

IMPACT OF HEALTH TECHNOLOGY ASSESSMENT (HTA) ON HEALTH CARE QUALITY IMPROVEMENT: CROATIAN VIEW

Mirjana Huić, MD, MSc
Assistant Director

Department for Development, Research and HTA
Agency for Quality and Accreditation in Health Care
Zagreb, Croatia



Agencija za
kvalitetu i
akreditaciju
u zdravstvu



Republika Hrvatska

Outline

1. What is HTA?
2. Literature data, with positive HTA impact on health care quality and cost reductions
3. HTA in Croatia



HTA

Multidisciplinary proces

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



- A Single Technology Assessment (**STA**): a single technology for a single indication
- A Multiple Technology Assessment (**MTA**): more than one technology, or one technology for more than one indication



Aims

- As **transparent, independent, scientific, multidisciplinary, evidence-based HTA process and reports** should serve 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
- HTA should serve as **bridge between research, decision-making and high quality health care** by ***optimizing the use of healthcare resources*** to ***maximize patient outcomes***



Relationship between EBM, CER, and HTA

CAN IT WORK?	DOES IT WORK?	IS IT WORTH IT?
	CER ↓	
Evidence development →	EBM →	HTA ↓
	Clinical guidelines ↓	
	Patient level decision making	← EB policy and decision making (coverage, reimbursement, investment...)



Impact of HTA reports

Battista RN et al. The evolving paradigm of HTA: reflections for the millennium. CMAJ;1999;160:1464-7.

- **Specific indicators** of the impact of health technology assessment, such as the **diffusion pattern of a given technology in hospitals** or a **changing clinical practice pattern**, are logical outcome measures

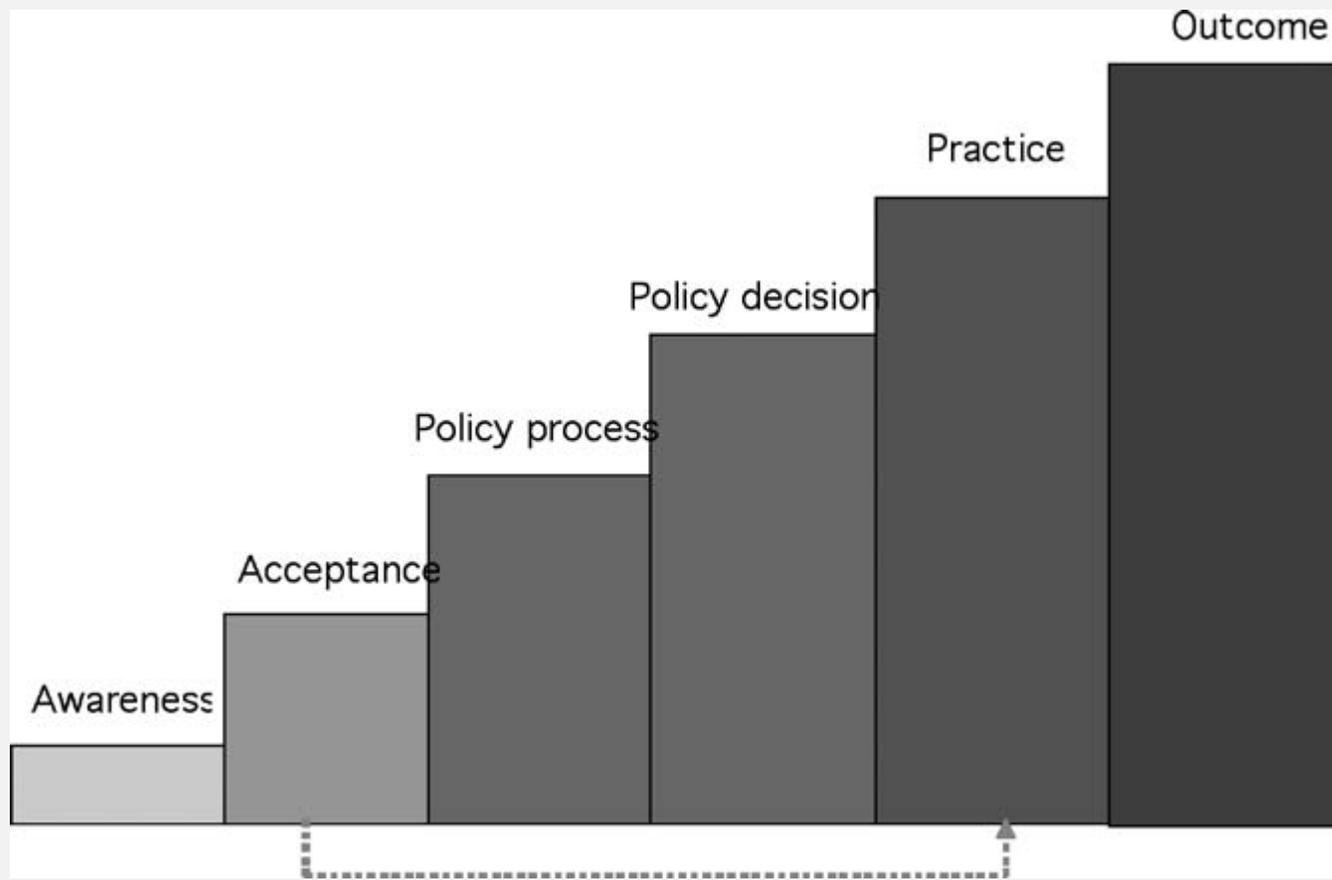
The six steps model (*Gerhardus A et al. What are the effects of HTA reports on the health system? Evidence from the research literature. HTA and Health Policy Making in Europe. WHO, European Observatory on Health System and Policies, 2008*)

- The **ultimate value of HTA** in a health system depends on **its contribution to improved health status or increased efficiency** rather than to increased knowledge
 - **The effects of HTA can be only indirect** and thus differ from other health technologies
1. **Awareness:** the corresponding stakeholder must know that the HTA is a prerequisite for influencing a decision.
 2. **Acceptance:** the report should also be useful in terms of validity, relevance and applicability and its findings acceptable.
 3. **Policy process:** the policy process within which the HTA is used (e.g. reimbursement or guideline development) should explicitly utilize the HTA report.
 4. **Policy decision:** the actual policy decision should be clearly influenced by the HTA's conclusions or recommendations.
 5. **Practice:** the policy decision has to be implemented in practice, through clear and measurable changes in clinical practice.
 6. **Outcome:** clinical practice must change before it is possible to begin to measure the true impact of an HTA, for example in terms of **health or economic outcomes**.

A limitation: final two steps will be subject to multiple influences



Hierarchical steps of the impact of HTA reports



Outcome: impact on health and economic parameters

Jacob R, McGregor M. Assessing the impact of health technology assessment. *Int J Technol Assess Health Care*. 1997;13:68-80.

- A detailed study of the impact of **21 assessments** in the **Quebec health system**: **19** reports were found to **have influenced policy**; **Cost savings** as a result of using the HTA findings: between **\$16 million and \$27 million per year**

A Case studies

Group 1 (Objective: to reduce costs)

- ***Routine Preoperative Chest Radiography***. 1991, in 55 of 118 hospitals questioned-hospital policy on routine chest radiograph before all operations
- **1992: HTA - negative recommendation**
- **1994 all but 3 of these 55 institutions had abandoned the policy of routine preoperative chest radiography**
- **In 79% of them, the HTA in question was specifically cited as a reason for their policy change**
- Assuming a unit cost of \$23 per chest radiograph, it could **be estimated that complete compliance** with this policy change would have brought about a **savings of \$7 million per year**
- **Still carried out in these hospitals before 30% of operations, the savings actually realized** would have been **\$4.9 million rather than \$7 million**

Group 2 (Objective: Optimization of Health Care System)

- It was **to optimize diffusion of the technology** in question by informing the Ministry, the principal decider, as to the **efficacy, costs, and needs for each technology** in Quebec. For example, the report on ***breast cancer screening***, which consider whether and for whom the intervention is effective, show an **important influence on the coverage policies for service**.

Jarvinen HJ et al. Controlled 15-year trial on screening for colorectal cancer in families with hereditary nonpolyposis colorectal cancer. *Gastroenterology*. 2000;118:829-34.

- In a **Finnish study of 252 HNPCC family members** without sign of disease, the **risk of CRC was reduced by 62%** in the group with **regular control colonoscopic examination of the large intestine**



Awareness:

- **Research products best known within hospital administrations, social security institutions and among different bodies of the ministry of health**
- Partial awareness among medical doctors and journalists

Acceptance:

- Research results useful to prepare negotiations by representatives of the ministry of health and of the social security institutions
- Hospital administrators: for initiating structural or organizational changes related to the use of technologies (e.g. for establishing guidelines)
- Medical professionals: partly helpful for administrative and research activities but less for direct patient work

Policy process/decision making:

- **An increasing number of decisions that are related to the inclusion of medical service items into a publicly funded hospital services basket and some vaccination programme funding decisions were justified on the basis of HTA results**

Clinical and reimbursement practice:

- Definite changes of clinical practice were identified **at the hospital level** for technologies that had been identified by the HTA-report as being oversupplied
- More restrictive inclusion of new technologies in public hospital funding is likely to result in less frequent use of those technologies
- At the **social security level** and within **hospital financing new forms of reimbursement (conditional coverage)** have been recognized

Final Outcomes:

- **Economic impact - most explicit at the hospital level (reduction of expenditure was estimated at a level of at least *several hundred million Euros*)**
- **The increasing use of evidence analyses for reimbursement decisions of new technology at the hospital level bears the potential to redistribute resources into effective and safe technologies**

Conclusions:

- **The strongest evidence: for 'awareness' and 'economic impact'**
- In terms of **target groups: strongest impact among the primary target groups of the LBI-HTA (representatives of the hospital management and hospital financing bodies, followed by social security institutions and federal bodies**



Hanney S, Buxton M, Green C, Coulson D, Raftery J. An assessment of the impact of the NHS Health Technology Assessment Programme. Health Technol Assess. 2007;11(53).

- The TARs for NICE: clearest impact on policy in the form of NICE guidance
- All the NICE TARs and more than half of the other case studies had some impact on policy making at the national level (through NICE, NSC, National Service Frameworks, professional bodies or the Department of Health)
- This underlines **the importance of having a customer or ‘receptor’ body**

Fronsdal KB et al. Health technology assessment to optimize health technology utilization: Using implementation initiatives and monitoring processes. International Journal of Technology Assessment in Health Care. 2010;26:309-16.

- The impact and use of HTA could **be increased** by ensuring **timely delivery of relevant reports to clearly determined policy receptor (decision-making) points**
- Monitoring data should be sufficiently robust so that they can be used in HTA to inform optimal use of technology
- Evidence-based implementation initiatives should be developed for HTA, to better inform decision makers at all levels in a health system about the optimal use of technology



Elshaug AG et al. Challenges in Australian policy processes for disinvestment from existing, ineffective health care practices. Australia and New Zealand Health Policy. 2007;4:23.

- Internationally, many health care interventions were diffused prior to the standard use of assessments of safety, effectiveness and cost-effectiveness
- **Disinvestment** from ineffective or inappropriately applied practices: a growing priority for health care systems (improved quality of care and sustainability of resource allocation)
- The potential **over-utilisation** of **less than effective clinical practices** and the potential **under-utilisation** of **effective clinical practices** result
 - in less than optimal care
 - fragmented, inefficient and unsustainable resource allocation
- **Systematic policy approaches to disinvestment will improve equity, efficiency, quality and safety of care, as well as sustainability of resource allocation**



Gerhardus A et al. The impact of HTA reports on health policy: a systematic review. GMS Health Technology Assessment 2005.

1. **Little experience with study designs or methods** that allow a valid assessment of the impact of HTA reports on the decisionmaking process in the health sector; the use of pre-defined indicators were identified that should be pursued and elaborated in further studies
2. Due to the **lack of a developed methodology** limited conclusions can be drawn

In order to produce evidence-based conclusions regarding the impact of HTA reports, **validated indicators should be used** (Study design should also aim at controlling for other influencing factors)

3. **None** of the studies explicitly aim at **examining the role of the factors that might be responsible for a low or high impact of the HTA reports**

(The non-systematic retrospective analyses do not allow reliable conclusions regarding the relevance of these factors: the factors identified here only serve for hypothesis formation)

- On the basis of these studies **not possible to give evidence-based recommendations on the way how to increase the impact of HTA on decision-making in Germany**

- Instead, a **concept for evaluation** should be **developed** that **combines quantitative and qualitative methods** and **considers the following questions:**

- (1) What **kind of impact** should be measured?
- (2) Which are **the target groups** and at **which level of the health system** are they located?
- (3) Which are **the outcome parameters** and **how can they be measured?**
- (4) Which are **the potential impact enhancing or limiting factors?**



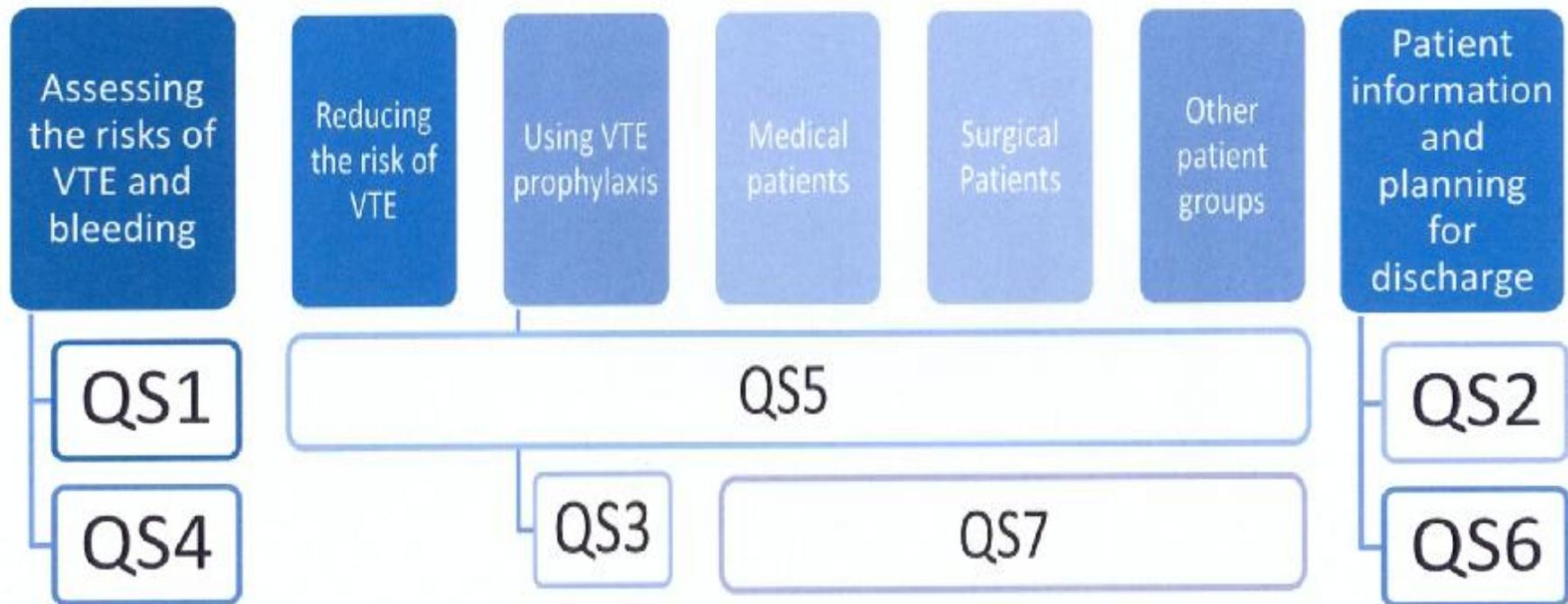
Douketis JD et al. Why A-level evidence does not make it to clinicians' A-lists: the case of thromboprophylaxis in medical patients. ACP Journal Club. 2008;149:2.

Bridging the gap between practice guideline recommendations and their uptake in everyday clinical practice: "knowledge translation"

- Each year, more than 6 people in every 1000 will develop DVT, 1 will die from pulmonary embolism (PE) - more deaths than from breast cancer, AIDS, or motor vehicle accidents
- DVT is easy to prevent and treat
- In contemporary audits of DVT prophylaxis practices, **65% to 83% of hospitalized medical patients at risk for DVT were not receiving prophylaxis**
- strong A level evidence that anticoagulants should be considered in all at-risk medical patients
- evidence that low-dose unfractionated heparin and low-molecular-weight heparin are effective for prevention of DVT and PE (including fatal PE) and have acceptable safety profiles



Clinical Practice Guidelines VTE: reducing the risk - Areas of Care Map and Quality standards (NICE, 2010)



HTA in Croatia

- 2006, **Strategy** of the development of the Croatian Health care system 2006 – 2011
- **Act on Quality of Health Care, 2007**, The Agency (as legal, public, independent, non-profit institution, three department), should provide **the procedure** for and **database on HTA**

Health technologies: pharmaceuticals, medical devices, diagnostic and screening techniques, surgical procedures, other therapeutic technologies and procedures, and health promotion activities

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?)

- **Ordinance** regarding reimbursement on drugs (*Official gazette No. 155/09*) and Ordinance regarding reimbursement on medical devices (*Official gazette No. 138/09*): not mentioned HTA process and role of HTA Department
- **Plan and program** of measures for insurance, improvement, promotion, and monitoring of health care quality, October 2010.
- **Department for Development, Research and HTA:** **formal activities** in the field **on HTA** actually began in **October 2009**



International Projects in the framework of the Second Programme of Community Action in the Field of Health (2008-13)

EUnetHTA Joint Action Project (2010-2012)

- EUnetHTA JA: co-funded by the European Commission and participating organizations during a period of 3 years, 2010-2012
- **Aim:** including work on **relative effectiveness of pharmaceuticals**, to put into practice an effective and sustainable HTA collaboration in Europe that brings added value at the European, national and regional level
- The EUnetHTA JA grant agreement was signed by the EU Executive Agency for Health and Consumers (EAHC) and the Coordinator (National Board of Health of Denmark) on behalf of 33 partners in 23 EU Member States and Norway
- Croatia participated as **EUnetHTA Partner**, as newly admitted organization in March 2010, financed outside of the EUnetHTA JA budget, with active scientific input in two Works packages, and voting rights on Plenary Assembly

EUnetHTA Joint Action 2 Project (2012-2014)

- EUnetHTA JA2 will be co-funded by the European Commission and participating organizations during a period of 3 years, 2012-2014 (decision in Sept 2011)
- **Aim:** to facilitate *collaborative production* of **Core HTA** and *different types* of **HTA Reports** on relative efficacy or short and long term effectiveness when applicable, to **avoid duplication** of assessments through timely, scientific, transparent, unbiased, objective, independent process, with appropriate stakeholders consultations
- HTA JA2 - test all possible models of collaboration, because JA output will **prepare ground for future establishment of a regular European HTA Network** according **Cross Border Health Care Directive**
- Croatia will participate as **Associated Partner (inside EU funds)**
- Indicative amount: 6.600.000€ (EU co-funding 70%)





eunethta

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

EUnetHTA Joint Action 2010–2012 | www.eunethta.eu



Experience in HTA JA 2010-1012

- Agency's appointment (by Croatian Ministry of Health) and participation in **EUnetHTA Joint Action** as a **EUnetHTA Partner** (March 2010)

WP8: Strategy and Business Model Development (from March 2010)

- ***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)*

WP4, strand B: development of two Core HTA Report (from April 2011)

- ***SCREENING: Abdominal aorta aneurysm screening***
- ***DIAGNOSTIC: Genetic test for cancer***

WP7 New Technologies (LP – HAS, France, Co-LP – LBI-HTA, Austria)

2 Strands – WP7A: **Facilitating Evidence Generation**), WP7B: **Collaboration on (pre-coverage) assessments**

- December 2010, EUnetHTA WP 7B, invitation for “**Collaboration on new high tech interventions in hospitals**“

Topic: ***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.

VASCULAR-ENDOTHELIAL-GROWTH-FACTOR-INHIBITORS (ANTI-VEGF) FOR DIABETIC MACULAR OEDEMA

SYSTEMATIC REVIEW

VIENNA AND ZAGREB, MARCH 2011



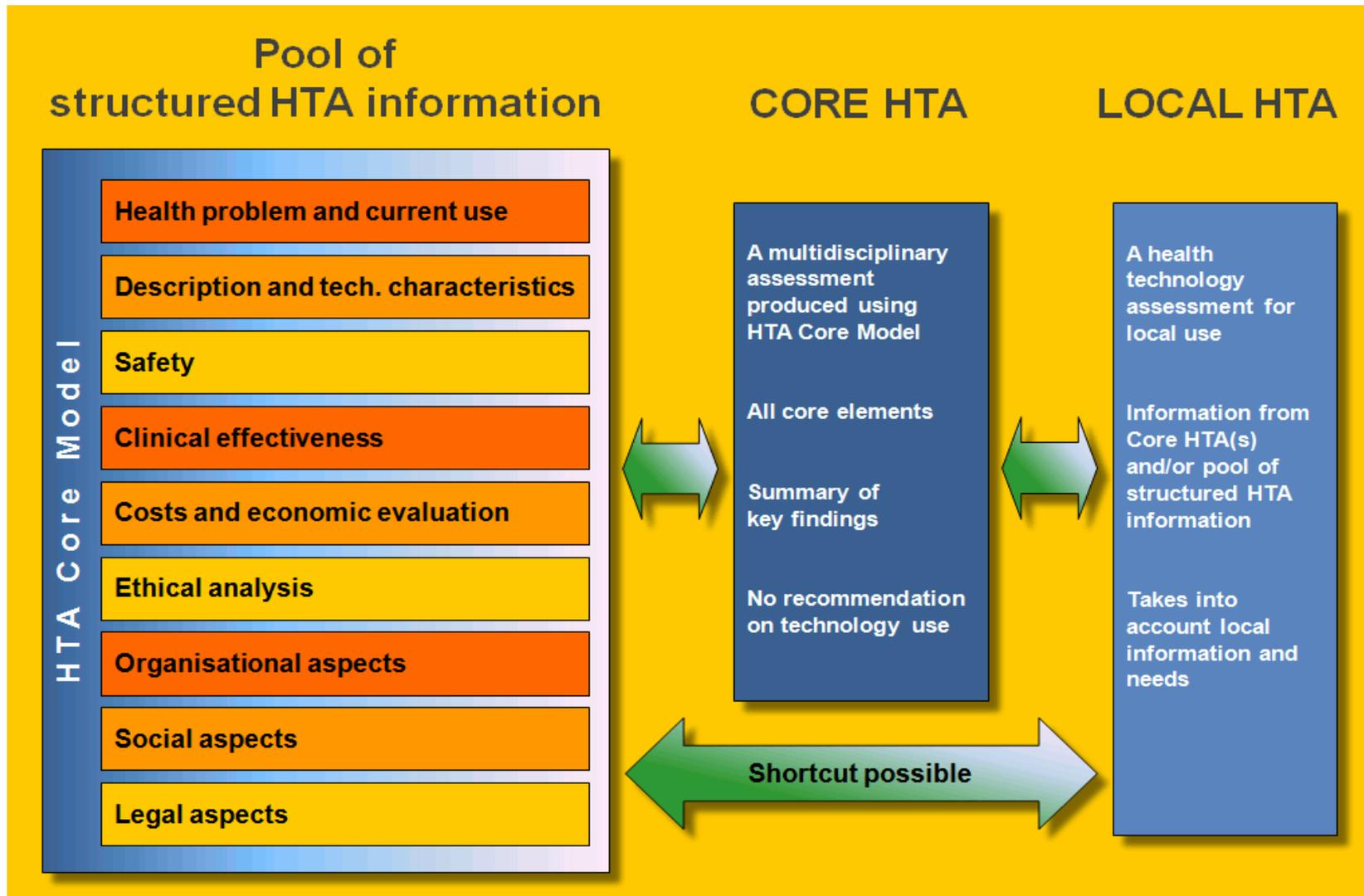
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Core HTA Structure



The Croatian Guideline for Health Technology Assessment Process and Reporting, 1st edition, February 2011, <http://www.aaz.hr/main.php?ID=21>

- **HTA Department** and **multidisciplinary HTA Working Group** (appointed by Agency for this purpose)

- **Content**

- I Introduction and legal framework**

- II HTA process**

- 1 Topics suggestion and selection process**

- 2 Scope prepared**

- 3 Assessment process**

- 4 Appraisal (Advice) 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: **Code of Practice for Declaring and Dealing with Conflicts of Interest in HTA process**

- Appendix III: **Authorship Statement**

- Appendix IV: **Selected data sources on Croatian population health, healthcare resource use and costs**



DIRECTIVE 2011/24/EU OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL of 9 March 2011 on the application of patients' rights in cross-border healthcare

Article 15 - Cooperation on health technology assessment

- 1. The Union shall **support and facilitate cooperation** and **the exchange of scientific information** among Member States **within a voluntary network connecting national authorities or bodies responsible for health technology assessment** designated by the Member States. *The members of the network shall participate in, and contribute to, the network's activities in accordance with the legislation of the Member State where they are established.* That network shall be based on the principle of **good governance** including **transparency, objectivity, independence of expertise, fairness of procedure and appropriate stakeholder consultations.**
- 2. The objectives of the health technology assessment network shall be to:
 - a) **support cooperation** between **national authorities or bodies**; b) support Member States in the **provision of objective, reliable, timely, transparent and transferable information** on the **relative efficacy** as well as on the **short- and long-term effectiveness, when applicable, of health technologies**, and to enable **an effective exchange of this information** between the national authorities or bodies; c) **support the analysis** of the nature and type of information **that can be exchanged**; d) **avoid duplication of assessments.**



3. In order to fulfill the objectives set out in paragraph 2, **the network** on health technology assessment **may receive Union aid**. Aid may be granted in order to:

- (a) contribute to the financing of administrative and technical support;
- (b) support collaboration between Member States in developing and sharing methodologies for health technology assessment including relative effectiveness assessment;
- (c) contribute to the financing of the provision of transferable scientific information for use in national reporting and case studies commissioned by the network;
- (d) facilitate cooperation between the network and other relevant institutions and bodies of the Union;
- (e) facilitate the consultation of stakeholders on the work of the network.



4. The Commission shall, in accordance with the regulatory procedure referred to in Article 16(2), adopt the necessary measures for the establishment, management and transparent functioning of this network.
5. Arrangements for granting the aid, the conditions to which it may be subject and the amount of the aid, shall be adopted in accordance with the regulatory procedure referred to in Article 16(2). **Only those authorities and bodies in the network designated as beneficiaries by the participating Member States shall be eligible for Union aid.**
6. The appropriations required for measures provided for in this Article shall be decided each year as part of the budgetary procedure.
7. Measures adopted pursuant to this Article **shall not interfere with Member States' competences in deciding on the implementation of health technology assessment conclusions** and shall not harmonize any laws or regulations of the Member States and shall fully respect the responsibilities of the Member States for the organization and delivery of health services and medical care.



Conclusion: future Croatian HTA perspective on national and EU level

- The way for establishing a **transparent, scientific, independent, evidence-based HTA process** in Croatia **not an easy and quick process**
- Croatia - **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 of ***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!

mirjana.huic@aaz.hr

- Conflict of interest: None

