Health Technology Assessment (HTA) in Croatia: First five years

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Outline

1. What we want?
2. Barriers; Factors facilitating HTA establishment in Croatia
3. Where we are?
4. Conclusion - Future perspective at national and EU level
Republic of Croatia

- Population ~ 4.3 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 Health Insurance Fund (HZZO)
- Total spending on healthcare (2000-12): ~ 6.8%-7.8% GDP
- Per capita spending on healthcare: ~ 800-1500 US$
What we want?

• Transparent, independent, scientific, multidisciplinary, evidence-based HTA process and reports on the whole range of health technologies 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.

• Appropriate Stakeholders involvement

• Bridge between research, decision-making and high quality health care by optimizing the use of healthcare resources to maximize patient outcomes.
Institutionalization of Agency for Quality and Accreditation in Health Care and Social Welfare

• Established under the Act on Quality of Health Care in 2007 as legal, public, independent, non-profit institution
• Three departments: 1) Department for Quality and Education, 2) Department for Accreditation in Health Care and 3) Department for Development, Research and HTA
• Formal activities in the field on HTA: October 2009
Barriers (limited legal framework, shortage of staff and funding);

Factors facilitating HTA establishment in Croatia
Plan for establishment of HTA process:

• *Croatian HTA Guideline*, [http://aaz.hr/hr/procjena-zdravstvenih-tehnologija](http://aaz.hr/hr/procjena-zdravstvenih-tehnologija)

• *International collaboration*, [http://aaz.hr/hr/projekti](http://aaz.hr/hr/projekti), [http://www.aaz.hr](http://www.aaz.hr)

• *National collaboration, education and HTA promotion* (congress, meetings, WSs, publications in Croatian language), [http://aaz.hr/hr/procjena-zdravstvenih-tehnologija/edukativni-materijali](http://aaz.hr/hr/procjena-zdravstvenih-tehnologija/edukativni-materijali)

• *Production of HTA Reports* (national, international), [http://aaz.hr/hr/procjena-zdravstvenih-tehnologija/baza](http://aaz.hr/hr/procjena-zdravstvenih-tehnologija/baza)

• *Scientific Publications*, [http://aaz.hr/hr/procjena-zdravstvenih-tehnologija/publikacije](http://aaz.hr/hr/procjena-zdravstvenih-tehnologija/publikacije)

• *Web page* [http://www.aaz.hr/](http://www.aaz.hr/), [http://aaz.hr/hr/procjena-zdravstvenih-tehnologija](http://aaz.hr/hr/procjena-zdravstvenih-tehnologija); [http://aaz.hr/hr/projekti](http://aaz.hr/hr/projekti)
Annual HTA budget and permanent staff in Croatia and HTA Agencies or Units in some European countries:

<table>
<thead>
<tr>
<th>Country</th>
<th>Since</th>
<th>Annual HTA budget (US $ million)</th>
<th>Population served (million)</th>
<th>Permanent staff in HTA Department</th>
<th>Consultants</th>
</tr>
</thead>
<tbody>
<tr>
<td>Finland</td>
<td>1995</td>
<td>2.0</td>
<td>5.1</td>
<td>18</td>
<td>65</td>
</tr>
<tr>
<td>Latvia</td>
<td>1995</td>
<td>0.05</td>
<td>2.3</td>
<td>8</td>
<td>variable</td>
</tr>
<tr>
<td>Denmark</td>
<td>1997</td>
<td>3.8</td>
<td>5.4</td>
<td>15</td>
<td>variable</td>
</tr>
<tr>
<td>Norway</td>
<td>2003</td>
<td>4.0</td>
<td>4.5</td>
<td>30</td>
<td>100</td>
</tr>
<tr>
<td>Croatia</td>
<td>2007</td>
<td>~0.4 (for whole Agency in 2009 and 2010)</td>
<td>~0.8 (for whole Agency in 2011 and 2012)</td>
<td>~0.7 (for whole Agency in 2013)</td>
<td>4 (from December 2013; 1, up to October 2013)</td>
</tr>
</tbody>
</table>
Legal framework in Croatia

• **2006**, *Strategy of the development of the Croatian Health Care System 2006-2011*
• **September 2012**, *Croatian National Health Care Strategy 2012-2020*

• **2007**, *Act on Quality of Health Care*
• **November 2011**, new *Act on Quality of Health Care and Social Welfare (Ordinance on HTA process and reporting)*

• **November 2012**, draft proposal *Ordinance on HTA process and reporting* to Croatian MoH (in process)

• **December 2009**, *Ordinance regarding reimbursement on drugs* (*Ordinance about establishing the criteria for inclusion of medicinal products in the Basic and the Supplementary reimbursement list of the Croatian Institute for Health Insurance, Official gazette No. 155/09*) and *Ordinance regarding reimbursement on medical devices* (*Official gazette No. 138/09*) – *HTA not mentioned*

**Applicants submission:** Marketing authorization approval; Calculation of drug price; Public health-clinical-pharmacological opinion; Scientific evidence proving the benefits of the drug; Tabular view of drug health insurance status in EU; Mandatory: *Budget Impact Analysis, BIA, according Guideline in Article 26*; Optional: the applicant may submit the Cost-effectiveness analysis

• **July 2013**, new *Ordinance regarding reimbursement on drugs, HTA not mandatory (if requested - 1 month timeframe)*
Croatian HTA Guideline, [http://aaz.hr/hr/procjena-zdravstvenih-tehnologija](http://aaz.hr/hr/procjena-zdravstvenih-tehnologija)
http://aaz.hr/hr/procjena-zdravstvenih-tehnologija

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I Introduction and legal framework
II HTA process
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  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
International collaboration, http://aaz.hr/hr/projekti, http://www.aaz.hr

• EU Projects

• Memberships: HTAi, ISPOR, ISPOR HTAR, ISPOR HTA Council, HTAN
Important international documents on HTA


• 2011, Article 15 of Directive 2011/24/EU;

• 2013, HTAN, COMMISSION IMPLEMENTING DECISION of 26 June 2013 providing the rules for the establishment, management and transparent functioning of the Network of national authorities or bodies responsible for health technology assessment (2013/329/EU);

• 2014, 67th World Health Assembly Resolution: Health intervention and technology assessment in support of universal health coverage
International projects

- **EUnetHTA Joint Action Project (2010-2012)**, as CP

- **EUnetHTA Joint Action 2 Project (2012-2015)**, as AP (total budget~9.43 mill EUR (Commission funding 70%))

- **FP7 Project EQUIPT (2013-2016)**, (total budget~2.57 mill EUR (Commission contribution 2.1 mill EUR))

*Project proposal in process*

- **H2020 SELFIE "Sustainable intEgrated care modeLs for multi-morbidity: delivery, Financing and performance"** (2nd Phase project proposal), 48 months duration

- **EAHC/2013/Health/10 Lot 2 " Multiple Framework Contracts with reopening of competition to support tobacco policies"**
European network for HTA Joint Actions (JA1, 2010-2012 and JA2, 2012–2015)
HTA Network (HTAN)

3rd HTAN meeting

- 29 October, 2014, Rome, Italy

- HTAN Strategy paper “EU cooperation on HTA”
Conference, October 2014

Under the patronage of the Italian Ministry of Health

Conference website: www.eunethta2014.it
EUnetHTA JA 2010-2012

Facilitation of national strategies for continuous development and sustainability of HTA

HTA training and capacity building

Anti-VEGF in diabetic macular oedema: A systematic review

The pre-market clinical evaluation of innovative high-risk medical devices

Core HTA on Prognostic tests for breast cancer recurrence

Core HTA on Abdominal Aortic Aneurysm (AAA) screening

EUnetHTA JA2 2012-2015

Fecal Immunochemical Test (FIT) versus guaiac-based fecal occult blood test (FOBT) for colorectal cancer screening

Duodenal-jejunal bypass sleeve (EndoBarrier®) for the treatment of obesity with or without type 2 diabetes

Canagliflozin for the treatment of Diabetes Mellitus Type 2

Intravenous Immunoglobulins in MCI and Alzheimer disease

EUnetHTA Plenary Assembly, March 2013, Zagreb, Croatia; WP4 F-F meeting, October 2013, Zagreb, Croatia
National collaboration, education and HTA promotion

http://aaz.hr/hr/procjena-zdravstvenih-tehnologija/edukativni-materijali

Congresses, meetings, WSs, publications in Croatian language, educational documents on web page
- Meeting with international experts for main HTA users (January 2010)
- HTA symposiums during the Croatian congresses on pharmacoeconomics and outcome research with international participation (2010-2013)
- 1st National Conference, 2013 (Health Care Quality, Accreditation and HTA)


- Huić M. Procjena zdravstvenih tehnologija u Hrvatskoj: uloga Agencije za kvalitetu i akreditaciju u zdravstvu. HČJZ. 2011;7:e.
“MoH Projects incubator”

Project proposal „Development of Health Technology Assessment“, January 2013 (to Croatian MoH for possible application on EU Funds)
• **Production of HTA Reports** (national, international), [http://aaz.hr/hr/procjena-zdravstvenih-tehnologija/baza](http://aaz.hr/hr/procjena-zdravstvenih-tehnologija/baza)

• **Web page** [http://www.aaz.hr/](http://www.aaz.hr/), [http://aaz.hr/hr/procjena-zdravstvenih-tehnologija](http://aaz.hr/hr/procjena-zdravstvenih-tehnologija); [http://aaz.hr/hr/projekti](http://aaz.hr/hr/projekti)
Agency HTA Database

http://aaz.hr/hr/procjena-zdravstvenih-tehnologija/baza
HTA reports (19 finished), 2011- July 2014

<table>
<thead>
<tr>
<th>Rapid HTA at national level</th>
<th>HTA at national level</th>
<th>HTA at international level</th>
</tr>
</thead>
<tbody>
<tr>
<td>4</td>
<td>8 (6 in process)</td>
<td>7 (1 in process)</td>
</tr>
</tbody>
</table>
VASCULAR-ENDOTHELIAL-GROWTH-FACTOR-INHIBITORS (ANTI-VEGF) IN DIABETIC MACULAR ODEMA

SYSTEMATIC REVIEW

VIENNA AND ZAGREB, MARCH 2011
HTA at national level

- Transcatheter Aortic Valve Implantation-TAVI: HTA, 01/2012 and 01a/2012

- Insulin glargine and insulin detemir in combination with oral antidiabetic therapy in patient with type 2 diabetes mellitus: HTA, 02/2012

- Sitagliptin and sitagliptin with metformin therapy in patients with type 2 diabetes mellitus: HTA, 03/2012

- Tandem mass spectrometry in expanded newborn screening for inherited metabolic disorders: HTA, 04/2012

- Particle Beam Radiation Therapies for Cancer: HTA, 05/2013

- Intensity-Modulated Radiation Therapy, IMRT: HTA, 06/2013

- Endovascular abdominal aortic aneurysm (AAA) repair: HTA, 07/2013
Scientific Publications, [http://aaz.hr/hr/procjena-zdravstvenih-tehnologija/publikacije](http://aaz.hr/hr/procjena-zdravstvenih-tehnologija/publikacije)
Scientific publications


- Huić M, Marušić M, Marušić A. *Completeness and Changes in Registered Data and Reporting Bias of Randomized Controlled Trials in ICMJE Journals after Trial Registration Policy.* *PLoS ONE.* 2011;6(9): e25258. doi:10.1371/journal.pone.0025258
Where we are?
Croatian process of decision-making; HTA process and main HTA users in Croatia
Croatian process of decision-making and HTA process

**Industry submission files**

**Croatian Health Insurance Fund (CHIF)**
- "Drugs Committee" and "Medical Devices Committee"
- "APPRaisal"

**CHIF Board**
- "DECISION"

**HTA document with recommendation**

**Agency for Quality and Accreditation in Healthcare and Social Welfare - HTA Department**
- "ASSESSMENT" (Currently not mandatory)

**MoH**
- "DECISION"

**Hospitals Management**
- "DECISION"

**EUnetHTA and HTA Network (Article 15, CBHC Directive)**
- Full Core HTA and Core HTA for Rapid REA of Pharmaceuticals and other health technologies

**National adaptation**

**Active collaborative production**

**Request**

**HTA document with recommendation**

**National adaptation**
Conclusion - the future of HTA in Croatia

• The way for establishing a transparent, scientific, independent evidence-based HTA process in Croatia was not easy and quick process

For further sustainable HTA process in Croatia:

• support and commitment of government institutions (political decision)
• appropriate legal framework and funding
• educated permanent staff
• further national and international cooperation and collaboration (network)
References:

- EUnetHTA JA1 Report. **Facilitation of national strategies for continuous development and sustainability of HTA, 2011.**
  

- EUnetHTA JA1 Report. **HTA training and capacity building, 2011.**
  


Thank you for your attention!

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