Procjena zdravstvenih tehnologija u Hrvatskoj: sadašnjost i budućnost

dr. sc. Mirjana Huić, dr. med.
Služba za razvoj, istraživanje i zdravstvene tehnologije
Agencija za kvalitetu i akreditaciju u zdravstvu i socijalnoj skrbi
Zagreb, Hrvatska
Croatian process of decision-making and HTA process

Industry submission files

Croatian Health Insurance Fund (CHIF)
“Drugs Committee” and “Medical Devices Committee”
“APPRAISAL”

HTA document with recommendation

Request

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

Request

HTA document with recommendation

National adaptation

Active collaborative production

HTA document with recommendation

EUnetHTA and HTA Network (Article 15, CBHC Directive)
Full Core HTA and Core HTA for Rapid REA of Pharmaceuticals and other health technologies
National/regional work produced in another country/region

Hospitals Management
“DECISION”

CHIF Board
“DECISION”

MoH
“DECISION”
Služba za razvoj, istraživanje i zdravstvene tehnologije (Služba za HTA), listopad 2009.

Plan i program za uspostavu HTA:

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

• **International collaboration**, http://aaz.hr/hr/projekti, 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

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

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

• **Web page**, http://www.aaz.hr/, http://aaz.hr/hr/procjena-zdravstvenih-tehnologija; http://aaz.hr/hr/projekti
Challenges (limited legal framework, human resources, funding, appropriate stakeholders involvement in HTA process)

Factors facilitating HTA establishment in Croatia
Zakonski okvir u Hrvatskoj

- **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**, *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)

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

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
International collaboration, http://aaz.hr/hr/projekti, http://www.aaz.hr

“If you want to go fast, go alone. If you want to go far, go with other.”

• EU Projects (EUnetHTA JAs; European study on Quantifying Utility of Investment in Protection from Tobacco – EQUIPT; Sustainable intEgrated care modeLs for multi-morbidity: delivery, FInancing and performance - SELFIE)

• HTAi, ISPOR, ISPOR HTA Roundtable Europe, ISPOR HTA Council
• HTA Network
• WHO National Contact Point on HTA

• ISPOR HTA Training Programe (June 2015)
Health Technology Life-cycle

Advise during early phases of development of a health technology product

- Facilitate Dialogue
- Rationalize evidence requirements
- Develop a collaborative approach
- Towards a consolidated, transparent and harmonised approach
- Between industry, multiple HTA bodies and regulators
- With key issues raised by HTA bodies and an aim towards consensus

HTA / REA

Early scientific advice

Rapid REA

Additional Evidence Generation

Submission Template

Time line of innovation
EUnetHTA documents, tools, process

Methodological Guidelines

Tools

• Core Model (as flexible format and content)

• Planned and Ongoing Projects Database (POP)

• Submission template for drugs and medical devices

Process

• Scoping meetings with Stakeholders
The Domains of the HTA Core Model® - assessing dimensions of value

**HTA Core Model DOMAINS**

1. Health problem and current use of technology
2. Description and technical characteristics
3. Safety
4. Clinical effectiveness
5. Costs and economic evaluation
6. Ethical analysis
7. Organisational aspects
8. Social aspects
9. Legal aspects

SCOPE

- Rapid REA
- Comprehensive/Full HTA

Value?
Figure 1: Schematic overview of the organisation of the process of the pilots - General Overview

It should be noted that these graphs represent the ideal picture; however, divergence is very possible for specific joint REA's.
EUnetHTA evidence submission template

- Procedures and processes
- Methodological guidance
- Decision making criteria

EUnetHTA evidence submission template (all evidence requirements)

Template adaptation process

Evidence requirements for European assessment

Company submission of evidence

European Assessment

Template adaptation process

Company submission of evidence

Local Assessment

Evidence requirements for local (national or regional) assessment

Local appraisal

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

---

**Agencija za kvalitetu i akreditaciju u zdravstvu i socijalnoj skrbi**

**Odjel za razvoj, istraživanje i zdravstvene tehnologije**

**Transkateterska implantacija aортne valvule** (engl. Transcatheter Aortic Valve Implantation-TAVI): Procjena zdravstvene tehnologije (engl. HTA), Broj 01a/2012.

Veljača 2012. godine

---

• **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)
**Sadržaj**

**Sažetak**

I Okvir za postupak procjene zdravstvenih tehnologija u Hrvatskoj

II Procjena zdravstvene tehnologije

1. Uvod i metode
2. Bolest u kojoj se primjenjuje zdravstvena tehnologija
3. Opis zdravstvene tehnologije
4. Klinička učinkovitost i sigurnost (neželjeni događaji) i kvaliteta života
   4.1. Sustavni pregledi kliničke učinkovitosti i sigurnosti (engl. Systematic Review, SR)
   4.2. Randomizirana kontrolirana ispitivanja (engl. Randomized Controlled Trials, RCTs)
   4.3. Opservacijska istraživanja (engl. Observational studies)
5. Troškovi i ekonomske analize
   5.1. Troškovi i ekonomske analize u zdravstvu
   5.2. Sažetak publikacija CUA ili CEA analiza
   5.3. Hrvatska
6. Organizacijski, legalni i etički aspekti
   6.1. Organizacijski aspekti
   6.2. Smjernice i stajališta profesionalnih stručnih društava
   6.3. Legalni i etički aspekti
7. Preporuke ustanova za procjenu zdravstvenih tehnologija i HTA (engl. Health Technology Assessment) publikacije
8. Zaključak i preporuke
9. Literatura

**Diagram**

<table>
<thead>
<tr>
<th>SCOPE</th>
<th>DOMAINS</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>1. Health problem and current use of technology</td>
</tr>
<tr>
<td></td>
<td>2. Description and technical characteristics</td>
</tr>
<tr>
<td></td>
<td>3. Safety</td>
</tr>
<tr>
<td></td>
<td>4. Clinical effectiveness</td>
</tr>
<tr>
<td></td>
<td>5. Costs and economic evaluation</td>
</tr>
<tr>
<td></td>
<td>6. Ethical analysis</td>
</tr>
<tr>
<td></td>
<td>7. Organisational aspects</td>
</tr>
<tr>
<td></td>
<td>8. Social aspects</td>
</tr>
<tr>
<td></td>
<td>9. Legal aspects</td>
</tr>
</tbody>
</table>
Agency HTA Database, [http://aaz.hr/hr/procjena-zdravstvenih-tehnologija/baza](http://aaz.hr/hr/procjena-zdravstvenih-tehnologija/baza)

**HTA reports** (31 finished), 2011- November 2015 (>65% on Medical devices/procedures)

<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>16</td>
<td>11</td>
</tr>
</tbody>
</table>
Transcatheter Aortic Valve Implantation-TAVI: HTA;
Tandem mass spectrometry in expanded newborn screening for inherited metabolic disorders: HTA;
Particle Beam Radiation Therapies for Cancer: HTA;
Intensity-Modulated Radiation Therapy, IMRT: HTA;
Endovascular abdominal aortic aneurysm (AAA) repair: HTA;
Biofeedback and Neurofeedback treatments for psychiatric disorders: HTA;
Impact of triclosan-coated sutures on surgical site infection: HTA;
Insulin glargine and insulin detemir in combination with oral antidiabetic therapy in patient with type 2 DM: HTA;
Sitagliptin and sitagliptin with metformin therapy in patients with type 2 diabetes mellitus: HTA;
Drugs in the treatment of lung cancer (afatinib, erlotinib, gefitinib, crizotinib, pemetrexed): HTA;
Sofosbuvir in Chronic Hepatitis C: HTA;
Drugs in the treatment of prostate cancer (cabazitaxel, enzalutamide, abiraterone)
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
- Prognostic tests for breast cancer recurrence
- 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
- Intravenous Immunoglobulins in MCI and Alzheimer disease
- Structured Telephone Support (STS) in adults with chronic heart failure
- Duodenal-jejunal bypass sleeve (EndoBarrier®) for the treatment of obesity with or without type 2 diabetes
- Transcatheter mitral valve repair in adults with chronic mitral valve regurgitation
- Canagliflozin for the treatment of Diabetes Mellitus Type 2
- Ramucirumab (Cyramza®) in combination with Paclitaxel as second-line treatment for adult patients with advanced gastric or gastro-oesophageal junction adenocarcinoma
- New pharmaceuticals in Chronic Hepatitis C
Added value

• Learning by doing; possibility to recognize barriers and facilitating factors; to make further changes and improvement on European and national level

• Less time for the production of national HTA reports (the number and quality of national reports will be increased)

• National awareness and political recognition of concrete benefits of HTA

• Effective communication and cooperation with relevant policy-and decision-makers

• Improved local competence and capacity in HTA

• Increased international visibility of the participating organizations (scientific visibility through scientific papers)


Scientific publications

- European collaboration on relative effectiveness assessments: What is needed to be successful? Health Policy. 2015 Feb 7.
- 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.
Zaključak

Trajan, sustavan i održiv HTA postupak
- stvaranje potpunog zakonskog i podzakonskog okvira
- zapošljavanje stručnjaka (u punom i nepunom radnom vremenu)
- uključivanje dionika
- adekvatna financijska sredstava

Sukladno
- 2011, Article 15 of Directive 2011/24/EU
- 2013, HTA Network, 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, Strategy paper for EU cooperation on HTA; 2015, Reflection paper on Reuse of Joint Work in national HTA activities
- 2014, 67th World Health Assembly Resolution: Health intervention and technology assessment in support of universal health coverage
Hvala na pažnji!