requiring the generation of additional evidence in order to reduce the uncertainty.

Objectives: WP 7 had two objectives: 1.) to identify, collate and inform health policy *via* the development of a European wide newsletter on emerging/new technologies based on knowledge derived from existing horizon scanning programs (strand B) and 2.) to help to support evidence generation on promising technologies by undertaking an overview of national experiences on AEG and by developing a web-based toolkit to facilitate collaboration on evidence generation (strand A).

Methods: For objective 1/ (strand B) a systematic review on horizon scanning programs and their processes and a survey among Associated Partners (AP) and Collaborating Partners (CP) on wishes for specific features (frequency and topic selection) was carried out, a prototype newsletter was designed (content, procedures, appearance), sent to APs/ CPs for distribution among national potential recipients and evaluated by them. Based on the comments the pilot newsletter was revised and finally launched on the EUnetHTA website. For objective 2/ (strand A) a literature review and a survey among APs/ CPs on already existing AEG mechanisms were performed. Collaboration modalities were discussed at a workshop attended by all WP7 Partners. Initial emphasis was on information sharing. Standardized forms for information sharing were developed and tested. An IT development phase followed with the creation of the web-based toolkit (website).

Results: Strand B: An European-wide newsletter with early alerting information on emerging or new health technologies was developed (http://www.eunetha.net/Communication/Newsletter_WP7_2008) by the means of a consistent and transparent method for priority setting for the topics to be covered in the EUnetHTA newsletter and by designing work-flows and processes. But despite the seemingly easy task, several obstacles during the processes and the evaluation had to be faced: a general lack of understanding what kind of information is available in early stages of technologies (hardly any cost data and no cost-effectiveness data are available), the range of very diverse interests among the various decision-makers and their requests for more diversification and finally a very time-consuming priority setting and production process.

Strand A: The overview of national experiences was used to draw up a generally applicable 5-step policy framework for AEG mechanisms. The critical factors for its success were identified: coordination, methodological guidance, funding and a regulatory framework. Countries were categorized on the basis of current implementation of the proposed policy framework. Important issues are collaboration with academic research, selection and prioritization of promising technologies, uncertainty thresholds, timing of requests, and relationship between HTA and AEG.

An important barrier, at the international level, is the lack of structured collaboration among the HTA agencies involved in AEG mechanisms. Therefore, three structured levels of collaboration on evidence generation on promising health technologies were set up: (1) sharing information, (2) coordinated action, (3) joint action. We focused our work on sharing information on evidence generation. A website was subsequently developed allowing access to structured and standardized forms for requesting information, posting information in response to a request, and posting information spontaneously on promising technologies. An online queryable database contains all the information requested or posted.

Conclusion/ recommendation: A growing number of European countries are now interested in getting early informed on emerging /new technologies and in using “access with evidence generation” mechanisms for promising technologies. The website for sharing information on evidence generation should help countries reaching robust decisions on the timely adoption of promising health technologies. The impact of the work developed by WP7 B and A (the newsletter and the web-based toolkit for facilitating European collaboration) regarding new and emerging health technologies will be important if the information provided is actually useful for advising EU Member States on healthcare policy and meets the needs of the target audience.

9.2 Foreword

Work Package 7 (WP7) on “Monitoring development for emerging/new technologies and prioritization of HTA” has two strands. Strand B led by the Ludwig Boltzman Institute of Health Technology Assessment and Strand A led by the French National Authority for Health (HAS).

New health technologies are continuously developed and rising in the horizon, but only a few numbers can be adopted by the healthcare system. They are assessed before decision about their introduction is made. Health technology assessment (HTA) informs decision makers to help them to adopt those that have highest value for the healthcare system. However, in one hand, all relevant data are not available at the moment where HTA is undertaken. In the other hand, when a technology is highly innovative and promising, decisions cannot wait until comprehensive evidence on their value is available. Therefore, there is need to anticipate and to gather all relevant information and data as early as possible and as quickly as possible. Health Technology Assessment is, thus, increasingly linked to horizon scanning activities (or Early Awareness and Alert Systems: EAAS) and to mechanisms that facilitate generation of complementary evidence while providing timely but, conditional and temporary access to promising technologies (Access with evidence generation: AEG).

WP7 Strands A and B provides a coherent approach to deal with new and emerging technologies with (see figure 1):

1. Early identification of new and emerging technologies (EAAS-strand B)
2. Definition of conditions for providing timely access to promising technologies with evidence generation (AEG-strand A)



Figure 1: Link between WP7 Stand A and Strand B

WP7 had two objectives:

- 1.) to identify, collate and inform health policy via the development of a European wide newsletter on emerging/new technologies based on knowledge derived from existing horizon scanning programs (strand B),
- 2.) to help to support evidence generation on promising technologies by undertaking an overview of national experiences on AEG mechanisms and by developing a web-based toolkit to facilitate collaboration on evidence generation (strand A).

9.3 Strand B: Early identification of new and promising technologies

9.3.1 Introduction

The early identification of new and emerging health technologies has been a field of interest within health technology assessment (HTA) agencies for many years: Various programmes have been developed under different synonyms that reflect the perspective of the agencies involved –horizon scanning, early warning, emerging technology assessment, alert system and latterly Early Awareness and Alert Systems (EAASs). In 1998, EuroScan (the international information network on new and emerging health technologies), a collaborative network of international (not only European) agencies carrying out horizon scanning activities, was founded. This was as a result of the growing number of agencies (in 2008 already: 15 agencies) investing in early identification, prioritization and assessment and the need for harmonization of definitions, processes and methodology in order to increase transparency and traceability of the outputs.

These outputs are sometimes – but not in all cases - published as short (4-6 page) reports - Technology Briefings (National Horizon Scanning Centre (NHSC), England), TechNotes (former Alberta Heritage Foundation for Medical Research/ Canada), Alerts (Swedish Council on Technology Assessment in Health Care, Sweden), Emerging Technology Bulletins (Canadian Agency for Drugs and Technologies in health (CADTH), Canada) -on the respective websites and are actively distributed to a small number of regional and national decision-makers.

The rationale for a EU-wide newsletter on new and emerging technologies seemed convincing, since within the EU the launching and the approval of some new technologies such as vaccines or many medicines are based on decisions of common regulatory agencies and legal formalities and even with those technologies (devices) regulated nationally the introduction to the market takes place all over Europe within nearly the same time period.

9.3.2 Objectives

The aim of EUnetHTA WP 7 (strand B) was to contribute to sharing by making the information gathered within formal horizon scanning activities available to a wider audience by disseminating information on new and emerging technologies beyond regional or national decision makers via an European wide newsletter.

The supposed added value to the EuroScan activities of scanning, identifying, collating data and producing early assessment papers is the collection of the information in one format and the wide distribution via the EUnetHTA partners.

To continue and further contribute to the previous thinking on the effective and efficient distribution of information on new and emerging health technologies relevant to so many European decision makers (payers, policy makers, regulatory bodies and health service planners) it was the task of the EUnetHTA WP7-strand B – work program to develop a prototype/ pilot for an European wide newsletter on new and emerging health technologies and to provide information on high volume, costly, rapidly developing technologies that may have significant impact on health care. This newsletter intends to contain information not only on the technology itself, but also on the nature of the condition (burden of disease), on the prevalence of the disease and on common standard treatments and their effectiveness.

Within the project EUnetHTA it was the task to develop a prototype of such a newsletter and to pilot the processes of production.

Since this newsletter would be highly visible and could have a potential impact on setting the agenda and discussing new and emerging technologies throughout Europe, the underlying processes of its production were required to be transparent and reproducible. This particularly applied to the methods used for selecting the technologies to be included in the newsletter.

9.3.3 Methods and Activities

In order to achieve this objective the following activities were conducted within the time period of 2006-2008

2006: It was the task of the 1st year to give an overview of horizon scanning systems, esp. on their methods and processes as the basis for i.e. the design (content structure and lay-out) of a structured information service on emerging/new technologies. APs were asked for vertices (main characteristics) for a European newsletter on emerging technologies produced by EUnetHTA: frequency of publication, content, and proposals for editorial board members. The newsletter design was developed in a multi-staged process in cooperation with the contract-partner (the University of Birmingham) and Euroscan.

2006/1 Literature review: The review aimed at supporting the newsletter development with transparent criteria for the selection of new technologies that will be reported on. The report was based on

- a systematic review of the literature,
- unpublished information from the relevant agencies (Horizon Scanning Systems/HSS)
- personal e-mail contacts with staff members from these agencies.

The report summarizes the activities of the currently 13 government-funded organisations that undertake horizon scanning. It presents an overview of methods, processes, similarities and differences between their horizon scanning activities.

The report was produced by LBI@HTA and peer reviewed by Carla Douw/DACEHTA.

2006/2 Survey: A survey was carried out among WP 7 Associated partners (18 in 9 countries). APs were asked to give their preferences/wishes and propositions on the frequency, the topic selection and the editorial board. The response rate was 61% (11/18). Responses are given in the tables below.

Table 1: Responses of Associated Partners to Newsletter survey

Agency	Issues/	Topic selection	Editorial board
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	year		
HAS, France	4	alternating*	Euroscan/ WP7Volunteers
LBI@HTA, Austria	4	alternating	Euroscan/ WP7Volunteers
Region Veneto, Italy	3	alternating	Selected Euroscan/EUnetHTA
iHIQA, Ireland	4	recent technologies	Selected Euroscan/EUnetHTA
DAHTA, Germany	2	disease-specific only	Euroscan/ WP7Volunteers
IZR-Slovenia	3	recent technologies	Euroscan/ WP7Volunteers
ASR, Italy	4	alternating	Selected Euroscan/EUnetHTA
Osteba, Spain	2	alternating	Euroscan/ WP7Volunteers
CVZ, NL	4	alternating	Selected Euroscan/EUnetHTA
SM Lübeck, Germany	4	alternating	Selected Euroscan/EUnetHTA
ISS, Italy	4	alternating	Euroscan/ WP7Volunteers

* Disease specific issues and issues on recent technologies alternately.

Table 2 : Summary of responses

Issues/year		Topic selection		Editorial board	
Quarterly	7 (64%)	Alternating	8 (73%)	Volunteers	6 (55%)
3 times/yr	2 (18%)	Recent technologies	2 (18%)	Selected	5 (45%)
Twice/yr	2 (18%)	Disease-specific only	1 (9%)		

(number of respondents (%) – baseline = 11 respondents)

2006/3 Design of structured information service on emerging/new technologies: The WP 7 lead partners met the contract-partners (University of Birmingham, Euroscan) on June 19 in Paris to discuss newsletter design and production. They drafted an agreement together on content, format, scope, the target audience, information gathering and selection process, the editorial board, and editorial control. WP 2 (Susanna Allgurun-Neikter/SBU) developed a design for the newsletter.

2006/4 Dissemination: The report was published and disseminated via the LBI@HTA website:
http://eprints.hta.lbg.ac.at/586/1/HTA-Projektbericht_002.pdf

2007: It was the task of the 2nd year not only to design a “prototype of the information service ”on emerging/new technologies in content and graphical layout (deliverable 2), but also to pilot the processes, to produce a pilot-product, present it in a workshop, discuss it with the APs and CPs there, evaluate it and redefine the processes for the final prototype of the information service, produced and distributed in year 3.

In order to fulfil the tasks a close cooperation with the subcontractors – the University of Birmingham – took place.

2007/1 Design of the prototype: The design of the prototype consists of 3 elements:

- The design of the content: definition of target audience (payers and policy makers), format (electronic) and language (English), scope (information on pharmaceuticals, medical devices, procedures, diagnostics, etc. in late stage of development, not yet licensed or not yet in widespread use), content (number of topic items: 12) and depth of information (3 levels of differentiation between topics).
- The design of the processes and responsibilities: Topic selection (identification and prioritisation), investigation and information gathering, role and tasks of panels (prioritizing panel & editorial board), role and tasks of EuroScan Secretariat (development of tools for prioritization, writing articles, managing the process), copyright issues and frequency and timetable of work-steps for newsletter.
- The design of the newsletter’s layout: the graphical design incl. the electronic format was done by WP 2 Lead Partner.

For solving and/or for anticipating intellectual property and liability issues of the newsletter and the possible shared responsibility between EUnetHTA and EuroScan an expert in “information and Intellectual property law” was asked to give advice (in form of a written document) and was subcontracted.

2007/ 2 Piloting the production of the prototype newsletter: The pilot newsletter was produced in the time-period between January 2007 and April 2007 within a time period of 12 weeks. During this period the different work-steps, the division of work and interfaces between the participating partners were tested.

The work-steps and roles/ responsibilities are reported in Table 3:

Table 3: Work-steps and roles/ responsibilities in the production of the prototype newsletter

Identify potential technologies	UoB/ University of Birmingham
Distribute list of technologies to the prioritisation panel	UoB/ University of Birmingham
Prioritize preliminary list	PP/Priorisation Panel
Collate responses from panel members and send to editorial board	UoB/ University of Birmingham
Agree final list for the next 2 newsletters	EB/Editorial Board
Investigate and gather information on selected technologies	UoB/ University of Birmingham
Write articles on selected technologies	UoB/ University of Birmingham
Write editorial and registry articles	EB/Editorial Board
Edit and insert articles in template	UoB/ University of Birmingham
Send draft newsletter to editorial board	UoB/ University of Birmingham
Carry out any changes requested by editorial board	EB/Editorial Board
Format final newsletter	EB/Editorial
Distribute electronic newsletter	EB/Editorial Board & EUnetHTA
Post newsletter on EUnetHTA and EuroScan websites	EUnetHTA/WP2

The members for the Panels (prioritisation panel and editorial board) are WP 7 members, volunteers and chosen for geographical distribution.

Priorisation Panel: I. Norderhaug (NOKC, Norway), I. Gutiérrez Ibarluzea (Osteba, Basque Country, Spain), AF. Faye (CEDIT, France), S. Simpson (NHSC, England), S. Robin (HAS/France), C.Wild (LBI-HTA/ Austria).

Editorial Board: C. Wild (Austria) – editor-in-chief (for the prototype), S. Simpson (England) - editor-in-chief, deputy, K. Douw (Denmark), S. Robin (France), I. Gutiérrez Ibarluzea (Spain), M. Kaila (Finland), HP Dauben (Germany).

The only problems that emerged during the prioritisation process was, that the panel members complained on not having enough information to prioritise the topics. This – lack of information – was therefore changed for the 2nd pilot/final prototype (February 2008). The panel members are provided with much more information. The methodology of the development of the prioritisation criteria will be specified in the 1st Editorial of the newsletter/ prototype of information service”.

2007/ 3 Feedback and evaluation of the pilot: The further objective in 2007 was to discuss and evaluate the newsletter with the APs and CPs.

- In April 2007 the pilot newsletter was presented and discussed at the WP7 workshop in Dublin,
- In June 2007 the pilot newsletter was presented at the EUnetHTA preconference workshop in Barcelona,
- In April to May 2007 the pilot newsletter was sent to all APs and CPs and they were asked to forward it to potential readers (payers and policy makers) and to ask them for evaluation of the relevancy, timeliness, readability, structural and key information. 40 responses (56% return rate) out of 71 were received and key issues for the adaptation of the 1st pilot were collected: Better targeting policy makers might be achieved by using less medical language, putting the focus on impact (costs) and giving explicit recommendations, are the main conclusions (paper of summary available)

2007/ 4 Dissemination: In June 2007 the pilot newsletter was presented at the EUnetHTA preconference workshop at the HTAi in Barcelona.

As an additional activity, a manuscript based on the 1st Deliverable of WP 7/strand /Overview of HSS) was written, submitted, revised and finally accepted by the Editors of “Health Policy”. It was published in early 2008⁵.

2008: Based on the experiences with the production processes and the comments of the evaluation process the newsletter it was the task of the 3rd year to readjust the pilot newsletter, presented it in its final format and distribute it.

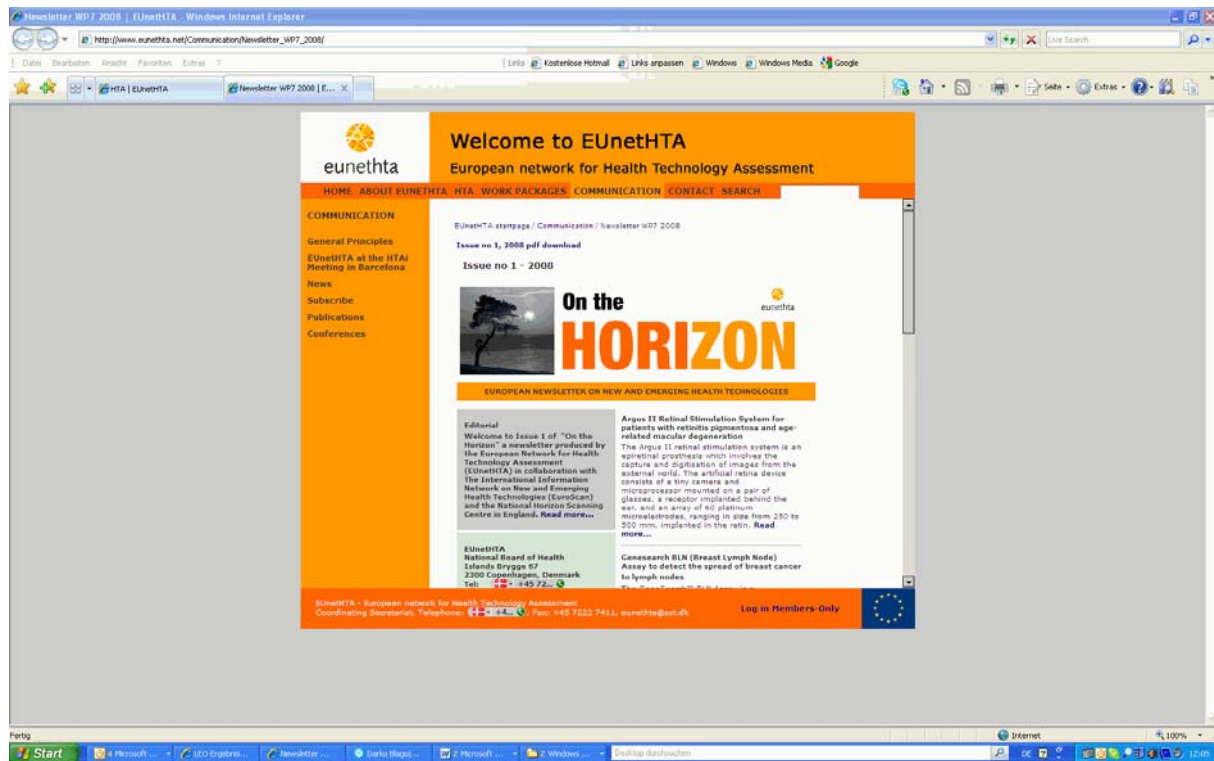
2008/1 Readjustment of processes: The revised prioritisation process took place in December 2007 with a revised, easier to handle excel information sheet containing information on 75 newly identified topics, that were

⁵ Wild, C., Langer, T. (2008): Emerging health technologies: Informing and supporting health policy early. In: Health Policy. 2008 (87): 160 - 171.

sent to the prioritization panel. Again 12 topics were chosen and decided upon by editorial board. The following short evaluation of the revised process by the panel-members showed that the process took a few hours less, but nevertheless made not much of a difference concerning time-consumption and resulting demotivation of panel members.

2008/2 Production of the final prototype: Finally the newsletter was produced in its template in a pdf and in an online format (Figure 1).

Figure 1: Screenshot of the online version of the final prototype of the newsletter



2008/ 3 Distribution: The launch of pilot issue of the EUnetHTA emerging tech newsletter took place in march by putting it on EUnetHTA Website, and more actively by distributing it among Austrian decision-makers.

2008/ 4 Dissemination: The results of the WP 7- B were presented at the final EUnetHTA Conference in Paris 20th of November 2008.

Additional, a manuscript on the objectives was of EUnetHTA/WP7-B was written for a Special Edition in IJTAHC and submitted to the Main Editors in late 2008⁶.

9.3.4 Man/ womanpower

Personnel involved

2006: In 2006 Thomas Langer, a junior researcher wrote the report under the supervision of Claudia Wild (LBI@HTA). C. Wild was responsible for EUnetHTA internal communication (WP1), reading and commenting of deliverables and WP 7 coordination.

2007: In 2007 Claudia Wild (LBI@HTA) coordinated all activities, incl. a subcontract on copyright issues carried out by Andreas Wiebe, Sue Simpson (University of Birmingham subcontractor) piloted the processes, Susanna Allgurin-Neikter (SBU) made templates and design, all panel members prioritised and commented, Stefan Mathis executed and collected the feedback survey to the APs/CPs. Sabine Geiger-Gritsch supervised and commented prioritization process.

⁶ Wild, C, Simpson, S, Douw, K, Geiger-Gritsch, S, Mathis, St, Langer, Th: Information service on new and emerging health technologies – identification and prioritisation processes for an EU-wide newsletter – under review, possible publication in autumn 2009.

2008: In 2008 Claudia Wild (LBI@HTA) supervised, Sue Simpson (University of Birmingham subcontractor) revised the processes, all panel members, esp. Karla Douw (CAST) gave input comments, Susanna Allgurin-Neikter (SBU) revised templates and design.

Partners and countries involved

A list of WP7 partners is reported in **Appendix I**.

2006: Answering a survey on frequency and topic selection for newsletter: The response/return rate was 61% (11/18).

2007/1: Volunteering for membership in Prioritization Panel or Editorial Board (Table 4):

Table 4: Volunteering for membership in Prioritization Panel or Editorial Board

Prioritization Panel:	Editorial Board:
6 experts from different European countries and selected for their experience in horizon scanning	7 representatives from different European countries
Anne-Florence Fay (CEDIT-France)	Claudia Wild (Editor in Chief, Austria)
Claire Parker (NHSC-England)	Sue Simpson (Deputy Editor in Chief, England)
Claudia Wild (LBI-HTA – Austria)	Karla Douw (Denmark)
Iñaki Gutiérrez (Osteba- the Basque Country)	Sun Lee Hae Robin (France)
Inger Norderhaug (NOKC – Norway)	Iñaki Gutiérrez (Basque Country)
Sun Lee Hae Robin (HAS – France)	Minna Kaila (Finland)

2007/2: In April to May 2007 the APs and CPs were involved in distributing the first edition of pilot newsletter to potential readers (payers and policy makers) and to ask them for evaluation of the relevancy, timeliness, readability, structural and key information. The response/return rate was 56% (40/71).

2008: In March 2008 all APs and CPs were informed on the launch of the revised pilot newsletter and asked to distribute it in their respective countries.

2006-2008: Two thirds of all 18 EuroScan members (as APs or CPs) were actively involved in planning and designing (EuroScan and NHSC) the newsletter or commenting on it.

9.3.5 Results: achievement of the objectives

It was the objective of EUnetHTA WP 7/B – based on the long experiences and know-how of EuroScan – to provide an European-wide newsletter with early alerting information on emerging or new health technologies: the supposed added value to the EuroScan members' activities of scanning, identifying, collating data and producing early assessment papers was the collection of the information

- in one format and
- the wide distribution via the EUnetHTA partners.

The aim to develop processes and to design a prototype/ pilot newsletter has been achieved. The method developed for priority setting for the EUnetHTA newsletter is now the only *formal* priority setting method or at least the only one published in this field. What this method adds as opposed to an informal method is a high level of consistency and transparency

But despite the seemingly facile intention, this task faced several obstacles:

1. Among the readers there is lack of understanding what kind of information is available in early stages of technologies: Hardly any cost data and no cost-effectiveness data are available.
2. The recipients are very diverse (not all decision-makers in health care have the same interests) and more diversification is necessary, tailor-made information is asked for, not so much broad range but more in-depths information.
3. On practicalities: the involvement of many EU-experts in prioritization is time-consuming (3 months) within the production of timely information. But time is crucial before market entry. The practicality of an EU-wide involvement of experts for scoring and prioritization was a time consuming process that is not only difficult to organize, but also prohibits the production of timely information.

We learnt that the ambitions of what can be provided and the illusion of what can be achieved by early information has to be articulated explicitly and honestly: the essential discussions of "value for money", "maximising health gain" or "societal value" definitely overload the idea of "alerting" on emerging technologies.

9.3.6 Recommendations

An important issue for all services providing information on new and emerging health technologies is if the information provided actually adds to useful policy advice for the EU Member States and meets the needs of the intended audience. Our recommendations are:

- Tailor-made information: For tailor-made, diversified information more attention has to be given to the exact information needs of the intended audience. An electronic information service “on-demand” might be a solution closer to the actual needs.
- Timeliness: The sharing of information on emerging and new health technologies remains at the top of priorities in collaboration.

9.4 Strand A: *Providing timely access to promising technologies with evidence generation*

9.4.1 Introduction

Access to new health technologies is subject to many constraints in most developed countries because the costs are high and the impact on health and the healthcare system is uncertain. To obtain marketing approval for a health product (medicine or medical device) requires evidence on quality, safety and for medicine on efficacy, collected in controlled settings (e.g. randomized controlled trials, RCT), designed and analyzed according to clearly defined standards. However, to obtain coverage or funding for health technologies (medicines, medical devices, and diagnostic, medical and surgical procedures) also requires evidence on clinical effectiveness and possibly data on quality of life, cost-effectiveness and impact (e.g. on organisation of care) (1,2). This evidence is generally collected in real-world, pragmatic studies, that may not be in the standard form of an RCT and for which no international guidance exists. The, benefit/risk ratio (efficacy/safety) and effectiveness of a health technology are thus assessed at different time points of its life cycle (3).

A major obstacle to ensuring timely access to new health technologies is inadequate evidence on which to base the decision to market or provide coverage, especially if the technology is highly innovative or “promising” (1). Manufacturers, clinicians and patient groups put pressure on decision-makers. They demand early decisions and rapid access but this increases the risk of inappropriate decisions. The authorities may unduly delay potential benefits to patients by waiting for stronger evidence or may endorse technologies that later turn out to have a low benefit-risk ratio, to be ineffective, cost-ineffective, or even harmful (1).

Several countries have therefore developed policy frameworks and mechanisms that allow temporary access to promising technologies whilst at the same time requesting the generation of additional evidence in order to reduce the uncertainty. We shall refer to these mechanisms as “access with evidence generation” (AEG). Their objective is an optimal trade-off between stakeholders’ needs, flexibility, responsiveness, and rigour. The decision taken is revised when the new evidence is made available (4,5). The connection of health organisations with interest in AEG mechanism within the Work Package 7 offered an opportunity to do an overview of national experiences on AEG.

At the international level, one of the main barriers to evidence generation is the lack of structured collaboration among the HTA agencies involved in AEG mechanisms. Information is passed on, mostly by e-mail, from person to person or within informal networks (e.g. INAHTA listserv). This is inefficient, time-consuming, a source of misunderstanding, and does not permit easy data storage and sharing. In addition, the information passed on is often incomplete or inadequate. More importantly, there is no way of ensuring that there is no duplication of effort. Valuable time and resources are being wasted.

A driving force in the EUnetHTA Project has been the development of communication facilities to support collaborative work among EUnetHTA Members. The project has thus offered an ideal opportunity to set up structured forms of collaboration on evidence generation relating to promising health technologies.

9.4.2 Objectives

The first objective of the WP7 strand A was to perform an overview of national experiences on AEG. The aim of the overview were to identify the AEG mechanisms implemented in various countries, to use them to draw up a common policy framework applicable at both marketing approval and coverage decision stages and to identify the key factors for its successful operation.

The second objective of WP7-A was to determine the types of structured collaboration that would facilitate evidence generation and to create a web-based toolkit that would support this collaboration.

9.4.3 Methods and Activities

Readjustment of the objectives

According to the grant agreement, a milestone of WP7 Strand A is an “overview of existing monitoring tools (Registers, Protocols, application-protocols, post-marketing studies)”. However, while performing these overview, several concerns appeared regarding this initial objective. Indeed, the term “monitoring” was very ambiguous in this context, as it was not self-meaningful to understand what monitoring tools are. In addition, “tools” can be effectively restricted to studies, registers etc but can also imply measures allowing the generation of evidence. Therefore, in order to be more comprehensive, an extensive work was performed in order to define a more adequate and non-ambiguous wording which led to the concept of “access with evidence generation” (AEG). In addition, we focused our overview on policy frameworks, as they involved all measures required to reduce uncertainty.

According to the grant agreement, the deliverable of WP7 Strand A is a “*tool to monitor emerging technologies in clinical practice with insufficient evidence of clinical or cost effectiveness*”.

Strand A will provide a tool to facilitate evidence generation on promising technologies, that are technologies in a more advanced phase of development than an emerging technology. Emerging technologies are within the scope of horizon-scanning activity, and this is the remit of the WP7 strand B.

Our initial intention was to develop a commonly shared data collection protocol for obtaining lacking evidence on promising technologies that are relevant to different type of technologies. This was not feasible as each technology needs a specific protocol. However, as the survey we performed in 2006 and literature review revealed that health technology agencies and other bodies in Europe share little or no information on promising technologies, we chose to develop a web-based toolkit to facilitate European collaboration on evidence generation on these technologies in a structured and standardised manner. We chose a web-based format as it is the most relevant facilities to facilitate collaboration among partners from different countries.

Overview of national experiences on AEG

A search for information on the AEG mechanisms used by 23 countries was performed (Table 5).

Table 5. List of investigated countries and EUnetHTA partners involved in this study

Countries	EUnetHTA partners
Austria	Ludwig Boltzmann Institute of Health Technology Assessment (LBI@HTA)
Australia	None
Belgium	None
Canada (Ontario)	None
Cyprus	Ministry of Health
Denmark	Danish Centre for Health Technology Assessment (DACEHTA) Centre for Applied Health Services Research and Technology Assessment (CAST)
Estonia	University of Tartu Department of public health
France	French National Authority for Health (HAS) Committee for Evaluation and Diffusion of Innovative Technologies (CEDIT)
Finland	Finnish Office for Health Technology Assessment (FinOHTA)
Germany	German Institute of Medical Documentation and Information (DIMDI) Institute for Social Medicine, Medical University of Lübeck Competence Center for Clinical Trials, University of Bremen
Ireland	Health Information and Quality Authority (HIQA)
Italy	Regional Agency for Health and Social Care (ASSR) for Emilia-Romagna <i>Universita Cattolica del Sacro Cuore</i> , Faculty of economics, HTA Unit <i>Istituto Superiore di Sanita</i> (ISS) on behalf of the It-Net-HTA group <i>Regione Veneto</i> , Health and social planning department
Latvia	Health Statistics and Medical Technologies State Agency
Netherlands	Health Care Insurance Board (CVZ)
Norway	Norwegian Knowledge Centre (NOKC)

Poland	Agency for Health Technology Assessment in Poland (AHTAPOL)
Portugal	Institute of Molecular Medicine (IMM)
Slovenia	Institute of Public Health of the Republic of Slovenia (IPHR)
Spain	National Health Technologies Assessment Agency (AETS) Andalusian Health Technologies Assessment Agency (AETSA) Basque Office for Health Technology Assessment (Osteba) Galician Health Technologies Assessment Agency (Avalia-t)
Sweden	Swedish Council on Technology Assessment in Health Care (SBU)
Switzerland	Swiss Network for Health Technology Assessment (SNHTA)
England & Wales	National Horizon Scanning Center (NHSC) National Institute for Health and Clinical Excellence (NICE)
US	Centre for Medical Technology Policy (CMTP)

Review of the Literature

A systematic review was performed within several databases (MEDLINE, BIOSIS Previews, Current Contents, and EMBASE) over the period 1990-2006 in order to retrieve English- or French-language publications on AEG mechanisms. Four different search strategies were employed. The main source was, however, the grey literature (government and institution reports on the websites of drug or HTA agencies and national insurance bodies). An initial version of this review was delivered as a milestone in 2006, as expected.

However, considering that AEG mechanisms (and particularly conditional coverage systems...) was highly discussed worldwide during 2007 and 2008, it was further decided to update this initial overview throughout the whole project from 2006 to 2008, in order to provide a more relevant picture of all AEG systems at the end of the EUnetHTA project. Furthermore, it was also decided to extend the review of the literature to marketing authorization stages, in order to have a more complete overview of the processes leading to a timely access to promising health technologies. In addition, as explained in the "readjustment of the objectives" section of this report, WP7 members have also highlighted the need to use a more specific terminology in order to avoid misunderstandings.

Taken together, these elements led to a final and more complete version of the review of the literature, which is currently under final peer-review by WP7 partners and external experts. Therefore, it will be available on the EUnetHTA website in the late spring 2009. However, all the major elements (methods, results, discussion and main conclusions) are reported in the present document.

Surveys targeting WP7-A Members

A preliminary literature review was used to design an electronic survey of the 27 WP7A Partners (conducted in 2006) to identify AEG mechanisms in Europe. The responses (25/27; 93%), together with the results of the systematic literature review, were used to identify the steps required to generate evidence effectively and revise decisions appropriately. A second survey conducted in 2008, after the enrolment of two new members (CMTP and NICE), attempted to identify those countries that had actually implemented some or all of these steps (response rate: 10/29; 34%).

Brainstorming – Meetings with WP7A Partners and Consultation of Key People with Experience in AEG Mechanisms

A meeting of all 27 WP7A members was held in April 2006 (Sevilla, Spain) and another in May 2007 (Dublin, Ireland) to discuss the scope of the overview and to draw up a preliminary policy mechanism. These points and others were also discussed with members attending international meetings (particularly during Health Technology Assessment international (HTAi) meetings in 2006, 2007 and 2008). Additional information on the implementation of AEG mechanisms was also gathered from personal communications or presentations of key people at these meetings. Throughout the project, contact was constantly maintained with partners by e-mail and/or phone.

Exclusions from the Overview

The following were excluded:

- (i) Early warning and horizon scanning systems: Their purpose is to identify and inform policy makers on forthcoming new health technologies and to help prioritize HTA. There is no prospective data collection (10).

(ii) Investigational use of non-approved medical devices or medicines with data collected in clinical trials requested by the regulatory bodies and funded by the applicant: It was considered to be part of the conventional procedure for obtaining marketing approval or licensing, e.g., Australia (7;8), US (9).

(iii) Compassionate use of health technologies: Specific groups of individuals (e.g., with rare diseases) can often obtain rapid access to innovative technologies. This does not, however, usually require data collection (15;14;16).

(iv) Special authorization for use of unapproved medicines: It provides patients with temporary access to medicines that are not yet available in the country, or that are still under development, i.e., before marketing authorization. It may be granted in France (Temporary Authorization for use – “Cohort ATU”) (17) and Italy (Uso terapeutico di medicinale sottoposto a sperimentazione clinica) (15) for medicines used to treat serious or rare diseases for which alternative treatments are not available and for which preliminary evidence strongly suggests a positive benefit/risk ratio. This mechanism focuses rather on enabling early access than on collecting evidence and cannot replace investigational clinical trials.

(v) “Routine” vigilance systems (11) for medicines and devices: These are based on spontaneous reporting of data. Data collection is neither systematic nor comprehensive (12;13).

Web-based toolkit to facilitate evidence generation

The need for international collaboration to facilitate evidence generation on promising health technologies became immediately apparent during the meetings and discussions among WP7 Partners. The WP7-A Lead Partner drafted a proposal on different modes of collaboration which was discussed and agreed upon at a workshop attended by all WP7 Partners (Dublin, April 2007)⁷. The decision was taken to focus first on sharing of information on evidence generation. This meant establishing which information should be shared and developing standard forms for information sharing. It also meant developing a web-based toolkit (a website) for data entry and access to an online database.

Selecting the information to be shared

The proposals made by the WP7-A Lead Partner on the information to be shared were discussed and agreed upon at the Dublin workshop (April 2007).

Standard information entry forms

Three meetings were devoted to the development of standard information entry forms. The two first meetings were between the leaders of WP7-A and WP2 (Communications) (Paris, Mar. & Oct. 2007). They were devoted to technical development planning and to a review of the first draft of the forms, respectively. The third meeting was an internal meeting of the HAS staff involved in the project (Paris, Nov. 2007) in order to make the necessary amendments to the draft forms.

Pilot tests

Two pilot tests of the forms were conducted. In the first pilot test, HAS staff and two WP7 Partners (CVZ and ASSR) completed the forms designed for requesting information, using as examples technologies in which they were particularly interested (Nov – Dec. 2007). WP7 Partners were then asked to complete the forms designed to answer queries (posting information form) (Jan. 2008). Their comments were used to amend the forms. In the second pilot test, WP7 Partners were asked to test both the forms for requesting and posting information on technologies in which they were particularly interested (May 2008). Their comments were again used to amend the forms. Each completed form was checked by the WP7-A Lead Partner to make sure that the information provided was in line with the items of the forms.

IT development

The website was developed by the IT department of HAS. The Lead Partner of WP2 (Communications) acted as IT consultant so that the website would be interoperable with the EUnetHTA HTA Information system. The work schedule was: (a) identification of needs, (b) definition of website content, (c) technical development (electronic forms and online database), and (d) website testing by WP7-A Lead Partner.

Work Performed in 2008:

Overview of national experiences on AEG

1. Review of the literature

⁷http://www.eunetha.net/WP7_documents/Workshop%20of%20Dublin/Minutes_%20Workshop%20of%20Dublin_online.pdf

As we have extended the scope of the overview to marketing authorisation stage for medicines and medical devices, and considering that conditional coverage was heavily discussed at the international level in 2008, an additional review of the literature focused on these topics was performed.

2. Surveys targeting WP7-A Members

A second survey attempted to identify those countries that had actually implemented some or all of AEG steps.

3. Consultation of Key People

Additional consultation of key people with experience in AEG Mechanisms was performed, mainly during HTAi 2008 conference (as conditional coverage was one of the major topics). In addition, the creation in 2008 of HTAi's interest special group about use with evidence development needed to be taken into account within the document.

4. Adaptation of the terminology

In addition to the update of the overview in terms of additional literature and experts positions, one of the major work performed in 2008 was to define an adequate terminology leading to the wording of "Access with evidence generation" and many other terms.

Web-based toolkit to facilitate evidence generation

1. Pilot tests of the standard information entry forms

(Reminder, in 2007, HAS staff and two WP7 Partners (CVZ and ASSR) completed the forms designed for requesting information, using as examples technologies in which they were particularly interested)

- Continuation of the first pilot test: WP7 Partners were asked to complete the forms designed to answer queries (posting information form). Their comments were used to amend the forms
- Second pilot test, WP7 Partners were asked to test both the forms for requesting and posting information on technologies in which they were particularly interested. Their comments were again used to amend the forms. Each completed form was checked by the WP7-A Lead Partner to make sure that the information provided was in line with the items of the forms.

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9.4.4 Man/ womanpower

Organisational and financial managements were performed by Esther Pensado, Céline Moty-Monnereau and Fabienne Quentin under the supervision of Sun Hae Lee-Robin and François Meyer.

Overview of national experiences on AEG

The review and analysis of the literature was performed by Cedric Carbonneil and Fabienne Quentin (Junior Researchers, HAS). Additional review of the literature was performed by Dominique Benedittini, Laurence Fort (subcontractors) and Boguslawa Osinska (trainee manager from AHTAPol), under the supervision of Sun Hae Lee-Robin (Head of department, HAS).

Surveys were designed and analyzed by Fabienne Quentin and Céline Moty-Monnereau (Junior Researchers, HAS) in 2006 and by Cédric Carbonneil and Fabienne Quentin in 2008 under the supervision of Sun Hae Lee-Robin. All WP7 partners were involved (see list of WP7 partners in appendix I).

During EUnetHTA WP7 and HTAi meetings, additional information was gathered by Fabienne Quentin, Cédric Carbonneil, Céline Moty-Monnereau and Sophie Blanchard (Junior researchers) under the supervision of Sun Hae Lee-Robin and François Meyer (Director). All WP7 partners were involved.

Web-based toolkit to facilitate evidence generation

The proposal of different mode of collaboration was drafted by Fabienne Quentin, Céline Moty-Monnereau and Sun Hae Lee-Robin and agreed by all WP7 partners.

Entry forms were developed by Fabienne Quentin Céline Moty-Monnereau, Cédric Carbonneil and Sun Hae Lee-Robin. They were submitted to WP7 members' comments and approval.

Pilot tests were performed by Fabienne Quentin, with the special collaboration of Elena Berti (ASSR) and Wim Goettsch (CVZ).

The website was developed by the IT department of HAS (Angélique Tatin, Jean-Philippe Auger, Edith Tassemla, Karine Rozet and François-Xavier Ratnam) and Webnet (subcontractor) and tested by Fabienne Quentin, Cédric Carbonneil Karine Rozet and Angélique Tatin.

Susanna Allgürin-Neikter (SBU) and Hans Peter Dauben (DIMDI) were WP2 correspondents for IT development.

9.4.5 Results : Achievement of the objectives

Overview of national experiences on AEG

AEG mechanisms are used when two important decisions are made during a technology's life-cycle: (i) marketing approval, (ii) coverage.

AEG Mechanisms associated with Marketing Approval Decisions

Medicines

We identified not only the AEG mechanisms recommended by the European Medicines Agency (EMA), applicable to EU countries and implemented by the European Commission (EC), but also country-specific mechanisms in 14/23 countries. These fell into two categories (Table 6):

- (i) conditional marketing authorization;
- (ii) post-marketing studies.

Table 6: Established AEG mechanisms associated with marketing approval decisions

	Conditional marketing approval	Post marketing studies ^{†#}
Objectives	To confirm preliminary results on safety and efficacy	To collect key data that are not a prerequisite for marketing approval: <ul style="list-style-type: none"> to confirm the benefit/risk ratio under real-life or experimental conditions to investigate safety concerns identified at the pre-marketing stage or during the marketing authorization procedure, under real-life conditions
Applicability	<ul style="list-style-type: none"> Drugs for the treatment, prevention or diagnosis of serious life-threatening or debilitating diseases or for use in emergency situations The public health benefit of immediate access outweighs the risk due to the lack of data 	<ul style="list-style-type: none"> Drugs giving rise to concerns about efficacy/effectiveness in real-life Drugs exhibiting observed safety concerns Drugs without any major safety concerns, but for which routine pharmacovigilance is not appropriate Drugs for which additional data are required in target populations not covered in clinical trials
Preliminary evidence requirement	Preliminary scientific evidence indicates positive benefit/risk ratio	Evidence suggests that the benefit/risk ratio is positive, but efficacy/safety concerns arise on real-life use or are suggested by the preliminary evidence

Data collection requirements	Systematic (clinical trials)	Systematic under experimental conditions (clinical trials in specified populations) and real-life conditions (registries; pharmacoepidemiological studies, comparative observational studies, drug use studies, sentinel sites, individual follow-up of patients...)
Data collection schedule		Agreed timeframe
Funding for data collection	Applicant	Applicant/holder or public institution
Schedule of reassessment	Annually	When data available (end of study)
Expected consequence	Should lead to the granting of a “conventional” marketing approval	May lead to a revised marketing authorization (or suspension or withdrawal)
Decision-making authority	EMA-EC/National medicine agencies/ Ministry of Health	EMA-EC/National medicine agencies/Ministry of Health
Countries	European countries (EMA), Belgium, Canada, Denmark, France, Germany, Italy, Spain	European countries (EMA)*, Australia, Belgium, Canada, Finland, France, Germany, Italy, Latvia, Netherlands, Portugal, Spain, US

* European risk management plan (RMP) may be complemented by a national RMP; †Include active pharmacovigilance surveillance; # Must not be disguised promotion or marketing

- Conditional marketing authorization

The EC may grant conditional marketing authorization when the new medicines have orphan status, or are intended for seriously debilitating, life-threatening diseases or emergency situations (e.g. pandemics). At least four conditions must be met:

- (i) preliminary evidence should indicate a positive benefit/risk ratio;
- (ii) the applicant should be able to provide comprehensive data;
- (iii) unmet medical needs should be fulfilled;
- (iv) the public health benefit of immediate access should outweigh the risk due to uncertainty.

The decision is taken before comprehensive clinical data is available. Authorization is granted on a yearly basis and carries the legal obligation to provide further evidence on safety and efficacy (completion or initiation of studies). Conventional marketing authorization may be granted after yearly review of the evidence generated (18). Some countries also have their own conditional marketing authorization mechanisms (e.g. Italy (19), Spain (14), Denmark (20), Germany (21), Belgium (22), Canada (23)).

- Post-marketing studies (including active pharmacovigilance)

Post-marketing studies are not a prerequisite to marketing approval but the data collected, for instance on safety or efficacy in a given population in the usual clinical setting, may impact at any time on the benefit/risk ratio and thus result in changes to the marketing authorization (Table 6). Most post-marketing studies address safety concerns as data on safety tends to be limited when approval is granted. Proactive actions to complement routine pharmacovigilance systems (spontaneous reporting of adverse events) are now implemented worldwide.

In the EU, whenever safety concerns arise during clinical trial assessments, the EMA requests further data collection and appropriate pharmacovigilance, with quantification of adverse events (11). Some member states implement additional active surveillance to meet their own specific needs (Belgium (22,24), Finland (25), France (26), Germany (21), Italy (19), Latvia (27), Netherlands (28,29), Portugal (30), Spain (31) and UK (32,33)). This also occurs in the US (34) and Australia (35,36).

Medical Devices

Much less information was found on medical devices than on medicines. Two types of AEG mechanisms for marketing approval were identified in 7/23 countries (Australia, Canada, Latvia, Spain, Switzerland, US and UK): (i) conditional licensing, (ii) post-marketing clinical follow-up.

- Conditional licensing

Conditional licensing may be granted to new moderate- or high-risk medical devices in Canada “*when there is reasonable assurance that the device is safe and effective but supplemental information is required to support this conclusion*” (16). The applicant has to fund and set up studies to collect additional clinical data to confirm the benefit/risk ratio within a set deadline (16).

- Post-marketing clinical follow-up (or post-approval surveillance)

There are several methods of follow-up (37,38): long-term surveillance of the patients who were included in pre-approval clinical trials (37), prospective observational studies (39), registries (40), or new clinical trials (41). The Global Harmonization Task Force (GHTF) has performed extensive work on regulatory approaches about post-market surveillance and clinical assessment of medical devices and has proposed guidance (42,43). Funding comes from either the holder of the marketing approval or public institutions.

A new EU directive applicable as from March 2010 (44) will request systematic data collection during post-marketing surveillance (unless non-applicability can be justified). This follows the guidance issued by the Medical devices evaluation committee (MEDDEV) (45) (already implemented by Latvia (27) and Switzerland (46,47)).

Conclusions on AEG Mechanisms associated with Marketing Approval Decisions

In summary, the AEG mechanisms associated with marketing approval decisions provide access to promising health technologies - whether medicines or medical devices - without the need to wait for comprehensive evidence on benefits and risks. For this, specified data must be collected in an appropriate study which is usually funded by the manufacturers. Other information may also be gathered by regulators. A decision is taken to provide interim, conditional access to the technology and to monitor data collection. Review of the data generated may lead to the granting of a conventional marketing approval, the renewal of conditional access, restriction of authorization, product suspension or withdrawal (48). As an illustration, the evidence generated in response to decision-makers' concerns has justified early access to promising anti-HIV and anti-cancer drugs. The AEG mechanisms for medicines, unlike those for medical devices, differ little among EU countries because of a long-standing “harmonized” regulatory framework.

AEG Mechanisms associated with Coverage Decisions

AEG mechanisms associated with coverage decisions, unlike those associated with marketing approval, are recent. Few countries have implemented such mechanisms so far (5,49-51), but an increasing number are showing interest and attempting to identify mechanisms that will meet their local needs and constraints. These mechanisms are applied to medicines, medical devices and/or procedures (Table 7). We identified only 12/23 countries implementing AEG mechanisms before coverage decisions (Canada (Ontario) (52-56), Spain, (57,58), Australia (59), US (51), Switzerland (61), Sweden (62,63), Belgium (64), Netherlands (65), France (66,67), England/Wales (49,50,68), Germany (49) and Italy (69)). They fell into three main categories that seems to be associated with different degrees of uncertainty:

- (i) the “No, unless...” category which considers that evidence is inadequate to grant coverage unless additional requirements are met;
- (ii) the “Yes, but...” category which considers that the evidence is reasonably adequate to grant coverage, but conditioned to additional evidence generation;
- (iii) the “Yes for now” category which considers that evidence is adequate to grant standard coverage and data on some specific aspects (e.g. on conditions of use) are asked

Access may be limited to the patients included in the required clinical trial (i), treated in centers collecting the required data (ii), or may not be restricted at all (iii). Tables 7 and 8 show the AEG mechanisms implemented by each category and the bodies involved.

Some countries (Canada (Ontario), Spain, Australia, US, Switzerland, Sweden, Belgium, Netherlands, France and England/Wales) implement an structured form of AEG (“conditional coverage”) which is usually part of an established policy framework, in which the initial decision on coverage is conditional to the generation of evidence in response to the decision-makers' requests (5,49,51). Data are collected prospectively under experimental conditions (clinical trials) or under real-life conditions (observational, pragmatic or health economics studies or registries). Their results are taken into account in the reassessment and in the subsequent revised coverage decision (5,49,51) that may lead to standard coverage, modification of coverage conditions, or even to delisting.

The strengths and weaknesses of all these AEG mechanisms are compared in Table 9.

Table 7: Main characteristics of AEG mechanisms associated with coverage decisions

AEG system (Name, country)	Health technologies concerned	Type of initial decision	Requirement for AEG decision	Examples
Only in research (England/Wales)	Medicines, medical devices, interventional procedures, and public health interventions	"No, unless..."	The use of a promising technology or a public health intervention is not supported by enough robust evidence	<ul style="list-style-type: none"> - Laparoscopic surgery for colorectal cancer - Taxanes as adjuvant in early node positive breast cancer - Verteporfin in ARMD...
Suspended coverage decision with pilot project (Germany)	Medical devices within a procedure	"No, unless..."	Not enough evidence to conclude on the benefit, necessity, or efficiency	<ul style="list-style-type: none"> - Acupuncture for chronic pain - Screening for skin cancer - Balneo-phototherapy...
Conditionally funded field evaluation (Canada, Ontario)	Medicines, medical devices, procedures and public health interventions	"Yes, but..."	<ul style="list-style-type: none"> - Uncertainty (low quality of evidence) about effectiveness, cost effectiveness, or safety - Need for quality controls prior to unrestricted diffusion - Potential disruptive effects - Large potential investment 	<ul style="list-style-type: none"> - PET scanners - Endovascular treatment of abdominal aneurysms - Drug eluting stents - Surgical treatment of epilepsy - Cardiac CT angiography...
Monitored use (Spain)	Medical devices, medical and surgical procedures	"Yes, but..."	Uncertainty about effectiveness and safety at the initial coverage decision stage	<ul style="list-style-type: none"> - Surgical treatment of epilepsy - PET scanners - Endovascular treatment of abdominal aneurysms...
Interim funding (Australia)	Medical devices, medical and surgical procedures	"Yes, but..."	For promising technologies which are (i) safe, effective but with uncertain cost effectiveness or (ii) with uncertain effectiveness and safety but potent cost effectiveness	<ul style="list-style-type: none"> - PET scanners - Deep-brain stimulators - Endovascular treatment of abdominal aneurysms...
Coverage with evidence development (CMS) (US)	Medicines, medical devices, medical and surgical procedures	"Yes, but..."	Evidence complementary to existing medical evidence is required on effectiveness, safety or cost effectiveness	<ul style="list-style-type: none"> - Lung volume reduction surgery - Cochlear implants - Implantable cardioverter defibrillators - PET scanners...

Medical service under evaluation (Switzerland)	Controversial procedures	"Yes, but..."	Uncertainty about effectiveness and safety at the initial coverage decision stage	<ul style="list-style-type: none"> - Bariatric surgery - Surgical treatment of epilepsy - Curitherapy in prostate cancer - Intervertebral disc replacement - Verteporfin in ARMD...
Reimbursement with conditions (Sweden)	Innovative medicines	"Yes, but..."	Uncertainty about effectiveness, safety, cost effectiveness, or conditions of use	<ul style="list-style-type: none"> - Diabetes and weight loss treatment - Cancer drugs and biologicals...
Conditional reimbursement (Belgium)	Innovative implants	"Yes, but..."	Uncertainty about effectiveness, safety, or condition of use	<ul style="list-style-type: none"> - Deep brain stimulation - Endovascular treatment of abdominal aneurysms - Drug eluting stents for diabetic patients - Contralateral cochlear implant...
Conditional reimbursement (Netherlands)	Hospital prescribed medicines (e.g., costly or orphan medicines)	"Yes, but..."	Uncertainty regarding relative therapeutic value, relative cost effectiveness, and importance to public health	<ul style="list-style-type: none"> -Bevacizumab, -Trastuzumab, -Anidulafungin...
Still in clinical research (France)	Medical and surgical procedures	"Yes, but..."	Clinical benefit cannot be fully established	<ul style="list-style-type: none"> - Intensity-modulated radiation therapy* - Extracranial stereotactic radiotherapy* - Biochemical markers of liver fibrosis*...
Post-listing studies (France)	Medicines and medical devices	"Yes for now..."	Uncertainty on conditions of use, safety, impact on organisation of healthcare...	<ul style="list-style-type: none"> - IFN-β - Anti TNF-α medicines - Transcutaneous implanted pulmonary valve...
Independent research on medicines (Italy)	Medicines, public health interventions	"Yes for now..."	<ul style="list-style-type: none"> - Rare diseases; - High impact in terms of public health or economy; - Long-term safety during treatment of chronic diseases... 	<ul style="list-style-type: none"> - IFN-β vs Azathioprine - Bevacizumab - Evaluation of impact of educational interventions of patient with psoriasis...

*: Recommended by national HTA agency, but no data generated; **AEG**: Access with Evidence Generation; **ARMD**: Age-related macular degeneration; **PET**: Positron emission tomography; **CT**: Computed tomography; **IFN**: Interferon; **TNF**: Tumor Necrosis Factor.

Table 8: Role of identified collaborators in AEG mechanisms associated with coverage decisions

AEG system (Name, country)	Coordinating structure	Source of funding for data collection*	Structure performing data collection	Structure performing data analysis	Decision making authority
Only in research (England/Wales)	NICE	-Public (NHS R&D, MRC...)	Various partners (health professionals,	Various partners (health professionals,	NICE

Suspended coverage decision with pilot project (Germany)	Statutory Health Insurance/ Association of statutory health physicians	-Private (manufacturers...) -Public (Statutory Health Insurance)	manufacturers...) Health professionals (mostly the Association of statutory health physicians)	manufacturers...) Not determined	GB-A
Conditionally funded field evaluation (Canada, Ontario)	OHTAC/MAS	Public (Ministry of Health and long-term care)	PATH, THETA, other academic partners, research organisations	PATH, THETA, other academic partners	Ministry of Health and long-term care
Monitored use (Spain)	National Health service's interterritorial Council	Public (Ministry of Health)	Public hospitals	HTA agencies (AETS, AETSA, Osteba, Avalia-t...)	Ministry of Health
Interim funding (Australia)	MSAC	Public (Ministry of Health and aging)	Associations of health professionals	Associations of health professionals	Ministry of Health and aging
Coverage with evidence development (CMS) (US)	CMS	Mostly public (CMS for clinical costs only, stakeholders for other costs...)	Various partners (institutions, health professionals...)	Various partners (institutions, health professionals...)	CMS
Medical service under evaluation (Switzerland)	Federal Office of Public Health	Mostly public (Sickness Funds or applicants)	Applicant (health professionals, manufacturers)	Not determined	Federal Department of Home Affairs (advised by ELK)
Reimbursement with conditions (Sweden)	TLV	Manufacturers	Manufacturers	TLV	TLV
Conditional reimbursement (Belgium)	KCE/INAMI	Public (INAMI)	Health professionals	KCE/INAMI	INAMI
Conditional reimbursement (Netherlands)	CVZ	Manufacturers/ ZonMW	Various partners (Manufacturers, health professionals, academic partners, institutions...)	CVZ	Ministry of Health, Welfare and Sport
Still in clinical research (France)	HAS	UNCAM for clinical costs only; currently no funding for other costs	Health professionals	HAS	HAS/UNCAM

Post-listing studies (France)	HAS	Manufacturers	Manufacturers	Manufacturers	Ministry of Health
Independent research on medicines (Italy)	AIFA	Public (AIFA)	Health professionals	AIFA	Regional institutions

*: Funding may not be systematically guaranteed; **AETS** : Spanish National Health Technologies Assessment Agency; **AETSA** : Andalusian Health Technologies Assessment Agency; **AIFA**: Italian Medicine Agency; **Avalia-t** : Galician Health Technologies Assessment Agency; **CMS** : American Center for Medicare/Medicaid services; **CVZ**: Dutch Health care insurance board; **ELK**: Swiss Federal Commission for general health insurance benefits; **GB-A**: German Federal-joint Committee; **HAS**: French High Authority for health; **INAMI**: Belgian National Health Insurance; **KCE**: Belgian Healthcare Knowledge Center; **MAS**: Medical Advisory Secretariat (Ontario); **MRC**: British Medical Research Council; **MSAC**: Australian Medical Services Advisory Committee; NHS: British National Health Services; **NICE**: National Institute for Health and Clinical Excellence; **OHTAC**: Ontario Health Technology Advisory Committee; **Osteba**: Basque Office for Health Technology Assessment; **PATH**: Program for the Assessment of Technologies in Health (Ontario); **THETA**: Toronto Health Economics and Technology Assessment Collaborative; **TLV**: Swedish Dental and Pharmaceutical Benefits Agency; **UNCAM**: French National Health Insurance; **ZonMW**: Netherlands organisation for Health Research and Development.

Table 9: Reported strengths and weaknesses of AEG systems at the coverage stage

ystem , country)	Reported strengths	Reported weaknesses
research d/Wales)	<ul style="list-style-type: none"> - Regulatory framework - Methodological guidance 	<ul style="list-style-type: none"> - No dedicated funding - No systematic collaboration between partners - Not a systematic process (opportunistic)
unded coverage on with pilot project y)	<ul style="list-style-type: none"> - Dedicated funding[†] 	<ul style="list-style-type: none"> - Incomplete regulatory framework as regards project implementation and use of results in decision making - For medical devices used as part of a procedure only - No methodological guidance - No systematic collaboration
Conditionally funded field evaluation (Canada, Ontario)	<ul style="list-style-type: none"> - Dedicated funding[†] - Systematic collaboration between partners - Regulatory framework - Methodological guidance - Operational system - Great way to engage end users. 	<ul style="list-style-type: none"> - High pressure - Regional system (limited to Ontario)
Monitored use (Spain)	<ul style="list-style-type: none"> - Dedicated funding[†] - Systematic collaboration between partners - Regulatory framework - Methodological guidance - Operational system 	<ul style="list-style-type: none"> - No selection criteria for technologies to be monitored
Interim funding (Australia)	<ul style="list-style-type: none"> - Dedicated funding[†] - Regulatory framework - Methodological guidance - Operational system. 	<ul style="list-style-type: none"> - For medical devices and procedures only - No systematic collaboration between partners - Funding (MBS) not fully adapted to “interim funding” - Trial duration too long (>3 yrs) for conditional coverage - National target populations too small; interim funding while awaiting results of international studies
Coverage with evidence development (CMS) (US)	<ul style="list-style-type: none"> - Regulatory framework - Methodological guidance (partial) 	<ul style="list-style-type: none"> - No dedicated global funding - No systematic collaboration between partners - Not a systematic process (opportunistic) - Difficulties in designing CED studies
Medical service under evaluation (Switzerland)	<ul style="list-style-type: none"> - Regulatory framework - Dedicated funding[†] - Operational system 	<ul style="list-style-type: none"> - For controversial medical procedures only - No systematic collaboration (depends on applicant) - Constraints of public administration human and financial resources
Reimbursement with conditions (Sweden)	<ul style="list-style-type: none"> - Regulatory framework - Dedicated funding[†] - Mandatory engagement of manufacturer - Operational system 	<ul style="list-style-type: none"> - For innovative drugs only - Difficulties in interpreting observational studies - Difficulties with effectiveness studies
Conditional reimbursement (Belgium)	<ul style="list-style-type: none"> - Regulatory framework* - Dedicated funding[†] - Collaboration between partners - Operational system 	<ul style="list-style-type: none"> - For innovative new implants only
Conditional reimbursement (Netherlands)	<ul style="list-style-type: none"> - Regulatory framework - Dedicated funding[†] -Mandatory engagement of manufacturer 	<ul style="list-style-type: none"> - For hospital-prescribed medicines (costly or orphan medicines) only

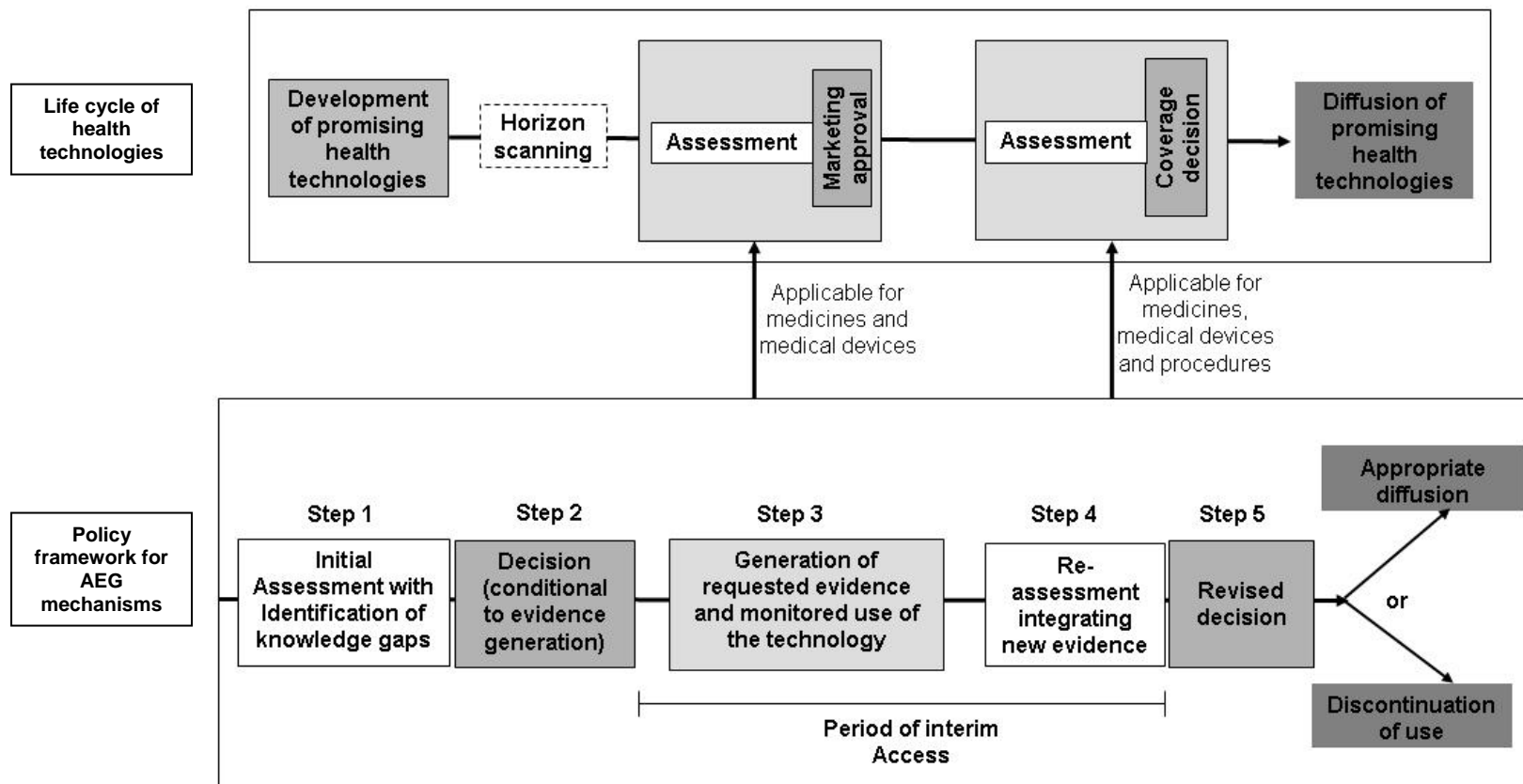
Still in clinical research (France)	<ul style="list-style-type: none"> - Regulatory framework* 	<ul style="list-style-type: none"> - For medical and surgical procedures only - No dedicated global funding - No collaboration between partners - No operational system.
Post-listing studies (France)	<ul style="list-style-type: none"> - Dedicated funding[†] (by the manufacturers) - Regulatory framework - Methodological guidance - Mandatory engagement of manufacturer 	<ul style="list-style-type: none"> - For medicines and medical devices only - Difficulties to find agreement on study design - No conditional or temporary coverage (but linked with strict conditions).
Independent research on medicines (Italy)	<ul style="list-style-type: none"> - Implemented regulatory framework - Dedicated funding[†] - Methodological guidance 	<ul style="list-style-type: none"> - For medicines only - No systematic collaboration (research projects only) - No conditional or temporary coverage

*A change in the law on innovative technologies has been proposed to achieve a more operational mechanism; †: Dedicated funding may not be systematically guaranteed

A Common Policy Framework for AEG Mechanisms (Marketing Approval or Coverage)

The above descriptions of the AEG mechanisms currently implemented, whether for marketing approval or coverage/reimbursement decisions, can be used to construct a “common-denominator” model underlying a policy framework (Figure 2).

Figure 2: General policy framework to describe AEG mechanisms for promising health technologies and time-points in their life cycle when AEG mechanisms are applicable



Its steps are:

Step 1. A first assessment is performed which pinpoints evidence gaps and data needs and proposes a plan for data collection (type of data and study, time period, etc.).

Step 2. A decision is made on conditional and temporary access to the technology. This decision is based on the first assessment and is accompanied by a request for evidence generation (which type of data needs to be collected and analysed to fill which evidence gaps and to answer any uncertainties formulated by the decision-makers).

Step 3. An interim period of conditional access to the technology follows during which the data requested is collected. During this time, conditions of use of the technology are usually restricted and well-defined, and use must be monitored.

Step 4. A second assessment is performed, including the additional evidence that has been generated.

Step 5. A revised decision on access to the technology based on this second assessment is taken.

However, the WP7-A members drew attention to the reported barriers to the setting-up and running of a completely operational system at the coverage stage (5,49,51) and stressed the need to establish critical success factors (Box 1). These factors are an indispensable adjunct to the 5 steps shown in Figure 2. The final outcome may be widespread and appropriate availability of the technology, restricted diffusion, or discontinuation of use.

Box 1. Barriers to and critical success factors for evidence generation	
Barriers	Critical success factors
<ul style="list-style-type: none">• Difficulty in agreeing on data requirements and study design• Evidence generated does not meet quality criteria and cannot therefore inform a decision• Lack of coordination among the partners and bodies overseeing data collection• Limited funds to finance the generation of evidence that meets HTA agency and decision-maker requirements• No well-defined regulatory framework governing coordination and financing	<ul style="list-style-type: none">• Coordinating body overseeing the contributions and collaboration of all participants• Scientific leadership and clear guidance on key methodological issues (e.g. study design) for relevant and high-quality evidence• Dedicated funding for data collection and analysis (e.g. studies and registries), regardless of source• Regulatory framework

This common policy framework and associated critical success factors apply to the implementation of AEG both at the marketing approval stages and coverage decision stages. It is derived from the current regulatory framework for medicines. However, whereas all 5 steps and all critical criteria of success are usually implemented for medicines (EMA has defined study designs, quality requirements, organized the coordination of bodies, etc), many steps are often not implemented for coverage decisions and many critical success factors are missing (see Table 9).

Ranking Implementation of AEG Mechanisms

We compared our observations on the implementation of AEG mechanisms with the model policy framework. To do this, we arbitrarily defined four levels of execution:

1. **Full implementation:** All 5 steps and all 4 critical success factors are implemented. The first assessment identifies evidence gaps. Data collection meets quality standards. The revised decision is based on an updated literature review and on the additional data generated.
2. **Partial implementation:** The 5 steps are fully operational. The first assessment identifies evidence gaps. However, data collection is hampered by national constraints on implementation of the success factors. The revised decision is based on an updated literature review but on partial data collection only (mostly registry data).
3. **Passive implementation:** The first assessment identifies evidence gaps but data is not collected usually for financial or regulatory reasons. The revised decision is based on an updated literature review only.
4. **No implementation:** There is no systematic identification of new technologies nor any follow-up of their diffusion. No second assessment is performed.

The 23 countries have been classified on this basis in Table 10. The degree of implementation depends strongly on the national context.

Table 10. Degree of implementation of AEG mechanisms by various countries

Country	Marketing approval		Coverage decision		
	Medicine	Medical device	Medicine	Medical device	Procedure
Canada (Ontario)	+++ ^N	+++	+++	+++	+++
Spain	+++ ^{E,N}	+++	+++	+++	+++
Australia	+++ ^N	+++	+++/ ⁺	+++	+++
US	+++ ^N	+++	+++	+++	+++
England & Wales	+++ ^{E,N}	++	+++	+++	+++
France	+++ ^{E,N}	++	+++	+++	++/ ⁺
Germany	+++ ^{E,N}	++	++	+++/ ⁺	++
Sweden	+++ ^E	-	+++	++	++
Belgium	+++ ^{E,N}	-	-	+++	-
Italy	+++ ^{E,N}	-	+++/ ⁺	+/-	+/-
Netherlands	+++ ^{E,N}	-	+++/-	-	-
Switzerland	-	+++	-	-	+++/-
Austria	+++ ^E	-	++	++	++
Denmark	+++ ^{E,N}	-	++	++	++
Latvia	+++ ^{E,N}	+++	-	-	-
Portugal	+++ ^{E,N}	-	-	-	-
Finland	+++ ^{E,N}	-	-	-	-
Poland	+++ ^E	-	-	-	-
Ireland	+++ ^E	-	-	-	-
Estonia	+++ ^E	-	-	-	-
Slovenia	+++ ^E	-	-	-	-
Cyprus	+++ ^E	-	-	-	-
Norway	-	-	-	-	-

+++; full AEG; ++; partial AEG; +; passive AEG; -: No AEG.

^E: AEG implemented by EMEA and applicable in European Countries; ^N: country-specific AEG implemented at national level.

Web-based toolkit to facilitate evidence generation

Types of collaboration

WP7 Partners decided on three possible levels of cooperation between EUnetHTA Members on promising health technologies: sharing information, coordinated action, and joint action (Box 2).

Box 2. Levels of collaboration

1. Sharing information: low level of commitment, i.e. just sharing relevant information on evidence generation.
2. Coordinated action: Intermediate level of commitment, i.e. getting coordinated by agreeing on a common core protocol. Actions are, however, conducted independently in each interested country.
3. Joint action: High level of commitment, i.e. setting up a joint study (e.g. multicenter, cross-border prospective data collection).

Information to be shared

WP7 Partners selected the following key information to be shared (see Box 3).

Box 3. Information on a promising technology

- HTA status (planned, ongoing, completed, reports available)
- Marketing authorization and coverage decision
- Status of interim period of conditional access with evidence generation requirements
- Protocols and available results (clinical studies or registries)
- Use to which the evidence generated has been put (second HTA report and/or revised decision on access, coverage).

Design and pilot testing of the standard forms

WP7-A was devoted to the development of a toolkit for information sharing among EUnetHTA Members (low level of commitment). Standard data forms for requesting and supplying information were designed by the WP7-A Lead Partner. They were tested by 7 of the 31 WP7 Partners in a first test and by 6 in a second test. The participation rate was thus low. Participants tended to be either WP7 partners with substantial experience of AEG mechanisms, or on the contrary partners with little experience. By participating, advanced partners were able to consolidate the quality of their work, and the less advanced partners were able to learn.

The participating partners tested the forms for 21 technologies (Table 11). Information was requested on 13 technologies; only 6/13 requests received a reply. Information was provided “spontaneously” on 8 technologies. More than one request or reply was recorded for 4 technologies (bevacizumab in age-related macular degeneration, transient elastography, implantable cardioverter defibrillator, intensity-modulated radiation therapy (IMRT)).

During quality control of the requests and replies, the WP7-A Lead Partner contacted each participant at least once for details. In general, the participant had not understood one or more items. These were reworded for greater clarity.

Table 11. Lists of health technologies used in the pilot tests

Technology	Request (N)	Reply (N)
Bevacizumab in age-related macular degeneration ⁽²⁾	2	0
Biochemical markers of liver fibrosis ⁽¹⁾	1	0
Blood titration of gamma-interferon ⁽¹⁾	1	0
Colorectal cancer screening ⁽²⁾	1	0
High-intensity focused ultrasound ⁽¹⁾	1	0

Magnetic navigation system ⁽²⁾	1	0
Transient elastography ⁽¹⁾	2	0
Bevacizumab in colorectal cancer ⁽²⁾	0	1
Cardiac multislice and coronary computed tomography ⁽²⁾	0	1
Deferasirox ⁽²⁾	0	1
Endovascular grafts for abdominal aortic aneurysms ⁽²⁾	0	1
Human papillomavirus vaccine for cervical cancer prevention ⁽²⁾	0	1
Lenalidomide ⁽²⁾	0	1
Natalizumab ⁽²⁾	0	1
Portable glycosylated haemoglobin measurement systems ⁽²⁾	0	1
Extra-cranial stereotactic radiotherapy ⁽¹⁾	1	1
Implantable cardioverter defibrillator ⁽¹⁾	1	3
Intensity-modulated radiation therapy ⁽¹⁾	1	2
Percutaneous aortic valve replacement ⁽¹⁾	1	1
Tympanostomy tubes ⁽¹⁾	1	1
Ventricular assistance ⁽¹⁾	1	1

⁽¹⁾ First pilot test, ⁽²⁾ second pilot test

Example of the value of sharing information

In the pilot test, the WP7-A Lead Partner completed a request for information on IMRT as HAS was planning a reassessment. It requested information on coverage, effectiveness, and appropriateness of use. Two partners replied to this request. One provided valuable information on the status of IMRT in their country (marketing authorization (CE mark) and coverage), on the AEG mechanisms that had been set up (registry and monitoring of use), the protocol implemented, and the sources of registry funding. On the basis of this reply, HAS decided to postpone the reassessment of IMRT until the additional data collected by this partner became available. The new data will be included in the HAS re-assessment report and will be used to support the decision on coverage.

Creation of the web-based toolkit: a website

The structured standard forms for information entry are available on a website (Eunetha Interface to Facilitate Furthering of Evidence Level (<http://eiffel.eunetha.has-sante.fr/>)). This website is for use by EUnetHTA members only and can be accessed through a link from the EUnetHTA website.

Website content

The website provides access to the forms for requesting information ("request form"), posting information in response to a request ("posting form"), and posting information spontaneously ("spontaneous posting form"). The website also provides an online queryable database containing all the information requested or posted. It will be fed automatically, as and when the forms are filled. The forms completed for 21 technologies during the pilot testing have been entered into the database.

When completing the forms, users must specify if the information provided is confidential (to be sent only to the user requesting the information) or semi-confidential (available to database users, i.e. EUnetHTA Members). Each member is responsible for the quality of the information they provide.

Website access

Figure 3 shows how the website is used:

- The user searches the database for information on a promising health technology (action 1).
- If no information is retrieved or if it is insufficient, he/she completes the standard "request form" on the request page (action 2).
- The "request form" undergoes a quality control process to ensure that the information entered corresponds to the items of the form (action 3).
- The "request form" is published on the website (action 4) and all EUnetHTA Members are notified by e-mail.
- Members who can provide the information requested complete the standard "posting form" (action 5).
- The "posting form" undergoes quality control to ensure that the information entered corresponds to the items of the form (action 6).
- The "posting form" is then published on the website (action 7) and the user who requested the information is informed by e-mail that a member has responded to his/her request.
- Any user can provide information spontaneously by completing the "spontaneous posting form" (action 5').

- All the information exchanged is automatically stored in the database. All members are informed of entries by e-mail alert.

Intended website users

The intended website users are EUnetHTA Members, i.e. “publicly funded” organisations that produce or contribute to HTA. Three user profiles were identified (Box 4).

Box 4. Website user profiles

Someone who seeks information on a promising health technology (e.g. on diffusion in other countries, clinical data) in order to complete an HTA report (assessment or reassessment).

Someone who seeks information within the context of AEG. This user would like to know about planned, ongoing, or implemented AEG in other countries (e.g. available clinical data, difficulties encountered, funding...) in order to advise on an interim period of conditional access for a given technology. At any time, this user can update the search to find out what progress has been made and whether the technology has been diffused.

Someone who provides information on a promising technology either in response to a request or spontaneously.

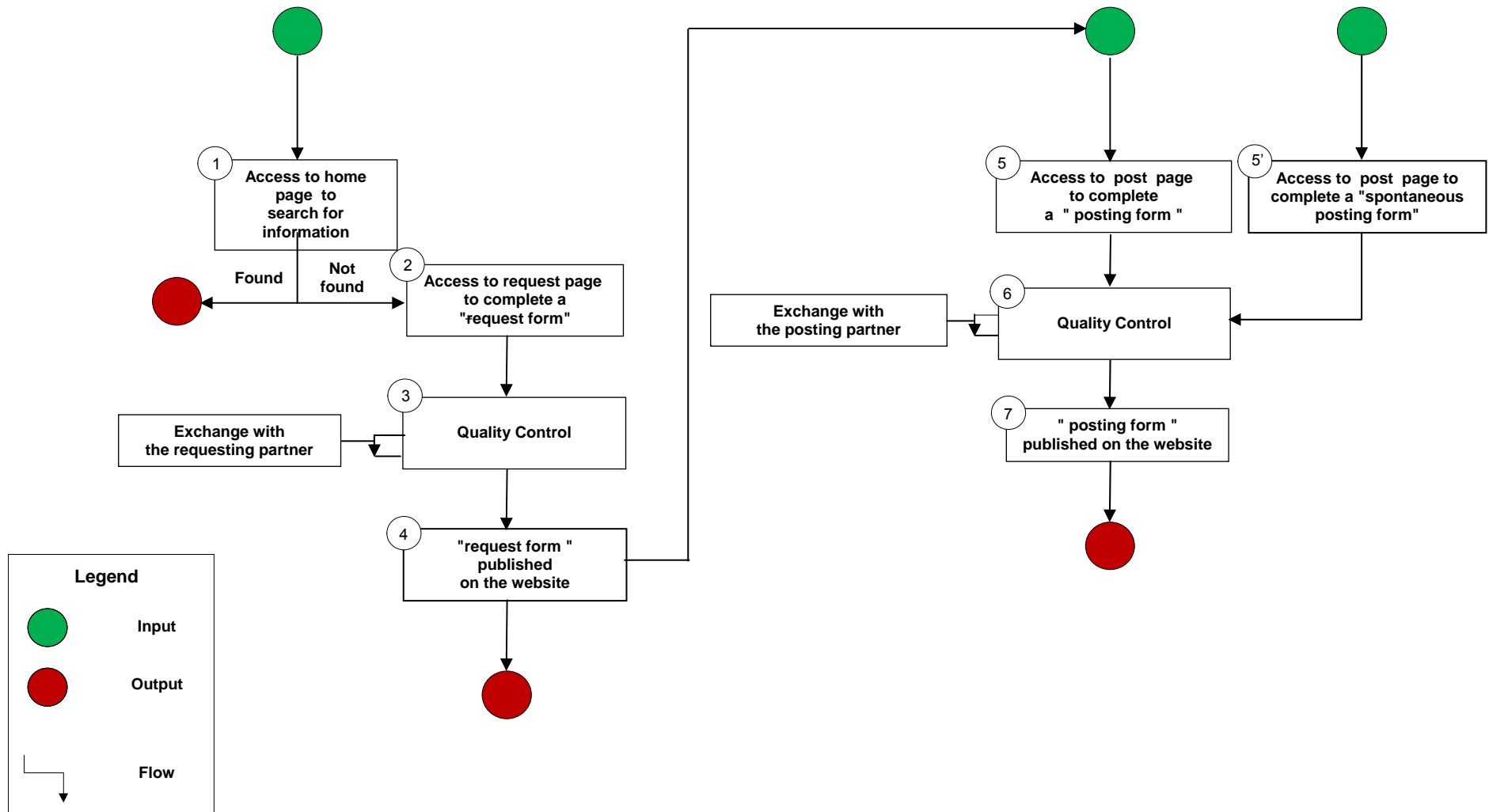


Figure 2. How to use the website

9.4.6 Recommendations

This study has shown how timely access to new promising technologies (marketing approval or coverage) can depend on the generation of additional evidence. Access with evidence generation (AEG) is well known in the context of marketing approval but is a more recent concept in relation to coverage, where it is sometimes known by the Medicare/Medicaid term “coverage with evidence development” (CED) (5,49,51). Few countries have experience of AEG as applied to coverage. The issue is hotly debated within not only WP7A but also the HTAi special interest group on “conditional coverage and evidence development for promising technologies” (70).

WP7A has produced the first overview of national AEG mechanisms associated with coverage decisions. It is based mainly on the grey literature (websites providing information on local laws, regulatory frameworks, and procedures), interviews, and surveys of WP7A partners, as published data, especially for European countries, is scarce. The result may not be totally accurate, complete or objective but it has served its purpose of informing a debate among WP7A partners in order to move toward international collaboration.

Coverage decisions were linked to AEG mechanisms in 10 of the 23 countries studied (Canada (Ontario), Spain, Australia, US, Netherlands, Sweden, Switzerland, England/Wales, France, Germany) (5,49,51). In most of these countries, requests for AEG filled knowledge gaps and enabled decisions to be taken on the appropriate diffusion of several promising technologies after conditional coverage. However, the system does not always work. For instance, no funding could be found for evidence generation on cochlear implants in the US, and the lack of meaningful endpoints meant that American ICD register results for implantable cardioverter defibrillators (ICD) were disappointing and of no use (71).

We used the overview to construct a 5-step model policy framework for AEG mechanisms for implementation and/or adaptation by interested countries. This framework, together with its critical success factors, is in fact an adaptation and generalization of the long-standing regulatory frameworks for medicines and also of newer conditional coverage frameworks. Thus, it is applicable to AEG at the marketing approval stage (where all steps are implemented) and at the coverage decision stage (where all steps are often not implemented). The framework revolved around the collection of relevant data on promising technologies that could effectively support decisions on appropriate diffusion or discontinuation of use. However, the actions needed to generate this data may require changes to currently applicable policy frameworks. Critical success factors are (i) coordination, (ii) methodological guidance, (iii) funding, and (iv) an implemented regulatory framework. Their absence can hamper data collection.

(i) A named body should coordinate all actions. For instance, in Spain and Canada, decision-makers, HTA organisations, healthcare professionals, and researchers cooperate to garner data and implement policy recommendations under the supervision of a coordinating body. In contrast, in the French system of conditional coverage for medical and surgical procedures, coordination between the Ministry of Health, national health insurance, HTA agencies, health professionals and industry has been poor despite each stakeholder's interest, partly because of the lack of a suitable funding mechanism. A scheduled change in the law on innovative technologies will hopefully lead to improvements. In the case of medicines, there is a need for collaboration between the regulatory setting (assessment and marketing decision) and the HTA setting (assessment and coverage decision) in order to avoid duplication of work. (e.g. between national medicine agencies and HTA agencies). Assessment reports from marketing authorization process or post-marketing data may also be useful in an initial HTA.

(ii) There must be a clear scientific guidance to define precisely the most appropriate type of data and study design in order to ensure that evidence will, at the end, be improved. The timeliness and duration of data collection are also important although there is no consensus on duration (5)(71).

(iii) Dedicated financing mechanisms for data collection and analysis are essential, especially before taking a decision on coverage. Funding should be adequate so that data collection does not end prematurely or result in the generation of low-quality data. It may be restricted to data collection in certain centres only. There may be just a single source of funding (generally public) or multiple sources (public, private, or mixed), often each covering a specific cost. For example, the National Heart Lung and Blood Institute (NHLBI) supported the funding and administration of the National Emphysema Treatment Trial (NETT) whereas Centres for Medicare/Medicaid Services (CMS) paid for patient care (72). Opportunity for public-private partnership can also be considered.

(iv) A regulatory framework should clearly state the role and responsibility of each partner and ensure that the AEG results are used during the revised decision process. For instance, in Germany, the results from pilot projects are not systematically taken into account during reassessment because of the lack of a regulatory framework.

Other challenging issues concerning promising health technologies and not listed among the above success factors are (i) collaboration with academic research, (ii) selection and prioritization, (iii) uncertainty thresholds, (iv) timing of evidence requirement request and (v) the relationship between HTA and AEG.

(i) Decisions on conditional access are usually taken independently of decisions on clinical research. We noted that AEG mechanisms were strengthened when HTA agencies, decision-makers and research institutions collaborate (e.g. “Conditionally funded field evaluation”, Ontario).

(ii) The process used to prioritize technologies that might benefit from an AEG mechanism should be transparent, especially as resources are limited (51,71). Prioritisation criteria were given only by the CMS (CED relative guidance) (73) and CMTF (60) in the US and the NICE Citizens’ Councils (50) in England/Wales.

(iii) The criteria for estimating the degree of uncertainty should be explicit (i.e. the criteria for postponing a decision, applying an AEG mechanism, or granting unconditional access).

(iv) When an authority should request evidence generation is a moot point. The trend is towards providing scientific advice in the early stages of the technology’s development, as some medicines agencies already do.

(v) Regarding HTA, the initial assessment should not only assess identified domains (see HTA Core Model) but also clearly quantify uncertainty, identify knowledge gaps and data needs, and indicate avenues for further research with possibly clear guidance on which data should be collected in which type of study to ensure that the evidence generated will match that required.

Some more general issues need broad debate: what is the status of generating new evidence within AEG with regard to the clinical research? Should the technology covered through AEG be considered still in development? What about ethical questions regarding access to technologies for which uncertainties remain?

A growing number of countries are interested in developing AEG policies, in particular for coverage decisions (see HTAi interest subgroup on conditional coverage (70) and WP7A). Methodological expertise needs to be shared, and experiences need to be combined in order to gather a critical mass of data within a reasonable timeframe, especially on technologies that concern few patients and involve long follow-ups. International collaboration would mean that resources could be pooled, duplication avoided, and more technologies assessed. The harmonisation of evidence requirements needs to be looked at (74) but, as a first step, WP7A has developed tools for evidence generation on promising technologies⁸.

An important barrier, at the international level, is the lack of structured collaboration among the HTA agencies involved in AEG mechanisms. Therefore, three structured levels of collaboration on evidence generation relating to promising health technologies were set up: (1) sharing information, (2) coordinated action, (3) joint action.

As information is scarce, not easy to find, and evidence is difficult to generate, pragmatic tools were developed to facilitate the first level of collaboration.

WP7-A has developed standardized forms for requesting and supplying information on promising health technologies which replace informal e-mails. The forms are available on a dedicated website for sharing information on evidence generation among EUnetHTA Members. It is called **Eunethta Interface to Facilitate Furthering of Evidence Level** (<http://eiffel.eunethta.has-sante.fr/>). The transfer of information thus becomes more efficient and the information garnered is more comprehensive. More importantly, the process permits easy storage of information, saves time, and can ultimately avoid duplication of work.

The overview of AEG mechanisms conducted by WP7-A found that the amount of required evidence generated for access to a promising technology differed according to country. Implementation of the AEG mechanism could be full (all the evidence required was generated), partial (only some of the evidence required was generated), or passive (none of the additional evidence required was generated). In practice, few countries obtain all the evidence they need for a sound and robust decision. The website will thus help them attain a critical mass of evidence faster, for a more evidence-based decision.

We identified three potential obstacles to website use: the “Not Invented Here” syndrome, frustration, and habit.

(i) The “Not Invented Here” syndrome: Users may be reluctant to use information that does not come from their own AEG mechanism as they cannot control its quality. A way of overcoming this obstacle is to issue regular reminders to users that they must ensure the accuracy of the information they supply. The supplier is responsible for the quality of the information given. In addition, before making use of the information, the interested party can directly e-mail the supplier to obtain confirmation that the information is indeed accurate.

(ii) Frustration: Clearly, users will be frustrated if the information they need is not in the database, as its content will not immediately reach a critical mass. To speed up supply, EUnetHTA Members will be regularly solicited for information. Users may also be frustrated, even annoyed, if the information is obsolete. Users will thus be regularly also asked to update information.

(iii) Habit: Users may be reluctant to use the website instead of just sending an informal e-mail. A training session on website use will be set up for EUnetHTA Members.

Three limitations of a more general nature were also identified: transferability of the information, lack of transparency, and wording.

⁸ {<http://www.eunethta.net/upload/Work%20Package%207/WP7A%20Deliverable%20December2008.pdf>}

(i) Transferability of information: Can the information really be transferred directly in order to be shared? Differences among countries, such as differences in terminology, technology use, physician training, and population risks, come into play⁹. Users will have to use the domain classification of the HTA Core Model (e.g. description and technical characteristics, current use by WP4)¹⁰, the glossary of HTA terms ((INAHTA¹¹, WP5¹²), and the toolkit for adapting an HTA report to their local context (WP5¹³).

(ii) Lack of transparency: Only WP7 Partners were involved in the project. Moreover, they were involved in the testing of forms for information requests and supply only, with a rather disappointing participation rate. They were not involved in website testing. Transparency will increase as soon as we have developed tests of the website for all EUnetHTA Members. Website access is currently restricted to EUnetHTA Members because some of the data on promising technologies (e.g. clinical data) is confidential and not intended for the general public. However, plans are being made to provide general access to the non-confidential items in the future (e.g. level of diffusion of the health technology in different healthcare systems, status of HTA report).

(iii) Wording: The wording used in the forms needs to be improved further. During the pilot tests, explanations had to be given to each participating WP7 Partner on how to complete the forms. The terms “new” and “promising” also need to be defined according to the level of diffusion of the technology in the healthcare system. For example, some partners considered technologies such as implantable cardiac defibrillators and tympanostomy tubes “promising” whereas they are in routine use in other countries. We plan to develop an online glossary of key terms used in the website to facilitate a common understanding.

In conclusion, for the website to become fully operational, it will be necessary to include the user reminders identified above concerning information supply, quality, and updating, to provide a glossary of key terms, to perform large-scale tests involving all EUnetHTA Members, and to organise training sessions on the final product.

The website will only be worthwhile if all EUnetHTA Members agree to supply relevant, accurate, and updated information, and use it regularly. Committed members will have to oversee the running and continuing development of the website.

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⁹http://www.eunethta.net/upload/EUnetHTA%20Collaboration%20proposal/EUnetHTA%20Collaboration%20Proposal_Final_June2008.pdf

¹⁰ http://www.eunethta.eu/EUnetHTA_Deliverables_project_2006-2008/

¹¹ <http://www.inahta.org/>

¹² <http://www.eunethta.eu/upload/WP5/Glossary%20of%20HTA%20Adaptation%20Terms%20November%202007.pdf>

¹³ http://www.eunethta.eu/upload/WP5/EUnetHTA_HTA_Adaptation_Toolkit_October08.pdf

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9.6 Appendices

9.6.1 Appendix 1

List of WP7 partners

Lead Partner

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- **Centre for Applied Health Services Research and Technology Assessment (CAST), Denmark:** Karla Douw;
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COLLABORATIVE PARTNERS

- **Center for Medical Technology Policy (CMTP), United States:** Sean Tunis;
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- **European Observatory on Health Systems and Policies, Belgium:** Joseph Figueras;
- **EuroScan, the International Information Network on new and emerging health technologies:** Claire Packer, Sue Simpson;
- **Israel Center for Technology Assessment in Health Care (ICTAHC), Israel:** Miriam Ines Siebzeher;
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10 Work Package 8: Systems to support HTA in MS with limited institutionalisation of HTA – Report on results and activities 2006-2008

10.1 Summary

The main objective of Work Package 8 was to support Health Technology Assessment (HTA) capacity building in Member States of the European Union with limited experience or without institutionalized HTA. The main output was a Handbook on Health Technology Assessment Capacity Building. WP 8 was made up of 11 associated partners and 17 collaborating partners. The Catalan Agency for Health Technology Assessment and Research was in charge of the coordination of WP8 and responsible for supervising the implementation of tasks, designing the surveys, data analysis and preparing the final reports. The Work Package partners met three times during the course of the project.

Surveys were done of HTA organisations; information management units and HTA educational programs. The results of the surveys were combined with expert opinion and a literature review in order to produce a Handbook on HTA Capacity Building

The literature review of existing HTA organisations was carried out in 2006 to learn about their characteristics in relation to structure, setting, process and visibility. Once the review was finished, the next step consisted in designing the survey that was sent out by email to a total of 149 potential HTA organisations in November of 2006. The response rate was 35%. Survey results offered relevant information on the profile of an HTA organisation, what barriers they face when they first start, what action scope (regional, local or international) they work in, what kind of institutions they collaborate with and what methods of product distribution they use, among others. The survey on information units of HTA organisations was sent to 137 organisations in January 2007. In this case the response rate was 22.6% and the information gathered was on the main activity of the information unit, the unit's staff's training and years of experience, as well as bibliographic management resources and tools that were frequently used. During 2007, a WP8 workshop was organised in Ljubljana with the participation of WP8 partners and invited HTA experts. Preliminary conclusions revolved around the main priorities of an organisation that takes off in the HTA field, the main barriers they come across and how to overcome them, and finally, deciding on the best product distribution strategies with the objective of achieving better visibility.

The findings from the international survey on HTA organisations (11), the survey on information management units (7), expert and stakeholder opinion as well as the analysis of other relevant literature were the main sources to build up the **Handbook on HTA capacity building**. During 2008 a web based international survey on HTA educational programmes was carried out identifying a total of 5 MSc in HTA, 1 MSc program was international in scope whereas national MSc programs in HTA were provided in Brazil, Canada, Italy and the United Kingdom. Other MSc programmes HTA related areas (HTA; Technology assessment in health care; Health Economic evaluation; systematic review, meta-analysis and Evidence-Based Medicine) were identified in Canada, Israel and Spain.

The **Handbook on HTA capacity building** was the main deliverable of WP8 and was developed by a group of WP8 partners. The handbook consists of nine chapters, each devoted to one specific field. After an introductory chapter, **Chapter 2** introduces concepts on HTA capacity building. **Chapter 3** elaborates on central aspects to be considered prior to the implementation of an HTA project. **Chapter 4** summarizes that collaboration nationally or internationally plays an important role in the process for the institutionalisation of an HTA programme. **Chapter 5** deals with the infrastructures and human resources relevant for an HTA organisation. **Chapter 6** introduces the work process of assessing health technologies. **Chapter 7** focuses on aspects related to the communication and dissemination of HTA products and results. Finally, the chapter on conclusions and recommendations (**Chapter 8**) drawn up on the basis of each chapter presented in the handbook and also a chapter on challenges and new future actions (**Chapter 9**).

Apart from the CAHTA, responsible for the co-ordination of the development, 20 external researchers from 13 different countries contributed to the Handbook. The Handbook underwent an internal peer review process and the document was also put through public consultation in the EUnetHTA website. The final version of the handbook was presented during the Final Conference of the EUnetHTA project in Paris in November 2008.

10.2 Introduction

The beginning of the 21st century has lifted Health Technology Assessment (HTA) from an academic niche to a prominent and visible position. Meanwhile numerous national health ministries, the European Commission (EC) and the World Health Organisation (WHO) have all proposed HTA as an indispensable coping strategy to appropriately confront the influx of new technologies and the rising costs. The experiences and options for

institutionalizing HTA in different countries and health systems were explored and moreover, its further development encouraged during a meeting in 2000 convened by the WHO Regional Office for Europe⁴. The institutionalization of HTA had been defined in that context as “promoting the structures and processes suitable to produce technology assessments that will be powerful in guiding policy and clinical practice towards the best possible health and cost outcomes”. HTA is in the process of becoming established and institutionalized both in individual countries and at the international level⁵. However, the majority (70%) of the total number of countries in the European region, and more than a half of European Union (EU) countries do not have formal HTA yet as it is shown in **Table 1**.

Table 1*. HTA agencies in European Countries (Nov 2008)¹

EU Countries		EU Candidate Countries	Potential EU Candidate Countries	Other European Countries	
<i>With formal HTA</i> (n=13)	<i>Without formal HTA</i> (n=14)	<i>Without formal HTA</i> (n=3)	<i>Without formal HTA</i> (n=4)	<i>With formal HTA</i> (n=2)	<i>Without formal HTA</i> (n=13)
Austria	Bulgaria	Croatia	Albania	Norway	Andorra
Belgium	Cyprus	Macedonia	Bosnia-Herzegovina	Switzerland	Armenia
Denmark	Czech Republic	Turkey	Montenegro		Azerbaijan
Finland	Estonia		Serbia ²		Belarus
France	Greece				Georgia
Germany	Ireland				Iceland
Hungary	Italy ²				Kazakhstan
Latvia	Lithuania				Liechtenstein
Netherlands	Luxembourg				Moldova
Poland	Malta				Monaco
Spain	Portugal				Russia
Sweden	Romania				San Marino
United Kingdom	Slovakia				Ukraine
	Slovenia				

Table 1 lists the countries with and without HTA agencies that are a member of the International Network of Agencies for Health Technology Assessment (INAHTA), which is regarded as an indicator for the institutionalization of the Agency. INAHTA membership implies that the organisation is non-for-profit, relates to a regional or national government and is funded by public sources for at least 50%.

¹ Formal HTA: Countries with HTA agencies that are INAHTA members; ² Considerable activity in HTA but no INAHTA member agency

The number of European countries that do have formal HTA is still limited. Moreover, little is known about the current state of HTA activities, in particular in new European Member States, candidate and potential candidate countries, and other countries in the European region as well as their endeavors towards establishing formal HTA. Knowledge on ongoing activities in the area of HTA as well as the barriers and solutions in both the establishment of the HTA units and in their daily work processes builds the basis for effective measures for its institutionalization. EUnetHTA Work Package 8 (WP8) **on Systems to support HTA in EU Member States with limited institutionalization of HTA** intended to consider such countries that either did not have formal HTA or were in the process of establishing formalized HTA. To accomplish the final aim of the WP8, which will be the supply of a Handbook on HTA capacity building, a literature review was conducted and some meetings with HTA experts and stakeholders were held. Additionally three international surveys were carried out: a survey of HTA organisations, a survey on information management units and a survey on HTA educational programmes.

WP 8 was made up of 11 associated partners and 17 collaborating partners (**Table 2**). CAHTA was in charge of the coordination of WP8 and responsible for supervising the implementation of tasks, designing the surveys, data

analysis and preparing the final reports. The Work Package partners met three times during the course of the project.

Table 2. WP8 Partners

Organisation	Country	Partner (CP/AP) ¹
Centre for Applied Health Services Research and Technology Assessment, University of Southern Denmark - CAST	Denmark	AP
Cochrane Collaboration, International Secretariat		AP
Galician Agency for HTA	Spain	AP
Health economics and Technology Assessment Unit, Department of Public Policy and Management, Corvinus University of Budapest - HunHTA	Hungary	AP
Health Statistics and Medical Technology State Agency - VSMTA	Latvia	AP
Institut za varovanje zdravja Republike Slovenije	Slovenia	AP
Instituto de Salud Carlos III (ISCIII), Agencia de Evaluación de Tecnologías Sanitarias - AETS	Spain	AP
Ministry of Health	Cyprus	AP
Norwegian Health Services Research Centre	Norway	AP
Università Cattolica del Sacro Cuore, Policlinico universitario "A. Gemelli", Health Technology Assessment Unit and Laboratori of Health Economics (Institute of Hygiene)	Italy	AP
University of Tartu, Department of Public Health	Estonia	AP
Agency for Health Technology Assessment in Poland – AHTAPol*	Poland	CP
Agenzia Nazionale per i Servizi Sanitari Regionali, Age.n.a.s. *	Italy	CP
Central and Eastern European Society for Technology Assessment in Health Care - CEESTAHC	Poland	CP
Council of Europe, Directorate General III Social Cohesion		CP
Directorate of Health	Iceland	CP
European Information Network on New and Changing Technologies - EuroScan		CP
European Observatory on Health Systems and Policies		CP
German HTA Association	Germany	CP
Hauptverband der Österreichischen Sozialversicherungsträger	Austria	CP
Health Technology Assessment International - HTAi		CP
Institute for Quality and Efficiency in Health Care - IQWiG	Germany	CP
Institute of Molecular Medicine	Portugal	CP
International Network of Agencies for HTA - INAHTA		CP
Ministry of Health*	Serbia	CP
National School of Public Health and Health Services Management*	Romania	CP
Public Health Genetics European Network – PHGEN at German Centre for Public Health Genetics	Germany	CP
Swiss Network for HTA - SNHTA	Switzerland	CP
WHO European Office, Health Evidence Network - HEN		CP

*From 2007; ¹CP (Collaborating partner); AP (Associated partner)

10.3 Objectives

The aim of WP8 was to support HTA capacity building in countries with limited experiences in HTA or without institutionalized HTA. Three objectives were delineated for Work Package 8:

1. Define the minimum components related to the scope, structure, process and visibility of an HTA organisation.
 - 1.1 To conceptualise the main characteristics of the specific setting (healthcare system, sociocultural context, links with academia and healthcare decision makers, collaborations -past or current- with other countries as well as organisation characteristics) which define different scopes and models of the HTA organisations
 - 1.2 To identify and specify key components when defining the scope of a new agency, unit or program by means of the strategic and business plan, lines of activity, products/services portfolio and target stakeholders.
 - 1.3 To characterize those essential elements defining an HTA organisation in relation to the structure, background human profile (research, technician, assistant, etc. in different areas of expertise), infrastructure resources and funding.
 - 1.4 To define key aspects of organisational visibility related to information and dissemination management strategies of the HTA products and services.
2. Develop tools for education support to institutions or health care systems in the process of evolving to/building an HTA organisation/capacity.
 - 2.1 To audit the information needs and establish an information policy for managing information resources in the HTA field.
 - 2.2 To update the compilation of national and international available programs and educational resources on HTA and related areas, specially focusing on virtual training programs.
3. Produce a handbook on HTA capacity building.

10.4 Methods and Activities

Surveys were done of HTA organisations; information management units and HTA educational programs. The results of the surveys were combined with expert opinion and a literature review in order to produce a Handbook on HTA Capacity Building

a) survey of HTA organisations

Objective. To gather knowledge on the current state of HTA worldwide and its degree of institutionalization as well as insight in characteristics and processes of such organisations.

Design. Cross-sectional study by means of a semi-structured questionnaire sent via email.

Period of the study. January 2007.

Sample. 149 HTA organisations worldwide. The list of HTA organisations included was compiled by merging information from various sources: Directory of EUnetHTA partners; INAHTA members; Websites of existing HTA units and HTA organisations that collaborated in previous projects and surveys.

Analysis. Standard descriptive analyses were conducted to characterize the organisations.

b) survey on Information Management in HTA Organisations

Objective. To describe the current state of development, the processes and resources used in HTA information management and the characteristics of personnel involved in HTA information services worldwide

Design. A cross-sectional survey by means of a semi-structured questionnaire sent via e-mail to information specialists.

Period of the study. January 2007.

Sample. 137 HTA organisations internationally. The survey sample was the same used previously by the other survey of HTA Organisations. However duplicate entries (due to agency name changes, and English versus national language agency names) were removed.
country

c) Survey on HTA educational programs

Objective. To provide an updated overview on most relevant educational programs on HTA and HTA related areas worldwide.

Design. Cross-sectional survey by means of a web-based survey

Period of study. April 2008

Sample. 80 organisations (INAHTA members, some members of the Health Technology Assessment international (HTAi); Cochrane Centres and selected WP8 partners outside the EU)

Analysis. Standard descriptive analyses were conducted and the programs were classified into three categories.

d) Production of the Handbook on HTA Capacity Building

The findings from the international survey on HTA organisations (11), the survey on information management units (7), expert and stakeholder opinion as well as the analysis of other relevant literature were the main sources to build up the **Handbook on HTA capacity building**. Both surveys were conducted internationally since EUnetHTA involved not only EU Member States, but also other health-related organisations worldwide. Thus, although the Handbook was developed within a European context, it can be considered globally relevant and applicable since its recommendations were based on international data. The Handbook was the main deliverable of WP8 and it addressed stakeholders who potentially had an interest in HTA capacity building such as: health care administrators (local, regional, national, international); public and private health care providers; health care industry; health care payers; health care researchers and other stakeholders.

10.5 Results

Experts' opinion on the current state of HTA activities: surveys and workshop results

In order to reach the established objective, different activities have been carried out during the three years of the project, such as an HTA organisation review (2006), a survey on HTA organisations (2007), a survey on the different information units of HTA organisations (2007), a *workshop* in Ljubljana (Slovenia; 2007), a survey on HTA educational programmes (2008) and the development of the **Handbook on HTA Capacity Building**⁶ (2008). The preliminary results have been presented to three international conferences, to the Health Technology Assessment International (HTAi)⁷8'9'10'11'12 to the European Public Health Association Conference (EUPHA)¹³ and to the International Society for Pharmacoeconomics and Outcomes Research (ISPOR)¹⁴.

During 2006, the project's first year, a review of existing HTA organisations¹⁵ was carried out to learn about their characteristics in relation to structure, setting, process and visibility.

Survey of HTA organisations¹⁶

Once the review was finished, the next step consisted in designing the survey that was sent out by email to a total of 149 HTA organisations in November of 2006 to obtain information on the characteristics (setting, functional, organisational, structural, work process and visibility) of those units, agencies or programs of active HTA or HTA being developed and to complete information that had not been detected in the review. Data collection ended in January of 2007. The response rate was 35% and was geographically distributed as follows: Europe (73.1%), North America (19.5%), South America (2.4%) and Oceania (2.4%), representing a total of 27 countries. Survey results offered relevant information on the profile of an HTA organisation, what barriers they face when they first start, what action scope (regional, local or international) they work in, what kind of institutions they collaborate with and what methods of product distribution they use, among others.

Establishment of the organisation

The main initiative in the establishment of the organisation was governmental (61.0%) followed by health researchers (29.3%) and decision-makers (24.4%). Respondents provided data on main barriers in the establishment of the organisation; specifically 58% reported having had barriers (**Table 3**).

Table 3. Barriers in the establishment of the organisation*

Barriers	N	%
Gathering trained staff	14	63.6
Funding	10	45.5
Reaching political interest	8	36.4
Impact on target groups	5	22.7
Agreement with stakeholders	3	13.6
Facilities (building, personal computers)	3	13.6

*Multiple choice question which allows to select more than one correct answer.

Specific background, aims and scope of the organisation

All the organisations were not-for-profit and 42.5% described their profile as Governmental agency and 32.5% as Academia/University. Most of the respondents reported collaboration (either at national or international level). They declared to collaborate at national level with academia/university (97.4%) and with other governmental agencies (94.9%). The majority reported having approved statutes (67.6%) and a strategic plan (82.9). The main lines of activity of the organisations were HTA (80.5%) followed by performing other types of health research (63.4%) and clinical practice guidelines (36.6%). The types of Health Technology (HT) most commonly assessed were pharmaceuticals (77.5%), medical (or surgical) procedures (75.0%) and medical devices (70.0%) (Table 4)

Table 4. Types of HT that the organisation assess*

Most frequent type of HT assessed	N	%
Pharmaceuticals	31	77.5
Medical (or surgical) procedures	30	75.0
Medical devices	28	70.0
Public Health Interventions	14	35.0
Horizon Scanning System / Early warning/ Emerging technologies/	14	35.0
Support System	11	27.5

*Multiple choice question which allows to select more than one correct answer.

Assessment reports (97.6%) and academic and training activities (78.8%) were the two types of products that the organisations most frequently produced. The respondents answered that in most cases producing an HTA report goes together with formulating recommendations (80.5%); the main target group to whom these recommendations are addressed were policy makers (90.9%) and public health care providers (81.9%) (Table 5).

Table 5. Main target people to whom the recommendations are addressed

Main target people to whom the recommendations are addressed	N	%
Policy makers	30	90.9
Public health care providers	27	81.8
Health professionals	24	72.7
Compulsory health care insurance (public)	17	51.5
Health researchers	15	45.5
Patients	12	36.4
Private health care providers	9	27.3
Private medical insurance	4	12.1

Structure of the organisation

The HTA Agencies were organised by having a Director, President or Manager (73.2%) followed by having a scientific or advisory committee (46.3%) Most organisations had administrative staff (94.6%), collaborating researchers (75.0%), and research assistants (55.9). The most important source of funding was the Government (80.5%) followed by the Research funding bodies (46.3%) and private industries (24.4%).

Work process of the organisation

The main responsibility for setting priorities in the organisation was with the Department/Ministry of Health (53.7%) followed by the Director (43.9%) and the Executive Board (29.3%). About 52.3% of the organisations used an explicit process. Respondents reported that the main available mechanisms to set priorities were Policymakers (54.3%) followed by Experts on specific topics (48.6%) (Table 6)

Table 6. Main available mechanisms for the organisation to set priorities

Available priority mechanisms for the organisation to set priorities	N	%
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Policymakers/Government representatives	19	54.3
Experts on specific topics	17	48.6
Health care professionals	15	42.9
Patient representatives	5	14.3
Health care insurance (private or public)	3	8.6
Industries, manufacturers	3	8.6

Visibility of the organisation

Respondents commented that they had a formal procedure to disseminate their products (75%). The most frequently used methods for dissemination included posting reports on the Agency's website (92.3%), participation and organisation of academic, scientific and training activities (84.6%) and by producing electronic and printed versions of reports (79.5%). The main target users of the products were Public health providers (82.5%) followed by Policy makers (77.5%) (**Table 7**).

Table 7. Target users of the products *

Most frequent target user**	N	%
Public health care providers	33	82.5
Policy makers	31	77.5
Health professionals (general practitioners and specialists)	31	77.5
Professional associations	25	62.5
Health related professionals	23	57.5
Health services researchers	21	52.5
Researchers	17	42.5
Compulsory health care insurances (public)	17	42.5
Pharmaceutical/ Devices industry	15	37.5
Patient groups / Carers	15	37,5
Private health care providers	11	27.5
Media	9	22.5
General Public	8	20.0
Private Medical Insurance	5	12.5
Consumer associations	4	10.0

* Multiple choice question which allows to select more than one correct answer.

** The question was measured by a ranking from 1 to 15; The category "Most frequent user" was obtained by grouping the answers from 1 to 5.

Survey on information units of HTA organisations¹⁷

The survey on information units of HTA organisations collected information on the resources, aptitudes, competences of these units with the objective of detecting what information was needed. The survey was sent to 137 organisations in January 2007. In this case the response rate was 22.6% and the information gathered was on the main activity of the information unit, the unit's staff's training and years of experience, as well as bibliographic management resources and tools that were frequently used.

Structure and Organisational Data

Role of the information unit:

The majority of the respondents to the open-question (87%) described the role of the information unit/service or library within the organisation as a supporter of the processes of the development of HTAs by providing and managing information and giving advice in search strategies. Six (26.1%) information specialists reported to be also active in the dissemination of the products partly combined with the maintenance of the organisations' websites. Activity in teaching and educating in their specialties (information retrieval and dissemination) as part of their role were described by two organisations (8.7%).

Main activities:

All respondents described as the principal work area or task of the information unit the performance of bibliographic searches in databases (100%). Further, widespread activities were acquisitions/subscriptions to information resources (82.6%), answering specific information questions (78.3%) and managing archiving (69.6%). On the contrary, webmaster tasks were declared to be carried out by 39.1% of the respondents (**Table 8**).

Table 8. Main work areas or tasks of the information unit/ library*

Work areas of the information unit/library	n (units)	%
Bibliographic searches in databases	23	100
Acquisition or subscription to information resources	19	82.6
Answering specific information questions	18	78.3
Document managing/archiving	16	69.6
Cataloguing/indexing	15	65.2
Webmasters (Internet/extranet)	9	39.1

*Multiple choice question.

Professional and Academic Background of the Staff

Total amount of professionals in the organisation:

Most (56.5%) frequent in the sample are the small organisations (**Table 9**). The amount of professionals working in total in the organisation ranged from 3 to 467 persons though 50% of the organisations employed less than 35 workers (Mean: 94.91; SD139.49).

Table 9. Size of the organisation according headcount¹

Size of the organisation	n (organisations)	%
Micro (< 10 workers)	2	8.7
Small (10- 49 workers)	13	56.5
Medium (50- 249 workers)	5	21.7
Big (> 250 workers)	3	13.0

¹ Categorization according to the definition of small and medium-sized enterprises of the European Commission

Managing Information Resources

Sources of information:

The most used sources of information for assessing health technologies were health bibliographic databases (100%), HTA reports (95.5%), search engines (95.5%) followed by grey literature (91.3%). Monographs or books (59.1%) and clinical administrative databases (21.7%) were less used (**Table 10**).

Table 10. Information sources used for Health Technology Assessment* by information specialists

Information sources	n (units)	%
Health bibliographic databases	23	100
HTA reports	22	95.7
Search engines	22	95.7
Grey literature	21	91.3
Monographs or books	14	60.9
Clinical administrative databases	5	21.7

*Multiple choice question.

Training and Research Activities

Training courses:

The majority of the information specialists (73.9%) offered training courses workshops or taught academic courses, a good number of them due to own initiative (29.4%). The majority of the information specialists (73.9%) declared not having participated itself as a teacher in distance learning courses through Internet.

WP8 Workshop

During 2007, a WP8 workshop was organised in Ljubljana. 8 associated partners, 2 collaborating partners and two invited HTA experts attended the workshop. It was divided in 3 work groups related to the structure, process and visibility of an HTA organisation. Preliminary conclusions revolved around the main priorities of an organisation that takes off in the HTA field, the main barriers they come across and how to overcome them, and finally, deciding on the best product distribution strategies with the objective of achieving better visibility.

Both survey reports and the Handbook on HTA capacity building are available in the EUnetHTA website (www.eunetha.net)

Handbook on HTA capacity building

The WP8's main product is the **Handbook on HTA capacity building**. Its objective is to provide guidance and support in the process of establishing HTA in countries with limited HTA capacity, and also to serve as a practical tool in other countries where HTA is more consolidated. The Handbook which is coordinated by the CAHTA, consists of nine chapters (**See Table 11**) and has been developed by a group of professionals who are members of WP8. The handbook underwent an internal peer review process and the document was also put through public consultation in the EUnetHTA website.

Table 11. Contents of the Handbook on HTA capacity building

Chapter	Contents
Chapter 1. Introduction	Focuses on the general background, objective, development and structure of the handbook
Chapter 2. Building HTA national capacity	Introduces concepts on HTA capacity building.
Chapter 3. Aims and scope	Elaborates on central aspects to be considered prior to the implementation of a HTA project
Chapter 4. Organisational and legal framework	Summarizes that collaboration either at national or international level played an important role in the process for the institutionalization of an HTA agency.
Chapter 5. Structure	Focuses on the infrastructures relevant for an HTA organisation: predominantly, the subject of human resources (including training and recruitment strategies) as well as necessary facilities.
Chapter 6. Work Process	Introduces the work process of assessing health technologies.
Chapter 7. Disseminating HTA products	Approaches on aspects related to the communication and dissemination of HTA products
Chapter 8. Conclusions, recommendations	Concludes some recommendations drawn from each different chapter
Chapter 9. Challenges and future new actions	Focuses on challenges and new future actions.

The first version was handed in December of 2007 to the project's Coordinating Centre and to the European Commission, and the final version was presented during the final conference of the EUnetHTA project in Paris on the 20th of November 2008 (**See Figure 1**).

Figure 1. Handbook on HTA capacity building



Chapter contents

Chapter 1 deals with the general background, objective, development and structure of the handbook. **Chapter 2** introduces concepts on HTA capacity building. Prior to institutionalising HTA there is a need for a solid commitment from politicians and key decision makers in the health system. Further, an appropriate organisational structure and an efficient institutional setup for HTA work needs to be identified (HTA agency or network model with a coordination mechanism, etc.). Sufficient investment funds should be estimated for establishing and sustaining HTA programmes. The success depends also on the quality and relevance of the HTA reports, an efficient information dissemination system and the willingness of the policy level to integrate HTA into the decision making. Finally, the national HTA concept should include an international network strategy (See Table 12).

Table 12. Main final remarks of Chapter 2 on Building of national HTA capacity

Establishing an effective HTA programme that guides key policy decisions for a national health care system is a challenging task. The basis for this task is a solid commitment from politicians and key decision-makers in the health system to integrate HTA findings and recommendations into key decision-making on the policy level. Further, an appropriate organisational structure and an efficient institutional set-up for HTA work need to be identified. This does not necessarily signify the establishment of a dedicated HTA Agency. There are good examples of network models with a co-ordination mechanism (e.g. 'HTA office') which could be appropriate for many countries. Ultimate success also depends on the quality and relevance of the HTA reports, an efficient information dissemination system and the willingness of the policy level to integrate HTA into decision-making. Sufficient investment funds should be made available to train professionals in HTA work. Funding for the recurrent operational costs of the established HTA structure should be identified and secured on a long term basis. HTA work is no longer done in national isolation. The national HTA concept should include an international network strategy right from the beginning.

Chapter 3 elaborates on central aspects to be considered prior to the implementation of an HTA project. All HTA organisations have the same aim but their scope depends on their resources, their liaisons and requirements. These organisations can work at local-regional, national or international level (See Table 13).

Table 13. Main final remarks of Chapter 3 on Aims and scope of an HTA organisation

Newly established HTA organisations in countries without any institutionalised HTA will have to develop gradually, starting from activities that do not require a large amount of resources. The acknowledgement of the quality of the results produced by this work, together with other related factors, may lead to increased funding and other resources, enabling the organisation to expand its activities. Its development must run alongside health policies and those, in most countries, are emphasising measurement, accountability, value for money and evidence-based policies and practices.

Networking, at regional, national and international level, can be very helpful for newly established HTA organisations with limited resources by avoiding repetition of HT assessments made previously by other HTA organisations. The form or type of the final products of newly established HTA organisations will be influenced by the local culture as well as by factors that determine the type of HTA questions (e.g. existence or otherwise of academic activity, existence or otherwise of research or not, level of healthcare etc.).

Chapter 4 summarizes the argument that collaboration either at national or international level plays an important role in the process for the institutionalisation of an HTA programme which is in fact a synthesis of a top-down and bottom up action and relies in the end on strong networking activities. Collaboration at national level is based on all types of institutions (Academia, Government, professional associations, hospitals, industry and patient associations) whereas internationally collaboration is largely with Academia and Governmental bodies (See **Table 14**).

Table 14. Main final remarks of Chapter 4 on Organisational and Legal Framework of an HTA organisation

The process of institutionalising a national HTA programme is a synthesis of top-down and a bottom-up action and relies on strong networking activities. It should always imply the involvement of all relevant stakeholders, together with action on decision-makers at the central level since they can set off the regulatory framework for the institutionalisation of HTA and provide the financial resources for funding the future agency. A bottom-up process can be activated by creating a positive interest among context's various actors and involving expertise at meso and micro level. Those activities are based on building a network which includes producers, health professionals, clinicians, decision-makers, patients' associations etc. A first purpose is communicating HTA benefits for individuals and the whole population. A second aim is to improve understanding of the importance of HTA as a means to rationalise the provision of healthcare at any level. Moreover, two-way communication is needed that helps to elicit stakeholders' points of view and perspectives on HTA and to embed them, as far as possible, in the final organisational profile given to the future HTA agency.

The action should also include international collaboration, which plays an important role. Newly established HTA organisations or those in the process of becoming an HTA agency should co-operate at national level by establishing a central body with a legal mandate for co-ordination and priority-setting, decentralising HTA research itself as well as funding, creating a platform for information exchange on HTA, ensuring multidisciplinary of HTA, and establishing some kind of formal links with health policy. The international collaboration should include participation in joint projects, cross-national issues should be given high priority and an exchange of information, and project reports and other HTA background material should be improved

Chapter 5 deals with the infrastructures relevant for an HTA organisation. In particular the human resources constitute a central element within the HTA organisation. Gathering the staff capable of working in this area is one of the most important difficulties that emerging and established HTA organisations are facing, whereas problems with facilities are playing a minor role. The teams in HTA organisations comprise various disciplines. Diverse models of contracting human resources that are needed are pointed out in the view of training and recruitment strategies (See **Table 15**).

Table 15. Main final remarks of Chapter 5 on the structure of an HTA organisation

The needs of different organisations are different depending on a large number of variables originating from the financial, legal and cultural backgrounds in which they operate.

We therefore provide very general recommendations:

- It can be recommended to employ core permanent staff and additionally engage external collaborators and advisors, which should also increase the multidisciplinary of the teams. For the development of internal and external staff, co-operation at national level as well as the integration in international networks of collaborating HTA organisations is suggested.
- Facilities appeared to be of less importance for the survey participants. It must be mentioned here that the result might be influenced by memory bias. However, it must be guaranteed that the HTA organisation has

sufficient access to the necessary databases.

- Vital elements of an HTA organisation or programme are:
 - Flexibility to collaborate and network with other HTA Agencies.

Chapter 6 introduces the work process of assessing health technologies. There are three steps in the work process of the HTA organisation: identification of the technologies to be assessed, priority setting, and assessment of health technologies. Furthermore, the work process gives suggestions on the formulation of recommendations, the process and product quality assurance and components of an assessment. It also offers links to work much more in-depth in each of these processes (**See Table 16**).

Table 16. Main final remarks of Chapter 6 on the work process of an HTA organisation

There is a considerable amount of information and expertise available to assist new Agencies in establishing work processes.

There are many possibilities for organising appropriate working processes, so the information in this chapter can be regarded as enlightening without being prescriptive.

HTA processes are complex and dynamic, a key for success of HTA staff is to be flexible with a commitment to lifelong learning.

Chapter 7 gives an approach on aspects related to the communication and dissemination of HTA products and results. Visibility and dissemination, as active ways of communicating and transferring the HTA results and recommendations to intended audiences, are key steps to improving the prestige and credibility of HTA organisations and their activities (**See Table 17**).

Table 17. Main final remarks of Chapter 7 on Disseminating HTA products

Dissemination activities are very important for obtaining adequate visibility of the HTA organisation and its products.

The dissemination process should be planned as carefully as possible, and consideration of it should start at the beginning of the development of public HTA reports, and not at the end of the report.

There is no “magic bullet” for disseminating HTA results. Different actions and strategies should be considered and carried out as an integrated plan.

Identifying HTA target audiences is also a key process in dissemination activities, especially when selecting key relevant stakeholders or opinion leaders.

Formal and complex dissemination strategies need extra resources (staff, budget)

Learning from experienced HTA organisations can be an efficient strategy to implement, increase and improve dissemination methods and activities.

Do not neglect the capacity of information technologies to communicate, especially the new ones that are under the concept of Web 2.0 or Social Web such as blogs, RSS and wikis among others that may be relevant to making communication more dynamic and raising interest in the HTA results.

Chapter 8 on Conclusions and recommendations drawn up on the basis of each chapter (**See Figures 2,3 and 4**).

Figure 2. What are the main aspects to be considered in the implementation of an HTA programme?
Before establishing an HTA programme different aspects should be considered:

1-. **Preparing the ground** with advisory work, discussion among relevant stakeholders and estimation of sufficient funds

2-. **Identifying suitable professionals and HTA** training opportunities

3-. **Integrating various professional disciplines, not only** professionals from medical disciplines but also public health specialists, psychologists, biomedical engineers and economists should form part of the core HTA staff team.

4-. **Analysing the current scene relevant to HTA**, such as institutions, regulations, financing system, publications, other HTA agencies, etc.

5-. **Networking and communication** for identifying national and international partners and collaborators

Figure 3. What should be taken into account when the new HTA organisation has been established?

The needs of different organisations regarding structure are different depending on a large number of variables, ranging from the financial and legal and cultural background at which they operate. Once the new agency has been established, different aspects **should be** taken into account:

1-. **Be sensible to their specific setting needs** (stakeholders, decision makers, patients associations, healthcare institutions and health insurance providers)

2-. **Establish liaisons** with, at least, other national organisations, with academic and health care institutions and with patients' groups and associations in order to obtain necessary inputs about HTA work, scientific information and socio-economics factors

3-. **Be benefited from the 'core' information** provided by the European HTA network about the effectiveness of technologies and shared among member states and also to benefit from the emerging HTA network

4-. **Look out for high quality products** in order to establish them as scientific evidence referents in their context

5-. **Ensure financial sources** for funding the future HTA agency. An HTA organisation requires moreover, sufficient resources that allow analysis of the impact of HTA on clinical practice and policy decisions, as well as resources that facilitate the maintenance of external relations and communication

6-. **Active action on decision makers** and involvement of all relevant stakeholders

7. **Have multidisciplinary teams**, that will ensure a continuous professional development which is necessary for the evolution of the HTA organisation. A core permanent staff, completed by additionally engaged external collaborators and advisors, can serve the multidisciplinary and increase the capability of the organisation to serve the various subjects that has to be explored

8-. **Co-operate at national level** by means of establishing a central body with some key functions such as: legal mandate for co-ordination, priority-setting, decentralizations of HTA research, funding, creation of a platform for information exchange on HTA, ensuring of multidisciplinary of HTA and establishment of formal health policy links

9-. **Look for international collaboration:** International collaboration should include participation in joint projects and an exchange of information, such as project reports on other HTA background material

10-. **Achieve legal support.** The achievement of legal support is top-down and bottom action that relies on strong networking activities

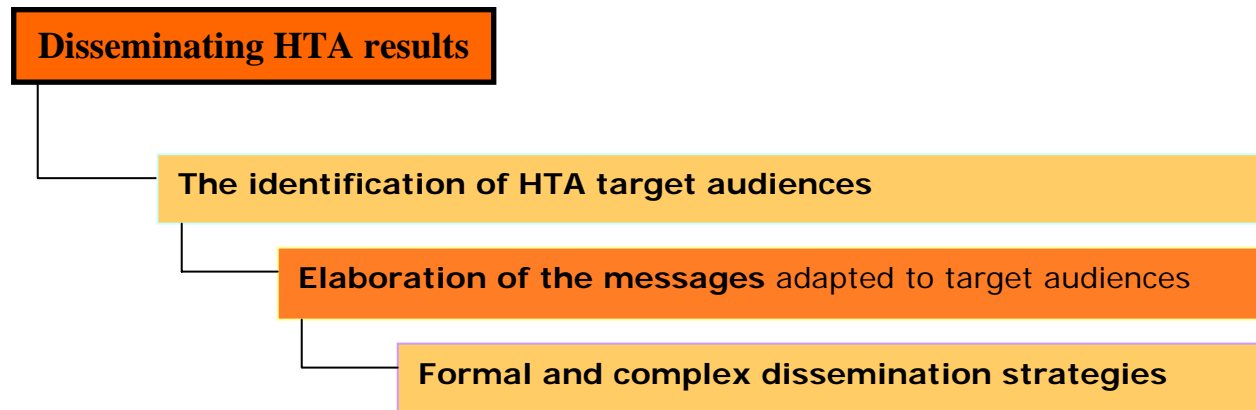
Finally, there is a chapter on conclusions and recommendations that has been drawn up on the basis of each chapter presented in the handbook and also a chapter on challenges and new future actions (See Table 10).

Figure 4. Why is the dissemination so important?

Dissemination and communication activities are very important for adequate visibility of the HTA organisation and its products in national health care systems.

There are no "magic bullets" for dissemination HTA results. Different actions and strategies should be considered and carried out as an integrated plan (**Figure 4**).

Figure 4. Strategies for disseminating HTA products



Current status of HTA programmes and courses

During 2008 an overview of the HTA existing courses and programs, especially at a European level was developed. The objective was to gather information on the HTA courses and programs that were currently being carried out. The information was extracted from the results obtained in the survey that was sent to several institutions that were asked about those HTA courses that they considered as most relevant at a local and international level. An exhaustive review on the characteristics of these courses was also carried out to learn about the current educational offer (**See Appendix 1**).

Tasks/Activities performed in 2008

The WP8 activities and tasks which have been done in 2008 are the following ones:

Handbook on HTA capacity building⁶ (WP8 Official Deliverable). The preliminary version was submitted to the EUnetHTA Coordinating Centre and to the European Commission in December 2007. The final version was submitted in October 2008 to the Coordinating Centre (DACEHTA).

Survey on HTA educational programmes. The last WP8 milestone was a survey on HTA educational programmes. The survey was sent in April and a current compilation of international MSc in HTA was published (**See Appendix 1**).

Wp8 Meeting in Santiago de Compostela (October 2008). A total of 10 WP8 partners attended the meeting. The agenda focused on final WP8 products and future wp8 collaboration. Additionally there were two presentations from experiences and new projects from two WP8 partners (**See Appendix 2**)

Other activities and meetings:

- HTAi in Montreal. A total of 5 presentations from WP8 work were presented during the last HTAi Conference in Montreal^{5,6,7,8,9}
- Final EUnetHTA Conference in Paris (November 2008). A poster from WP8 showing the work done during the three years of the project was presented during the EUnetHTA conference in Paris (**See Appendix 3**).
- Preparation of the WP8 Final Technical Report

10.6 Recommendations

Currently there is a high level of collaboration in the field of HTA among both EU countries and non-EU countries. However, one should take into account that often only a small proportion of an HTA agency's activities are embedded in international projects. Thus, this collaboration should be promoted and supported by the EU, since it can lead to among others, reduction of repetition, and therefore a more efficient use of resources, and assurance of timeliness of HTA reports.

The European Commission should support measures and systems under the framework programmes in order to help agencies to join together and build HTA capacity at European level, especially in Eastern Europe where most countries have not yet introduced formal HTA.

10.7 Appendices

10.7.1 Appendix 1. Main educational programmes on Health Technology Assessment and HTA related areas worldwide



Work Package 8 – System to support HTA

EUnetHTA – European network for Health Technology Assessment

SURVEY ON HTA EDUCATIONAL PROGRAMMES (2008)

Justification: the Catalan Agency for health Technology Assessment and Research (CAHTA) has carried out a web based survey on HTA education programs and related areas in the period April 2008 – May 2008. The study was conducted as part of the work package 8 of the project EUnetHTA (European Network for Health Technology Assessment), which was commissioned by the European Union.

Objective: to provide an updated overview on most relevant educational programs on health technology assessment (HTA) and HTA related areas worldwide.

Methodology: A cross-sectional survey web-based survey among Cochrane centres and HTA agencies worldwide; additionally, a follow-up search of the educational programs in the program's websites was carried out.

MSc in HTA

Country	MSc	Offering Institution
Brazil	Health Technology Management	• UNIFESP/Cochrane Centre (Sao Paulo)
Canada	Health Technology Assessment	• University of Alberta
Canada, Italy, Spain.	International Master in Health Technology Assessment and Management (Ulysses Program)	• University of Toronto • University of Montreal • Università Cattolica del Sacro Cuore. Lazio Regione. Public Health Institute • University of Barcelona
Italy	Health Technology Assessment ¹	• Università Cattolica del Sacro Cuore
UK	Evidence Based Healthcare and Health Technology Assessment	• Birmingham University

MSc HTA related

Country	Courses	MSc	Offering Institution
Canada	1. Health Technology Assessment*; 2. Health Economic Evaluation*	MSc in Epidemiology	• University of Ottawa
Israel	1. Health Technology Assessment*; 2. Technology Assessment in Health Care* 3. Economic Evaluation of Health Technologies*; 4. Medical Technology Assessment*	MSc in Management of Health Services	• Leon Recanati Faculty of Management, Tel-Aviv University
Spain	1. Systematic review and Meta-analysis*	MSc in Health Research ¹	• Autonomous University of Barcelona. Virtual Campus
Spain	1. Health Economics*	MSc in Public Health	• Pompeu Fabra University
Spain	1. Systematic Review; 2. Meta-analysis; 3. Evidence Based Medicine	MSc in Evidence Based Medicine	• Spanish Cochrane Centre

*Courses as part of the MSc; ¹Distance learning course.



The EUnetHTA project is supported by a grant from the European Commission

Postgraduate HTA related courses

Country	Courses	Postgraduate course	Offering institution
Argentina	Systematic review* Evidence Based Medicine* Health Economic evaluation* Health Technology Assessment and Health Economics Evaluation*	Clinical Effectiveness ¹	Institute for Clinical Effectiveness and Health Policy (IECS)
Australia	Health Economics* Epidemiology* Health Technology Assessment*	Public Health	University of Adelaide
Canada	Health Economics*	Health Research Methodologies Program	McMaster University
Romania	Health Technology Assessment- an introduction* Evidence Based Practice*	Postgraduate course on Health Care Management for Medical Doctors	National School of Public Health and Health Services Management
UK	Health Economics: Concepts and Analysis*	Health Economics for Health Care Professionals	University of York

*Courses as part of the Postgraduate course; ¹Distance learning course.

Other HTA related courses

Country	Courses	Offering institution
Australia	Comprehensive Systematic Review training program	Joanna Briggs Institute
Austria	HTA course	Danube University of Krems ²
Austria	HTA and Clinical Epidemiology	Private University Medical Informatics and Technology ²
Austria	Public Health Programme with HTA and health economics	Institute of Social Medicine at Medical University of Graz ²
Belgium	Systematic reviews and metaanalysis	CEBAM
China	1. Systematic review and Meta-analysis; 2. Evidence Based Medicine; 3. Introduction to HTA; 4. Health Economics on HTA	Chinese Cochrane Centre
Denmark	1. Systematic reviews; 2. Evidence Based Medicine	Danish Cochrane Centre
Greece	Health Economics	University of Macedonia
Greece	Economic and Financial Management of Health Care Services	Hellenic Open University
Hungary	1. Health Economics; 2. Health Technology Assessment and Pharmacoeconomics	Corvinus University of Budapest
Iceland	Introduction to clinical guidelines and HTA	Department of Medicine. University of Iceland
Poland	1. Cascade trainings in Evidence Based Medicine; 2. Pharmacoeconomics with elements of Evidence Based Medicine.	Agency for Health Technology Assessment in Health Care ²
Spain	Health Technology Assessment	Agencia Lain Entralgo ²
Poland	Evidence Based Medicine	CEESTAHC
Spain	1. Evaluation of Health Services; 2. Information skills in medicine	CAHTA and Open University of Catalonia ²
Spain	Ethical and legal aspects in Health Technology Assessment	Fundación Organización Médica Colegial ²
Spain	Health economic modeling of Technologies and Health programmes	Oblikue and Medtronic company ²
Spain	Research methods in Health Technology Assessment	Agencia Lain Entralgo ²
Switzerland	Public Health Policy and Management	Swiss School of Public Health
Thailand	1. Introduction to Evidence Based Medicine; 2. Completing a Cochrane review	Khon Kaen University
UK	Introduction to statistics for Clinical Trials	Cochrane Centre York
UK	Systematic reviews in health care	University of Bristol
UK	Advanced modelling methods for health economic evaluation	Public Health and Health Policy section. University of Glasgow
UK	Introduction to systematic reviews	Centre for Reviews and Dissemination. University of York
US	Understanding Evidence-based Healthcare: A Foundation for Action	United States Cochrane Centre

²Language courses are given in the official languages.

10.7.2 Appendix 2. WP8 meeting summary

WP8 FACE-TO-FACE MEETING
October 2, 2008
Santiago de Compostela

1. List of participants

Name	Organisation	Country
Alessandra Lo Scalzo	AGE.NA.S	Italy
Ewa Kiersztyn	AHTAPol	Poland
Gottfried Endel	Hauptverband der Österreichischen Sozialversicherungsträger	Wien
Hindrik Vondeling	Centre for Applied Health Services Research and Technology Assessment (CAST)	Denmark
Mar Polo	Agencia de Evaluación de Tecnologías Sanitarias, Instituto de Salud Carlos III.	Spain
María Sobrido	Galician Agency for Health Technology Assessment (AVALIA)	Spain
Montse Moharra	Agency for Quality, Research and Assessment in Health, AQuRA health	Spain
Stelios Christofides	Ministry of Health	Cyprus
Teresa Cerdá	Galician Agency for Health Technology Assessment (AVALIA)	Spain
Toni Parada	Agency for Quality, Research and Assessment in Health, AQuRA health	Spain
Ivan Kalman	Internova	Germany

2. Agenda

THURSDAY, OCTOBER 2
16:00-16:15: Welcome speech
Teresa Cerdá
Director
Avaliat

16:15-16:30

WP8 final products

Montse Moharra

WP8 Coordinator

16:30-18:00:

Handbook presentation (chapters 3, 4, 5, 6 & 7)

FRIDAY, OCTOBER 3

9:30-10:15:

Evaluation of the bibliographic impact of HTA reports and scientific papers published by HTA organisations. Bibliometric analysis. Toni Parada (CAHTA)

10:15-11:00:

HTA in Poland, evolution of the AHTAPol and its role in polish health care system. Ewa Kiersztyn. (AHTAPol).

11:00-11:30: coffee break

11:30-13:00: EUnetHTA and WP8 future collaboration (2009)

13:00-14:00: lunch

14:00-15:30: Final remarks and Conclusions

3. Meeting Summary

3.1 Welcome Speech

Teresa Cerdá, AVALIA's Director welcomes and made a short speech based on the main aim, objectives and activities of AVALIA.

3.1. WP8 Final products

During the three years of project, different products have been developed; among them five main products can be distinguished

1. Review on HTA organisations
2. Survey on HTA organisations
3. Survey on information management units
4. Handbook on HTA capacity building
5. HTA curricula compilation

3.2. Handbook presentation (chapters 3, 4, 5, 6 & 7)

During the internal meeting in Santiago de Compostela, one author of each chapter presented the main contents of the chapter.

Chapter 3. Aims and scope. Presenter: Stelios Christofides

Chapter 4. Organisational and Legal framework. Presenter: Alessandra Lo Scalzo

Chapter 5. Structure. Presenter: Stelios Christofides

Chapter 6. Work Process. Presenter: Hindrik Vondeling

Chapter 7. Disseminating HTA products. Presenter: Antoni Parada

Some issues came up on the contents of the handbook. Firstly, some people commented that the handbook did not take into consideration the existence of different health care systems in different countries. Secondly, the issue about impact assessment was not included in any chapter. It was agreed that maybe next year would be possible to update and produce a second edition on the handbook, depending always on the EUnetHTA future collaboration.

3.3 Evaluation of the bibliographic impact of HTA reports and scientific papers published by HTA organisations. Bibliometric analysis. Toni Parada (CAHTA)

Toni Parada from CAHTA presented the project about the evaluation of the bibliographic impact of HTA reports. The main aim of this project is to know the bibliographic impact of the products, reports and scientific papers of Spanish HTA agencies and to identify also the strength and weakness of these products in the HTA product distribution.

In order to carry out this work, a cross sectional internet based survey among Spanish health care practitioners, researchers and managers and policy makers to know the state of the art of the knowledge and visibility of HTA Spanish units and their products.

3.4 HTA in Poland, evolution of the AHTAPol and its role in polish health care system. Ewa Kiersztyn. (AHTAPol)

Ewa Kiersztyn from AHTAPol presented the slides about the Polish Health Care system, the AHTAPol organisational structure and the tasks and activities that have been developed in the new Polish Agency.

3.5 EUnetHTA and WP8 future collaboration (2009)

3.6.1 Recommendations for future work of EUnetHTA; Results of the “Serbia Health Project”

Dragana Atanasijevic (from the Ministry of Serbia, current WP8 collaborating partner) could not attend the meeting but sent the slides on the recommendations for future work of EUnetHTA based on the results of “Serbia Health Project” and its subcomponent “Health Technology Assessment”. The model depends on needs and capacities of a particular country. In this case, the model was done and developed taking into account the local Serbian conditions

3.6.2. Function: Facilitating the establishment and continuous development of HTA institutions.

1. Producing an electronic format from the Handbook on HTA capacity building. The Handbook on HTA capacity building could be also made available as an electronic source (with active links to websites, documents, and practical info of the experience of countries). This would be mainly produced during Phase 1 (2009-2010).

2. Preparing the generic structure of the Curriculum content:

2.1. Updating the compilation of national and international available programs and educational resources on HTA and related areas, specially focusing on virtual training programs (this task would be based on WP8 milestone: HTA curricula). This would be mainly produced during Phase 1 (2009-2010).

2.2. Developing an electronic tool. The HTA curricula directory would need a process of keeping all the information updated, this means including new programs, resources periodically. Thus, the idea of this future activity is to produce an electronic tool with a full list of all the available programs on HTA. This would be mainly produced during Phase 1 (2009-2010).

2.3. Preparing a directory of HTA units and HTA experts To know and compare other emerging HTA units from other European settings that have not been contacted (This list should compile these units which are not present in any other directory (i.e. INAHTA website). and also to prepare a directory of HTA experts. This would be mainly produced during Phase 1 (2009-2010).

3.6 Final remarks and Conclusions

Concerning the new future function on **facilitating the establishment and continuous development of HTA institutions**, some issues were discusses and agreed:

It was agreed that it would be worth producing a second edition of the handbook on HTA capacity building, trying to make it relevant to the health care system, to describe much more better which skills do we need for HTA staff and also being sensitive that the profile staff varies a lot depending on the countries, for instance in Western Europe informatics at the beginning were very much involved in the HTA processes.

It was also agreed that the HTA database experts should be developed using the EUnetTHA platform, for instance creating a template that people could just fill in.

10.7.3 Appendix 3. WP8 Poster presented during the final EUnetHTA Conference (November 2008)



Work Package 8 – System to support HTA

WP8 PARTNERS

Lead Partner: CAHTA
WP8 Project Manager: Montse Moharra
CAHTA's working group: M. Espallargues,
 N. Kubisch, M.O. Estrada, A. Parada,
 M. Cortés, JMV Pons

11 Associated Partners

AETS Spain; CAST Denmark; Cochrane Collaboration United Kingdom; Galician Agency for HTA Spain; HunHTA Hungary; Institute of Public Health of the Republic of Slovenia Slovenia; Ministry of Health of Cyprus Cyprus; NORK Norway; Universta Católica del Sacro Cuera, HTA Unit Italy; University of Tartu, Department of Public Health Estonia; VSMHTA Latvia

17 Collaborative Partners

AHTAPol, Agency for HTA Poland; CEESDA, NC Poland; Council of Europe, Directorate General III Social Cohesion France; European Observatory on Health Systems and Policies Belgium; EuroScan United Kingdom; German HTA Association Germany; Hauptverband der Österreichischen Sozialversicherungsträger Austria; HDJ Canada; INAHTA Sweden; Institute of Molecular Medicine Portugal; IOWIG Germany; Public Health Genetics European Network (PHGEN) Germany; SNHTA Switzerland; WHO Health Evidence Network (HEN) Denmark; University of Iceland Iceland; AIE.NAS Italy; Ministry of Health of Serbia, Serbia.

OBJECTIVES

Overall Objective
 Work Package 8 is linked to the EUnetHTA objective:
 "Work Package 8 will support HTA capacity building in countries with limited experiences in HTA or without institutionalised HTA."

Objective 1

Define the minimum components related to the scope, structure, process and visibility of an HTA organisation

Objective 2

Audit the information needs and establish an information policy for managing information resources in the HTA field.

PRODUCTS

SURVEY ON HTA ORGANISATIONS

- International email survey sent out to 149 potential HTA organizations (November 2006) to obtain information on the characteristics of those units, agencies or programs of active HTA or HTA being developed.
- Response rate was 35% and geographically distributed as follows: Europe (73.1%), North America (19.5%), South America (2.4%) and Oceania (2.4%), representing a total of 27 countries.
- Survey results offered relevant information on the profile of an HTA organization, barriers they face, action scope (regional, local or international) they work in, institutions they collaborate with and methods of product distribution, among others.

SURVEY ON INFORMATION MANAGEMENT UNITS

- Survey on information management units of HTA organizations sent to 137 potential HTA organizations (January 2007) to collect information on the resources, aptitudes, competences of these units
- Response rate was 23%. Most organisations (78.1%) employed professionals educated in information science and also personnel with a background in health sciences (34.8%).
- The information gathered was on the main activity of the information unit, the unit's staff's training and years of experience, bibliographic management resources and tools that were frequently used.

WP8 WORKSHOP

- A WP8 workshop was organized in Ljubljana (March 2007); 8 associated members, 2 collaborating members and two invited HTA experts attended the workshop.
- Preliminary conclusions revolved around the main priorities of an organization that takes off in the HTA field, the main barriers they come across and how to overcome them, and finally, deciding on the best product distribution strategies with the objective of achieving better visibility.

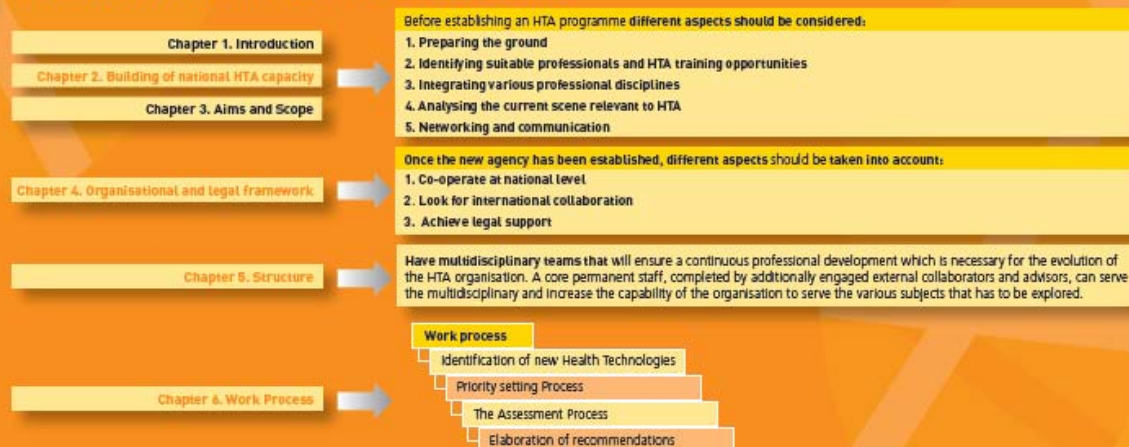


SURVEY ON HTA EDUCATIONAL PROGRAMMES

- To provide an updated overview on most relevant educational programs on health technology assessment (HTA) and HTA related areas worldwide.
- Cross-sectional survey web-based survey among Cochrane centres and HTA agencies worldwide.

The WP8's main product is the *Handbook on HTA capacity building*. Its objective is to provide guidance and support in the process of establishing HTA in countries with limited HTA capacity, and also to serve as a practical tool in other countries where HTA is more consolidated. The Handbook, which is coordinated by CAHTA, consists of nine chapters. The handbook will be available at www.eunethta.

HANDBOOK ON HTA CAPACITY BUILDING



10.7.4 Appendix 4. Manpower for the execution of activities in WP8

Partner	Institution	Contact persons	Questionnaire on Systems to support arrival	Participating in the e-meeting 20th December 2006	Attended the WP8 workshop in Ljubljana (March 2007)	Attended the WP8 face-to-face meeting in Barcelona (June 2007)	Collaborate in producing or reviewing the WP8 handbook on HTA capacity building	Collaborator as author in the handbook	Attending the meeting in Santiago de Compostela (October 2008)
Lead Partner	CAHTA; Catalan Agency for Health Technology Assessment and Research, Spain	Mònica Cortés*		X			X	X	
		Mireia Espallargues*		X			X	X	
		MD Estrada*		X	X	X	X	X	
		Nadine Kubesch*		X	X	X	X	X	
		Montse Moharra*		X	X	X	X	X	X
		Toni Parada*	X	X	X	X	X	X	X
AP	Unit of Health Economics and HTA- Corvinus University of Budapest, Hungary	Laszlo Gulácsi Valentin Brodsky	X		X	X	X	X	
AP	VSMTA Health Statistics Latvia	Igors Trofimovs			X	X	X		
AP	AETS; Agencia de Evaluación de Tecnologías Sanitarias Madrid, Spain	Antonio Sarriá Mar Polo de Santos	X			X	X		X
AP	Avalia-t, Galician HTA agency Santiago de Compostela, Spain	Teresa Cerdá Maria Sobrido	X	X	X	X	X		X X
AP	Univ. Cattolica HTA Unit Roma, Italy	Marco Marchetti Matteo Rugeri	X		X				
AP	Cochrane Collaboration Oxford, UK	Xavier Bonfill	X						
AP	NOKC, Norwegian Knowledge Centre For Health Services	Lise Lund Haheim Atle Fretheim	X	X	X		X		
AP	Institute of Public Health, Ljubljana, Slovenia	Eva Turk	X	X	X	X	X	X	
AP	CAST (Centre for Applied Health Services)	Hindrik Vondeling	X	X	X	X	X	X	X
AP	Ministry of Health Cyprus	Stelios Cristofides	X		X	X	X	X	X
AP	University of Tartu (Department of Public Health)	Kersti Meiesaar	X			X	X	X	

Partner	Institution	Contact persons	Questionnaire on Systems to support arrival	E-Meeting Sept 26	Attended the WP8 workshop in Ljubljana (March 2007)	Attended the WP8 face-to-face meeting in Barcelona (June 2007)	Collaborate in producing or reviewing the WP8 handbook on HTA capacity building	Collaborator as author in the handbook	Attending the meeting in Santiago de Compostela (October 2008)
CP	AHTAPol The Agency for Health Technology	Norbert Wilk Ewa Kierszyn	X						X
CP	Euroscan University of Birmingham, UK	Claire Packer	X						
CP	German HTA Association	Matthias Perleth	X						
CP	Institute of Molecular Medicine Lisbon Portugal	Cristina Sampaio	X						
CP	Swiss Network for HTA Swiss Tropical Institute HT Unit	Christoph Kunzli Martin Raab	X			X	X	X	
CP	WHO Health Evidence Network WHO Regional Office for Europe	Leena Eklund	X						
CP	University of Iceland Department of Public Health	Sigurdur Helgason	X	X	X	X	X	X	
CP	Hauptverband der Österreichischen	Gottfried Endel	X						X
CP	CEESTAHC Central and Eastern European Society for Technology Assessment in Health	Magdalena Wladyziuk Robert Plisko	X	X		X	X	X	
CP	Evidence-Based Medicine ** Health Information Technology National School of Public Health, Romania	Catalin Tufanaru				X	X	X	
CP	AGENAS** Age.na.s., Italy	Marina Cerbo Alessandra Lo Scalzo				X	X	X	X
CP	Ministry of Health. Serbia**	Dragana Atanasijevic			X	X	X	X	

* Employees of WP8 LP that contributed also as members of WP coordinating team in different tasks (internal meetings; developing the questionnaires; writing and reviewing reports; presenting results to international conferences and meetings,) during the 3 years of the project

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