Joint Action (JA) on Health Technology Assessment (HTA)

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Outline

1. HTA in Croatia (definition and framework)
2. JA on HTA
3. Future perspective at EU level
HTA

Multidisciplinary process

- summaries information about medical, social, economic and ethical issues related to the use of a health technology
- in a systematic, transparent, unbiased, robust manner
- to inform the formulation of safe, effective, health policies that are patient focused and seek to achieve best value
Aims

• As transparent, independent, scientific, multidisciplinary, evidence-based HTA process and reports should serve as recommendation for evidence-based health care policy and decision making, in strategic planning and investment, as well as in disinvestment opportunities, in decision on funding (reimbursement) and management and the implementation of technologies in health care.

• HTA should serve as bridge between research, decision-making and high quality health care by optimizing the use of healthcare resources to maximize patient outcomes.
Core HTA Structure

Pool of structured HTA information

- Health problem and current use
- Description and tech. characteristics
- Safety
- Clinical effectiveness
- Costs and economic evaluation
- Ethical analysis
- Organisational aspects
- Social aspects
- Legal aspects

CORE HTA

- A multidisciplinary assessment produced using HTA Core Model
- All core elements
- Summary of key findings
- No recommendation on technology use

LOCAL HTA

- A health technology assessment for local use
- Information from Core HTA(s) and/or pool of structured HTA information
- Takes into account local information and needs

Shortcut possible
February 2006, *Strategy for the development Croatian Health care system 2006 - 2011*

- The **importance of HTA and evidence-based decision-making** in Croatian medicine

- **Investments** in new technologies or decisions to include certain procedures **under the coverage** of the HZZO need to be **based on the best available evidence** (principles of evidence-based medicine) and **cost–effectiveness**

- The assessment of new technologies should be in charge of an **independent institution** (National Institute for Health and Clinical Excellence, NICE, UK, as an example)
Institutionalization of the Agency for Quality and Accreditation in Health

• 2007, *Act on Quality of Health Care*: The Agency for Quality and Accreditation in Health (as legal, public, independent, non-profit institution), responsible for HTA process and report and database on HTA

*Health technologies*: pharmaceuticals, medical devices, diagnostic and screening techniques, surgical procedures, other therapeutic technologies and procedures, and health promotion activities

• Three departments: 1) Department for Quality and Education, 2) Department for Accreditation in Health, and 3) **Department for Development, Research and HTA**

• Formal HTA activities actually began in **October 2009**
International Projects in the framework of the Second Programme of Community Action in the Field of Health (2008-13)

EUnetHTA Joint Action Project (2010-2012)

- EUnetHTA JA: co-funded by the European Commission and participating organizations during a period of 3 years, 2010-2012

- **Aim:** including work on relative effectiveness of pharmaceuticals, to put into practice an effective and sustainable HTA collaboration in Europe that brings added value at the European, national and regional level

- The EUnetHTA JA grant agreement was signed by the EU Executive Agency for Health and Consumers (EAHC) and the Coordinator (National Board of Health of Denmark) on behalf of 33 partners in 23 EU Member States and Norway

- Croatia participated as EUnetHTA Partner, as newly admitted organization in March 2010, financed outside of the EUnetHTA JA budget, with active scientific input in two Works packages, and voting rights on Plenary Assembly

EUnetHTA Joint Action 2 Project (2012-2014)

- EUnetHTA JA2 will be co-funded by the European Commission and participating organizations during a period of 3 years, 2012-2014 (currently in preparation process)

- **Aim:** to facilitate collaborative production of Core HTA and different types of HTA Reports on relative efficacy or short and long term effectiveness when applicable, to avoid duplication of assessments through timely, scientific, transparent, unbiased, objective, independent process, with appropriate stakeholders consultations

- HTA JA2 - test all possible models of collaboration, because JA output will prepare ground for future establishment of a regular European HTA Network according Cross Border Health Care Directive

- Croatia will participate as Associated Partner (inside EU funds); Works Packages are not yet finally established

- Indicative amount: 6.600.000€ (EU co-funding 70%)
European network for HTA
Joint Action between European Commission and EU Member States

A total of 35 government appointed organisations from 24 EU Member States, Norway and Croatia and a large number of relevant regional agencies and non-for-profit organisations that produce or contribute to HTA
EUnetHTA JA organisation

Eight Work Packages (WP1-WP8)

- **WP1 – Coordination** (Lead Partner (LP) – NBoH, Denmark)
- **WP2 – Dissemination** (LP – IPH-RS, Slovenia; Co-LP – SBU, Sweden)
- **WP3 – Evaluation** (LP – NETSCC, United Kingdom)
- **WP4 – Core HTA** (LP – THL, Finland; Co-LP – AGENAS, Italy)
  - 2 Strands – WP4A (electronic tool and Core Model development), WP4B (Core HTA production)
- **WP5 – Relative Effectiveness Assessment (REA) of Pharmaceuticals** (LP – CVZ, Netherlands; Co-LP – HAS, France)
- **WP6 – Information Management System** (LP – KCE, Belgium, Co-LP – DIMDI, Germany)
- **WP7 – New Technologies** (LP – HAS, France, Co-LP – LBI-HTA, Austria)
  - 2 Strands – WP7A (Facilitating Evidence Generation), WP7B (collaboration on (pre-coverage) assessments)
- **WP8 – Strategy and Business Model Development** (LP – NBoH, Denmark)
  - specific lines of activities – a) HTA training and capacity building (focus on EUnetHTA tools) and b) facilitation of national HTA strategies.
  - Responsible organisation for a) – ISCIII, Spain
  - Responsible for b) – AHTAPol, Poland
Experience in HTA JA 2010-1012

- Agency’s appointment (by Croatian Ministry of Health) and participation in EUnetHTA Joint Action as a EUnetHTA Partner (March 2010)

WP8: Strategy and Business Model Development  (from March 2010)
- Facilitation of national strategies for continuous development and sustainability of HTA
  - Section coordinated by AHTAPol (Poland)
- HTA training and capacity building
  - Section coordinated by ISCIII (Spain)

WP4, strand B: development of two Core HTA Report  (from April 2011)
- SCREENING: Abdominal aorta aneurysm screening
- DIAGNOSTIC: Genetic test for cancer
WP8: Strategy and Business Model Development; Facilitation of national strategies for continuous development and sustainability of HTA, HTA training and capacity building

- March 2010, e-meeting: „Introduction to WP8 National Strategies, Presentation of draft concept of the survey and preparation to f-t-f Warsaw meeting 19-20 April”
- May 2010, WP8 WS, “HTA capacity and facilitation of national strategies for HTA sustainability”, Warsaw, Poland
- July 2010, EUnetHTA WP8 Survey, on Strategy and business model development
- February 2011, WS work on the 1st draft of the “Facilitation of the national HTA strategies development document”, Warsaw, Poland on the basis of „Survey on national strategies for continuous development and sustainability of HTA, Results of Barrier analysis”
- December 2011, WP8 partners and other EUnetHTA Partners HTA training course (in EUnetHTA tools and other available HTA process support solutions), Prague, Czeck Republic
EUnetHTA JA Plenary Assembly

• 1st Plenary Assembly meeting, May 2010, Ljubljana, Slovenia

• 2nd Plenary Assembly meeting, May 2011, London, UK
WP4, STRAND B, development of two Core HTA Report

e-meetings and e-mails
- Analysis of HTA topic selection and priority setting processes among WP members
- Analysis of stakeholder involvement policies among WP members
- Consideration of collaborative models for producing Core HTAs
- Production of two Core HTAs and Validation of the Core HTAs:

2 HTA Topics:
SCREENING - Abdominal aorta aneurysm screening
DIAGNOSTIC - Genetic test for cancer

- WS April 2011, Rome and September 2011, Wien; 19 researchers of a Core HTA (10 per core hta) divided among participating APs + 2 from Strand B leader + 1 from LP
- several e-meetings will be arranged to support practical work within both strands, every 2 months

- Croatian comments on „Document on working group for WP4“ - Finland
- Peer-review on „HTA Core Model on Screening“ - Finland
WP7 New Technologies (LP – HAS, France, Co-LP – LBI-HTA, Austria)

2 Strands – WP7A (Facilitating Evidence Generation), WP7B (collaboration on (pre-coverage) assessments

- Quarterly **e-mail requests for Planned and Ongoing Projects (POP) Database** (till now 4 request within all EUnetHTA Joint Action partners)

- December 2010, EUnetHTA WP 7B, invitation for “Collaboration on new high tech interventions in hospitals“

**Topic 1: Intravitreal vascular endothelial growth factor (VEGF) inhibitors for the treatment of diabetic macular edema**

Project coordinator, 1st author: Ingrid Zechmeister (LBI-HTA, Austria)
2nd author: Mirjana Huic (Agency for Quality Accreditation in Health, Department for Development, Research and HTA, Croatia)
3rd author: Marco Marchetti (University Hospital “A. Gemelli”, Italy)

This evidence-analysis has been commissioned by the Austrian Ministry of Health.

VASCULAR-ENDOTHELIAL-GROWTH-FACTOR-INHIBITORS (ANTI-VEGF) FOR DIABETIC MACULAR ODEMA

SYSTEMATIC REVIEW

VIENNA AND ZAGREB, MARCH 2011
EUnetHTA JA2

• EC Health and Consumers DG, November 12 2010, Letter to Health Attaches - Preparation for 2nd Joint Action on HTA
• to thank the Croatian authorithies for their active involvement in the ongoing EUnetHTA JA on HTA (2010-2012)
• for support 2011 Work Plan authorising the launch of a new JA in 2012, and to re-appoint the HTA agency/representative in new HTA JA2

• Invitation for participation in WS on JA, January 2011, Luxembourg
Active work with Croatian Ministry of Health and Social Welfare (Independent Service for International Cooperation and Information)

- November 2010 Letter of support of the Ministry of Health and Social Welfare of the Republic of Croatia to the Health Technology Assessment (HTA) Second Joint Action in 2012

- WORK PLAN 2011 – Adjusted text proposal from Croatia
  3.3.1.3. Complementary joint action on pilot HTAs on targeted health technologies

- EUROPEAN COMMISSION
  HEALTH AND CONSUMERS DIRECTORATE-GENERAL
  Public Health and Risk Assessment
  Health Programme and Knowledge management

Luxembourg, 30/11/2010

Dear Committee Members,

Please find attached comments from Croatia and Norway as a follow up to the Health Programme Committee Meeting on 16 November 2010.

Croatia: 
Norway:

Best regards, 
SANCO C1
EUnetHTA JA2

February 28 2011 e-meeting on HTA JA 2
March 8 2011 1st preparatory meeting for the 2nd JA on HTA, Brussels
March 9 2011 Croatian suggestion for WP4 and WP5
March 15 Croatian suggestion for WP8
March 18 2011 Invitation for active participation in “Task Force”

Task Force members: Gottfried Endel, HVB, Austria; Claudia Wild, LBI, Austria; Raf Mertens, KCE, Belgium; Patrice Chalon, KCE, Belgium; Mirjana Huic, Agency for Quality and Accreditation in Health, Croatia; Finn Børlum Kristensen, NBoH/EUnetHTA Secretariat, Denmark; Julia Chamova, NBoH/EUnetHTA Secretariat, Denmark; Kristian Lampe, THL, Finland; Francois Meyer, HAS, France; Mairin Ryan, HIQA, Ireland; Marina Cerbo, AGENAS, Italy; Wim Goettsch, CVZ, Netherlands; Gro Jamtvedt, NOKC, Norway; Iga Lipska, AHTAPol, Poland; Anders Lamark-Tysse, DG SANCO, EU Commission

March 20 2011 comments on received documentation for Task Force member

HTA JA2 Associated Partners (APs) guidelines for decision in which JA2 work packages organisation will participate in

- required to submit a correctly filled JA2 Associated Partner Form by April 26, 2011
  - on May 2 the Coordinator will send to each Associated Partner a Declaration of Honour to be signed, stamped and sent back to the Coordinator by May 11, 2011
  - a JA2 AP should commit to contribute resources to one of the 2 production WPs (WP4 and 5)
  - not to participate in more than 3 WPs (to allow sufficient availability of resources to be dedicated to the production WP) – maximum 3 WPs
  - indicate in which chosen work package they will be willing and able (financially, competence-wise) to participate as an “active contributor” (eg, willing to accept a task of “primary investigator”/”investigator”) and as “less-active contributor” (eg, task of “reviewer”)

April 2011 2nd preparatory meeting for the 2nd JA on HTA, Brussels
Future Croatian HTA perspective on EU level

Directive on the application of patients' rights in cross-border healthcare (so called Cross-Border Health Care Directive), with Article 15 on Cooperation on health technology assessment

- Croatia - prepared for participation and contribution to the cooperation and exchange of objective, reliable, timely, transparent and transferable information among Member States within a voluntary network (in accordance with the legislation of the Member State where they are established) connecting national authorities or bodies responsible for health technology assessment designated by the Member States

- Importance of support and commitment of government institutions, adequate legal framework and funding, educated permanent staff, national and international cooperation and collaboration (network)

- Thank you for your attention!
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- Conflict of interest: None