

The current status of HTA in Croatia

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kvalitetu i
akreditaciju
u zdravstvu



Republika Hrvatska

Outline

1. The establishment of the HTA process in Croatia
2. Legal framework, boundaries
3. Will the Agency be a part of future pricing and reimbursement decisions?



Republic of Croatia

- Population ~ 4.4 million
- GDP per capita ~14.000 US\$ (10.245 €)

Croatian Health Care System

- Principles of **social health insurance**, financed from several sources
- The agreement and payment of the **national mandatory health insurance** is conducted through the **Croatian Institute for Health Insurance (HZZO)**
- Total spending on health (2005-10): **10%-14% GDP**
- Per capita spending on health: **1200 US\$**
- HZZO budget for 2010: ~22 billion HRK (~2.9 billion €)
- HZZO expenditure on prescription drugs: **16.7%** of total health expenditure
- Special Fund for very expensive drugs: ~377.400.000,00 HRK (~50 million €)



Decision making process

Ministry of Health and Social Welfare:

- 1) *health policy*, planning and evaluation, including the drafting of legislation, regulation of standards for health services and training;
- 2) *public health program*, including monitoring and surveillance of health status, health promotion, food and drug safety, and environmental sanitation;
- 3) *regulation of capital investments* in health care providers in public ownership

Agency for Medicinal Products and Medical Devices (HALMED);

- 1) marketing authorization of drugs
- 2) regulation of medical devices

Croatian Health Insurance Institute (HZZO);

- 1) *managing the Health Insurance Fund* and *contracting health care services*
- 2) key role in the *definition of basic health services* covered under statutory insurance
- 3) the establishment of *performance standards and price setting* for services covered by the HZZO

- pricing and reimbursement decision on drugs and medical devices



Croatian Legal Framework for HTA

- 2006, **Strategy** of the development of the Croatian Health Care System 2006-2011
- 2007, **Act on Quality of Health Care** - Agency for Quality and Accreditation in Health Care (Department for Development, Research and HTA)
- December 2009, **Ordinance** regarding reimbursement on drugs (*Official gazette No. 155/09*) and Ordinance regarding reimbursement on medical devices (*Official gazette No. 138/09*) – HTA not mentioned
- October 2010, **Plan and program** of measures for quality assurance, improvement, promotion, and monitoring of health care quality
- November 2011, new **Act on Quality of Health Care and Social Welfare (Ordinance on HTA process and reporting)**



Annual HTA budget and permanent staff in Croatia and HTA Agencies or Units in some European countries:

Country	Since	Annual HTA budget (US \$ million)	Population served (million)	Permanent staff in HTA Department	Consultants
Finland	1995	2.0	5.1	18	65
Latvia	1995	0.05	2.3	8	variable
Denmark	1997	3.8	5.4	15	variable
Norway	2003	4.0	4.5	30	100
Croatia	2007 (formal activities from 2009)	~0.4 (for whole Agency in 2009, 2010) ~0.9 (for whole Agency in 2011)	4.4	1 (out of three planned in 2009) 1 (from April 2011, for one year period) 1 was contracted (from September 2010 - March 2011)	



Agency for Quality and Accreditation in Health Care (Department for Development, Research and HTA): Plan for establishment of HTA process

- International collaboration (EU Projects, HTAi)
- National collaboration, education and HTA promotion (congress, meetings, WSSs, publications in Croatian language)
- Croatian HTA Guideline
- Web page <http://www.aaz.hr/>, <http://www.aaz.hr/main.php?ID=24>
- Production of HTA Reports
- Scientific Publications



International Projects

- EUnetHTA Joint Action Project (2010-2012), as CP
- EUnetHTA Joint Action 2 Project (2012-2014), as AP
- **TAIEX Project**, http://ec.europa.eu/enlargement/taieux/dyn/taieux-events/detail_en.jsp?EventID=43260, December 2010, organized by the Technical Assistance Information Exchange Instrument of the European Commission (TAIEX) in co-operation with our HTA Department: **2 days Workshop - “Health Technology Assessment; main principles, HTA process and report”**
- **MPAP Pre-accession Projects Programme** (Dutch Government)
„Capacity building in Health Technology Assessment (HTA) process and reporting” (negative decision)
- **FP7-HEALTH-2012-INNOVATION-1**; Work programme: HEALTH.2012.3.2-2: **New methodologies for health technology assessment**;
“Incorporation of Prognostic Evidence in the HTA-process” (WP4: The inclusion of prognostic evidence into the HTA process) (negative decision)





eunethta

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 Joint Action 2010–2012 | www.eunethta.eu



Active involvement in HTA JA 2010-2012

WP8: Strategy and Business Model Development (from March 2010)

- *Facilitation of national strategies for continuous development and sustainability of HTA*
- *HTA training and capacity building*

WP4, strand B: development of two Core HTA (from April 2011)

WP7 New Technologies, strand B: collaboration on (pre-coverage) assessments

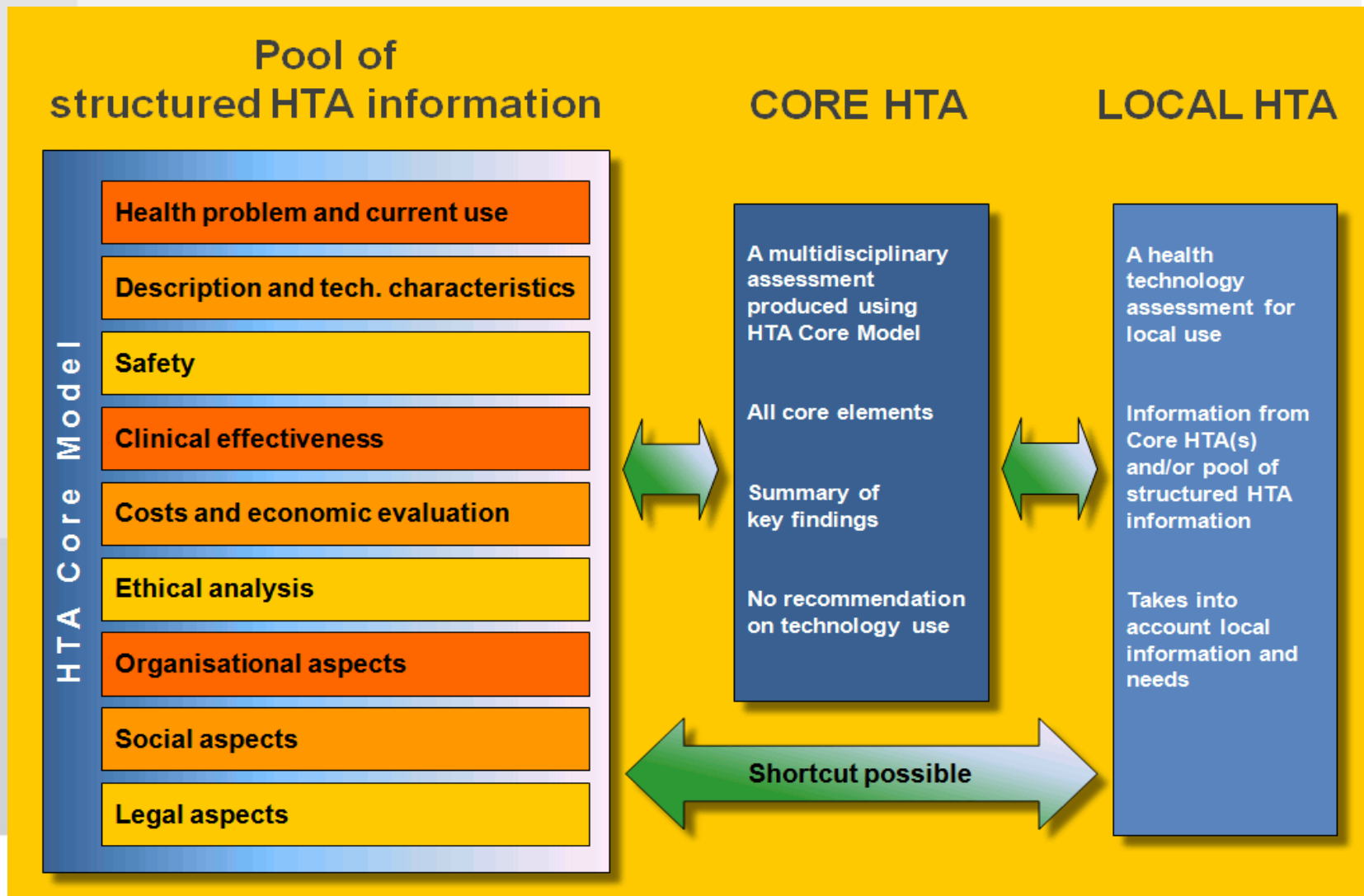


WP4, strand B: development of two Core HTA (from April 2011)

- ***Abdominal aortic aneurysm screening*** (as Reviewer)
- ***Genetic tests for breast cancer*** (as Primary Investigator in “Clinical Effectiveness Domain”)



Core HTA Structure



WP7 New Technologies, strand B: collaboration on (pre-coverage) assessments

In December 2010, call from **LBI-HTA, Austria:**

- **“Collaboration on new high tech interventions in hospitals“ - Topic 1:**
Intravitreal vascular endothelial growth factor (VEGF) inhibitors for the treatment of diabetic macular edema



Zechmeister I, Huic M. Anti-VEGF in diabetic macular oedema: A systematic review. Decision Support Dokument No. 43. 2011. <http://eprints.hta.lbg.ac.at/917/>,
http://eprints.hta.lbg.ac.at/917/1/DSD_43_english.pdf.

VASCULAR-ENDOTHELIAL-GROWTH-FACTOR-INHIBITORS (ANTI-VEGF) IN DIABETIC MACULAR OEDEMA

SYSTEMATIC REVIEW

VIENNA AND ZAGREB, MARCH 2011



Ludwig Boltzmann Institut
Health Technology Assessment



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- Zechmeister-Koss I, Huic M. Vascular endothelial growth factor inhibitors (anti-VEGF) in the management of diabetic macular oedema: a systematic review. **Br J Ophthalmol. 2011**; doi:10.1136/bjophthalmol-2011-300674

Collaboration with KCE, Belgium

- Hulstaert F, Neyt M, Vinck I, Stordeur S, Huić M, Sauerland S, Kuijpers MR, Abrishami P, Vondeling H, Van Brabandt H. **The pre-market clinical evaluation of innovative high-risk medical devices.** Health Services Research (HSR). Brussels: Belgian Health Care Knowledge Centre (KCE). 2011. KCE Report 158C. D/2011/10.273/31. <http://kce.fgov.be/publication/report/the-pre-market-clinical-evaluation-of-innovative-high-risk-medical-devices>



EUnetHTA Conference 2011



Before Conference:

Meeting between John Dalli and representatives from EU HTA agencies: *Dir. 2011/24/EU and the HTA network*

EUnetHTA Conference (<http://www.eunetha2011.pl/>):

- Results of EUnetHTA Joint Action 1;
- EUnetHTA Joint Action 2 and the EUnetHTA long term strategy;
- Vision on HTA now and in the future;
- Roundtable on future in international HTA collaboration;
- The view of the EC on the results of the EUnetHTA JA1 so far and role of cross-border (rapid) assessments in the future;
- Possible role of European collaborative assessments in national reimbursement processes;
- Roundtable on how to proceed with European collaborative assessments



“The Croatian Guideline for Health Technology Assessment Process and Reporting”, 1st edition, February 2011

(with international peer-review process)

- **Contents**

I Introduction and legal framework

II HTA process

1 Topics suggestion and selection process

2 Scope prepared

3 Assessment process

4 Advice (Appraisal) process

5 HTA Report

6 Guide for the Economic evaluation of health technologies: Croatia

Appendix I: **Bibliography of recommended HTA Guidelines and methodology references**

Appendix II: **A Code of Practice for Declaring and Dealing with Conflicts of Interest in HTA process**

Appendix III: **Authorship**

Appendix IV: **Selected Data Sources on Croatian Population Health, Healthcare Resource Use and Costs**



Assessment process

A “pre-assessment” of the existing evidence on each selected topic is prepared by HTA Department staff (including existing Core HTA and/or HTAs from other countries), final decision about HTA process, **Assessment phase**, will be done according Algorithm;

Algorithm for HTA process (Assessment phase):

1. Already published Core HTA and/or HTAs from other countries (Yes or No)

If **Yes**, HTA will be critically appraise for quality by INAHTA checklist for the appraisal of HTA Reports; further adaptation will be done according EUnetHTA Adaptation Toolkit with **primary health economic evaluation** according the part of this guideline - Guide for the Economic evaluation of health technologies: Croatia

If No, 2. Already published Systematic Reviews (SR) on clinical effectiveness and safety (Cochrane database of SR, DARE database) and SR of economic analyses (Yes or No)

If **Yes**, SR will be critically appraised and new clinical trials will be added if necessary, with **primary health economic evaluation** according the part of this guideline - Guide for the Economic evaluation of health technologies: Croatia

If No, 3. **New SR on clinical effectiveness and safety (with protocol) and SR of economic analyses (with protocol)** (will be based on Cochrane Handbook for Systematic Reviews or the CRD guidance for systematic reviews), with **primary health economic evaluation** according the part of this guideline - Guide for the Economic evaluation of health technologies: Croatia



Element of HTA	Reference case for economic analysis
Defining the decision problem	The scope developed by the Agency
Comparator	Therapies routinely used in the Croatian health system, including technologies regarded as current best practice
Perspective on costs	Croatian Institute for Health Insurance (HZZO, as public payer) (societal perspective, including all cost and benefits outside the health care system, may be presented in addition, if considered relevant for some topics)
Perspective on outcomes	All direct health effects on individuals
Type of economic evaluation Time horizon	Cost-effectiveness analysis (CEA) or Cost-utility analysis, (CUA), depending on the particularities of the technology being assessed sufficiently long to reflect all important differences in costs or outcomes between the technologies being compared
Synthesis of evidence on outcomes	Based on a Systematic Review with/or without Meta Analysis (Head-to-Head RCTs preferred, indirect comparisons and observational studies may be accepted)
Measure of health effects	Natural units (CEA) or QALYs (CUA)
Source of data for measurement of HRQL	Reported directly by patients and/or carers (EQ-5D)
Source of preference data for valuation of changes in HRQL	Representative sample of the public (using a choice-based method)
Discount rate	An annual rate of 5 % on both costs and health effects (in sensitivity analyses between 3% and 10%)
Equity weighting	An additional QALY has the same weight regardless of the other characteristics of the individuals receiving the health benefit
Sensitivity analysis, Modelling, Subgroup analysis	Yes

HTA in process at national level

- Transcatheter aortic valve implantation (TAVI) in patients with severe aortic stenosis: HTA
- Insulin glargine and insulin detemir in combination with oral antidiabetic therapy in patient inadequately controlled on oral therapy alone: HTA
- Sitagliptin and sitagliptin in combination with metformin as an adjunct therapy in adult type 2 diabetes mellitus patients previously uncontrolled with other oral antidiabetic agent: HTA



Will the Agency be a part of future pricing and reimbursement decisions?

- Answer will be in the new **Ordinance on HTA process and reporting** according the new *Act on Quality of Health Care and Social Welfare* (November 2011)



The future of HTA in Croatia

At national level

- Permanent production of HTA reports;
- Further educational activities for HTA users, HTA doers, and promotion of HTA

At international level

- Active participation in current EUnetHTA JA and JA 2; Further collaboration and education on HTA process and reports; Further application for different EU Projects

According *Cross-Border Health Care Directive*, with Article 15 on Cooperation on HTA - **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 connecting national authorities or bodies responsible for HTA designated by the MSs**

Importance: *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

