Health Technology Assessment (HTA) in Croatia: the present and the future

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Agencija za kvalitetu i akreditaciju u zdravstvu

Republika Hrvatska

Republic of Croatia

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

Croatian Health Care System

• Principles of **social health insurance**, financed from several sources

• A major part is financed according to a **national health insurance model**

• Provision and funding of services: largely **public**

• The agreement and payment of the **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***
- *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* (in process), new ***Act on Quality of Health Care and Social Welfare*** **(Ordinance on HTA process and reporting)**

Annual HTA budget and permanent staff in HTA Agencies or Units in some Europen 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)	

Plan for establishment of HTA process

- International collaboration (EU Projects, HTAi)
- National collaboration, education and HTA promotion (congress, meetings, WS, publications in Croatian language)
- Croatian HTA Guidelines
- 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 (*2010-2012*),** as CP
- **EUnetHTA Joint Action 2 (*2012-2014*),** as AP

- **TAIEX Project**, *http://ec.europa.eu/enlargement/taiex/dyn/taiex-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 Goverment) **„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)

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)

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

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

- December 2010, **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

Agencija za kvalitetu i akreditaciju u zdravstvu

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://www.kce.fgov.be/index_en.aspx?SGREF=5211&CREF=20267

"The Croatian Guideline for Health Technology Assessment Process and Reporting", 1st edition, February 2011 (with international peer-review process)

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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 horizont	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 preffered, 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 Sensitivity analysis, Modelling, Subgroup analysis	An additional QALY has the same weight regardless of the other characteristics of the individuals receiving the health benefit 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

The future of HTA

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 health technology assessment - **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: *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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