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

- Promote the **multidisciplinary** nature of HTA

<table>
<thead>
<tr>
<th>Domain</th>
</tr>
</thead>
<tbody>
<tr>
<td>Health problem and current use of technology</td>
</tr>
<tr>
<td>Technical characteristics</td>
</tr>
<tr>
<td>Safety</td>
</tr>
<tr>
<td>Clinical effectiveness</td>
</tr>
<tr>
<td>Costs and economic evaluation</td>
</tr>
<tr>
<td>Ethical analysis</td>
</tr>
<tr>
<td>Organisational aspects</td>
</tr>
<tr>
<td>Social aspects</td>
</tr>
<tr>
<td>Legal aspects</td>
</tr>
</tbody>
</table>
HTA Type

- Single Technology Assessment, STA
- Multiple Technology Assessment, MTA
Aims

- To contribute to policy-making, strategic planning, management and the implementation of technologies in health care
- To contribute to decision on funding (reimbursement) and investment/planning
- Bridge between research and decision-making
## Relationship between EBM, CER, and HTA

<table>
<thead>
<tr>
<th>CAN IT WORK?</th>
<th>DOES IT WORK?</th>
<th>IS IT WORTH IT?</th>
</tr>
</thead>
<tbody>
<tr>
<td>CER</td>
<td></td>
<td></td>
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<tr>
<td>↓</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Evidence development</td>
<td>EBM</td>
<td>HTA</td>
</tr>
<tr>
<td>→</td>
<td>→</td>
<td>↓</td>
</tr>
<tr>
<td>Clinical guidelines</td>
<td></td>
<td></td>
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<tr>
<td>↓</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Patient level decision making</td>
<td></td>
<td>← EB policy and decision making (coverage, reimbursement, investment...)</td>
</tr>
</tbody>
</table>
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 Agency for Quality and Accreditation in Health

- 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, and 3) Department for Development, Research and HTA
- Formal activities in the field on HTA actually began in October 2009
Legal framework on HTA

Act on Quality of Health Care, 2007

- The Agency should provide the procedure for and database on HTA
First experience in Croatia (from October 2009)

International collaboration and support were established

- Membership in international society, HTAi

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

**WP8: Strategy and Business Model Development**
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

2 special lines of activities

- *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)
First experience in Croatia from October 2009 (cont.)

Two meetings were organized;

- a meeting with international experts for main HTA users (January 2010)

- HTA symposium during the 1st Croatian congress on pharmacoeconomics and outcome research with international participation (April 2010)
The Project documentation (TAIEX, Twinning) for training on HTA users and producers, further capacity building, and internships in European HTA Agencies is under development.

Together with established multidisciplinary HTA Working Group, Agency started the preparation of Croatian HTA Guidelines, Conflict of Interest Form, and Guidelines for transparent topic selection process, with the aim to produce first Single Technology Assessment (STA), with international peer review process.
Challenges and possible solutions
I Challenges for building HTA institutional and technical capacity

- a lack of qualified personnel, funds, educational and training opportunities in HTA
## HTA agencies and units in Europe:
Austria, Belgium, Denmark, Finland, France, Irland, Italy, Germany, Hungary, Latvia, Netherland, Poland, Spain, Sweden, UK, Norway, Switzerland

<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)</td>
<td>4.4</td>
<td>1</td>
<td>1 (out of three planned in 2009)</td>
</tr>
</tbody>
</table>
Importance of adequate legal framework

- Changes required (Amendment or Ordinance on HTA: responsibility for final decision about topics, assessment priorities, contribution to decision on funding (reimbursement) and investment/planning, cost-effectiveness threshold?)
HTA should be recognized as an important tool to support governments and other stakeholders involved in decision making about *investment opportunities* as well as *disinvestment opportunities*.

All stakeholders should invest in HTA capacity building.

**HTA network:** Appropriate *national and international collaboration* with independent academic and scientific institutions, Cochrane centers, HTA agencies that *each run part of HTA report* (combination of internal and external HTA process).

EU Project (Twinning and TAIEX, EUnetHTA project)
II Training and education on HTA

- **Permanent HTA courses** for „HTA users“ and „HTA doers“
  - For “HTA users”: basic courses for decision makers at all levels and for Appraisal Committee members for critical appraisal of evidence and understanding a HTA reports
  - For “HTA doers”: basic and advances courses for their continuous education

- **European curriculum** as a basis for training and education on HTA at University level (basic modules at undergraduate and whole modules at postgraduate study-MSc)

- **Network model** among Universities and HTA Agencies that *each run part of educational programme* (e-learning model as part of curriculum)

- TAIEX, Twinning Project, EUnetHTA Project
III Adopting HTA to use in local setting (already published HTA reports including core HTA reports)

- Should be written in English language
- Greater international collaboration for openly sharing reports and methodology
- Should be mentioned in national guidelines on HTA
- Adequate training for establishing skills on adaptation methods
- Clinical and some epidemiological evidence is usually considered transferable, economic studies cannot (the use of general models populated with local data considering limitations and adaptations)
IV HTA and reimbursement

- Adequate legal framework, capacity and resources for independent, timely, transparent, scientific, evidence-based HTA report
- HTA reports on drugs, medical devices, and other technologies as well
- Transparent topic selection (setting assessment priorities, importance for adequate criteria)
- Transparent and timely decision making process
- National cost-effectiveness threshold?
- Having an appeal process
- Independent assessment vs. critical appraisal of industry submission
- Management of conflict of interest
- How to incorporate organisational, ethical analysis and patients views into HTA?
V Health economic evaluation in HTA

- Gold standard (cost-effectiveness, cost utility analysis)
- Societal perspective vs. public payers’ perspective?
- Availability of data for health economic analyses
- Training for critical appraisal (how to read) of economic analyses and making de novo analyses

- Collaboration with established independent, public, non-profit national academic or scientific Center/Institute/Unit for health economic analyses
- Collaboration with independent, public, non-profit international academic or scientific Center/Institute/Unit for health economic analyses
The way for establishing a transparent, scientific, independent evidence-based HTA process in Croatia will not be an easy and quick process, but with all ongoing cooperation and collaboration activities we are sure in our success.