
Health Technology Assessment (HTA) in Croatia- Institutionalization and first experience

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HTA

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

- n To contribute to policy-making, strategic planning, management and the implementation of technologies in health care
 - n To contribute to decision on funding (reimbursement) and investment/planning
 - n Bridge between research and decision-making
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Croatian health care system

- n Population of 4.4 million, GDP per capita 12.000 US\$
 - n Based on the principles of social health insurance, financed from several sources
 - n A major part of the Croatian health system is financed according to a national health insurance model
 - n The agreement and payment of the mandatory health insurance is conducted through the Croatian Institute for Health Insurance
 - n a small number of health services are paid through additional health insurance from private insurance companies
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Ministry of Health; responsible for 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; and (3) regulation of capital investments in health care providers in public ownership

Croatian Health Insurance Institute; public body, responsible for managing the Health Insurance Fund and contracting health care services; plays a key role in the definition of basic health services covered under statutory insurance, the establishment of performance standards and price setting for services covered by the Institute

The Drug and Medical Products Agency,

established in 2003 under the Drug and Medical Products Act, main activities:

- n authorization and quality control of medicinal products
 - n regulation of medical devices
 - n monitoring of adverse reactions on drugs, vaccines and medical devices
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February 2006, Strategy of the development of the Croatian health care system 2006 - 2011

- n The **importance of HTA** and evidence-based decision-making in Croatian medicine
 - n **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**
 - n 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)
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Institutionalization of Agency for Quality and Accreditation in Health

- n Established under the Act on Quality of Health Care in 2007 as legal, public, independent, non-profit institution
 - n Three departments: 1) Department for Quality and Education, 2) Department for Accreditation in Health, and 3) **Department for Development, Research and HTA**
 - n Formal activities in the field on HTA actually began in October 2009
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Legal framework on HTA

Act on Quality of Health Care, 2007

- n The Agency should provide **the procedure** for and **database on HTA**
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28 December 2009 new 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

- n HTA is not mentioned in this process
 - n If desired, the applicant may submit a proposal and analysis of cost-effectiveness
 - n Request for Budget Impact Analysis, and available published health-economic studies (including Budget Impact Analysis, studies of the cost of illness, studies of the cost effectiveness, etc.)
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First experience in Croatia (from October 2009)

International collaboration and support were established

- n Membership in international society, **HTAi**
- n Agency's appointment (by Croatian Ministry of Health) and participation in **EUnetHTA Joint Action** as a **EUnetHTA Partner**

WP8: Strategy and Business Model Development

WP8

2 special lines of activities

n ***Facilitation of national strategies for continuous development and sustainability of HTA***

q *Section coordinated by AHTAPol (Poland)*

n ***HTA training and capacity building***

q *Section coordinated by ISCIII (Spain)*

Two meetings were organized;

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

I Challenges for building HTA institutional and technical capacity

- n a lack of qualified personnel, funds,
educational and training opportunities in HTA
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HTA agencies and units in Europe:

Austria, Belgium, Denmark, Finland, France, Ireland, Italy, Germany, Hungary, Latvia, Netherland, Poland, Spain, Sweden, UK, Norway, Switzerland

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	0.4 (for whole Agency in 2009)	4.4	1 (out of three planned in 2009)	

Importance of adequate legal framework

- n *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?)
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- n HTA should be recognize as important tool to support governments and other stakeholders involved in decision making about *investment opportunities* as well in *disinvestment opportunities*
 - n All stakeholders should invest in HTA capacity building
 - n **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**)
 - n EU Project (Twinning and TAIEX, EUnetHTA project)
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II Training and education on HTA

- n **Permanent HTA courses** for „HTA users“ and „HTA doers“
 - n 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
 - n For “**HTA doers**”: basic and advances courses for their continuous education
 - n TAIEX, Twinning Project, EUnetHTA Project
 - n **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)
 - n **Network model** among Universities and HTA Agencies that ***each run part of educational programme*** (e-learning model as part of curriculum)
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III Adopting HTA to use in local setting (already published HTA reports including core HTA reports)

- n Should be written in English language
 - n Greater international collaboration for openly sharing reports and methodology
 - n Should be mentioned in national guidelines on HTA
 - n Adequate training for establishing skills on adaptation methods
 - n 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)
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IV HTA and reimbursement

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

- n Gold standard (cost-effectiveness, cost utility analysis)
 - n Societal perspective vs. public payers' perspective?
 - n Availability of data for health economic analyses
 - n Training for critical appraisal (how to read) of economic analyses and making de novo analyses
 - n Collaboration with established *independent, public, non-profit **national*** academic or scientific Center/Institute/Unit for health economic analyses
 - n Collaboration with *independent, public, non-profit **international*** academic or scientific Center/Institute/Unit for health economic analyses
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Conclusion

- n 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
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