National HTA Strategy for Lithuania
(Focus Medical Devices)

Vilnius/ Lithuania
Aug. 5th 2015
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2 Preliminary remarks
Only a contribution from external experts. Ownership must be taken by YOU. suggestions, propositions.....
Mode of Decision-making = Part of Culture

“To introduce HTA in the decision-making process is like cultivating a garden in a snowstorm.”

(Günter Jonitz, President of the Berlin Chamber of Physicians, Oct. 28th 2009)

To reflect about HTA strategy for MedDevices (only) is contradiction!
HTA

HTA is part of medical & political (decision-making) culture of a country.

Changes from single expert to evidence-based decision-making of culture take years
(e.g. 10 years UK, 15 years Austria)
Good arguments for HTA

- Economic pressure: prioritization
- Cost-containment, cost-savings
- Improvement of Public Health (not only individual health)

Showcase projects !!!

e.g. Avastin vs. Lucentis
Overview

1. Health Technology Assessment
2. Introduction to National HTA Strategy
3. Methodology
4. Results
5. Recommendations and Activities
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EUnetHTA

Definition of HTA

Its aim is to inform the formulation of safe, effective, health policies that are patient focused and seek to achieve best value.

Despite its policy goals, HTA is always firmly rooted in research and the scientific method.

(European Network for Health Technology Assessment EUnetHTA 2006)
HTA vs. decision

- **HTA** = support for rational decision-making

- **Decision** = value-judgement (thresholds for appropriateness, need vs. demand, „enough“ benefit for the costs)
HTA vs. decision

HTA does NOT replace (sometimes difficult) decisions, but makes argumentation under pressure from interest groups much easier.

HTA „opens eyes“ – effectiveness and relation benefit-risks (and not economics) is in the centre.

HTA requires a certain „civilized courage“ to question medical authorities/ industry and requires creativity to invent new policy instruments to implement HTA.
HTA: in arm’s lengths

HTA ist „only“ (academic) paper without counterpart „user of HTA“ (decision maker), willing and having the power to change something.
HTA

Be aware:
HTA is full of conflicts

Powerful interest-groups are protecting large spheres of interest and lucrative markets
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Lithuania and HTA

- 1993: Swedish Council on Health Technology Assessment
- 1999: World Bank
- 2013 – 2015: EU funded projects for capacity building at SHAA and IoH
- 2014: Establishment of MoH HTA Committee (in response to government action plan)
Strategy

- Plan to achieve (one or more) goals
- Comprehensive way to try to pursue these ends
- Involves the setting of goals
- Determining of actions to achieve those goals
- Mobilizing of resources to execute these actions
Broad aims of National HTA Strategy

- Establish a solid and comprehensive (so called “evidence-based”) foundation for decision making for the introduction and utilization of health technologies at all levels in the health care system;

- Ensure that HTA becomes an integrated part of routine decision making for planning and operational policy within the health care system.

(WHO. Health for All Targets: The Health Policy for Europe. 1991)
Narrower aims of National HTA Strategy

- Establish a framework to promote (enforce, facilitate) HTA uptake.
- Establish organizational structures for the timely, efficient and good-quality provision of HTA information that satisfies needs.
- Increase acceptance and demand for HTA information by offering tailor-made services.
- Boost the use of HTA information.
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Analytical framework: international and national

Analysis of
1. Legal framework and regulatory context of decision-making
2. Utilization of HTA in health care and barriers
3. HTA institutionalization and financing
4. Human resources and capacity building
5. HTA processes and products, special focus assessment of medical devices
Methodologies

- Literature review for examples from countries
- Detailed analysis of Lithuanian system: institutions, regulations, processes, HTA (national experts: M. Stricka, L. Karnickas)
- 19 interviews with Lithuanian decision-makers (14: MoH and subordinate institutions - NHIF, SHAA, IoH, SMCA, University Hospitals; 2: academia, 3: experts on health system)
Endproducts (Aug 15th)

- 1 Background Analysis (see above) 90 pages, English
- 1 Booklet with recommendations and proposed activities, English + Lithuanian, 10 pages each language
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General

• It is all there: but it is not filled with life!
• Highly centralized system, regulations in place, decision-makers are aware and mostly positive = ideal setting
In Detail
Legal framework and regulatory context of decision-making

- **INT:** Regulatory environment for role of HTA essential

- **INT:** Most impact of HTA if conducted for concrete decisions

- **LT:** Regulatory instruments for Drug + MedDev approval and reimbursement (in-/exclusion in benefit catalogue) are in place, Planning of Big Equipment + PH-interventions (service licensing) in infancy = no need for further regulations, but for introducing HTA in existing processes

- **LT:** HTA activities are in their early stages and fragmented. No proof of concept projects.
Utilization of HTA in health care and barriers

INT: Wide range of applications of HTA for decision support

LT: 3 (-4) most important HTA-utilizations

- Input to benefit-catalogues + positive lists
- Relative Effectiveness Assessments of (e.g. PH-interventions)
- Planning + localization of specialized services (neurosurgery, onco-services)
- Disinvestment from obsolete interventions
Health Policy Information Needs

- In-/exclusion of single interventions to benefit catalogue
- Relative effectiveness of alternative interventions
- Planning and placement of devices/services
- Dis-Investment of obsolete interventions
- Quality improvement
- Appropriate use of medical interventions
- Procurement of new technologies
- Controlled diffusion: coverage with evidence development
Barriers to Utilization of HTA

Challenge: transition from “eminence based” (selective/ biased) to “evidence based” (systematic, unbiased)

INT: To overcome barriers, HTA needs to be

- timely
- of good quality (“waterproof”)
- with clear messages
Barriers to Utilization of HTA

LT: Barriers for HTA are lack of
- Clear and transparent HTA process and place of HTA in existing decision-process
- Coordination of demand for knowledge and supply
- Independence of HTA doers (no distance)
  - from policy makers
  - from regulators
  - from industry
HTA institutionalization and financing

- **INT**: No ONE “best practice model” of HTA institutionalization: many forms of organizations exist
- **INT**: Credibility of HTA depends on independence from interest groups
- **INT**: Critical requirement: stable funding
HTA institutionalization and financing

LT: Need for mechanisms to safeguard independence

- clear and transparent process descriptions
- monitoring of the scientific quality of HTAs
- external peer-review for all HTA products
- separation of recommendations based on an HTA and the policy decision
Human resources and capacity building

**INT:** Sufficient national capacities to carry out HTA and implement it necessary for evidence-based decision making

- HTA core staff
- Training to understand and implement HTA for policy makers, clinicians and health care managers
- Academic research capacity in HTA methodologies
Human resources and capacity building

LT:

- SHAA and IoH have “some” core staff (juniors and seniors with training)
- But in need for sufficient funding to keep them
- Need for further (advanced) training could be nationally satisfied by academic HTA modules
- European Collaborations! (networking, partnering, exchanges etc.)
HTA processes and products, special focus assessment of medical devices

INT: Transparency of HTA process and products of utmost importance:

**HTA-Process:** prioritization of topics, scoping: policy question/ research question etc. ..........recommendation, decision....

**HTA-results** must be valid, reliable, open to scrutiny
HTA processes and products, special focus assessment of medical devices

LT lacks many **steps in the transparency in processes and results**, e.g.

- Prioritization
- Quality assurance (peer review)
- CoI/ Conflict of Interest management
- Safeguarding independence
- Publication of results
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Narrower aims of National HTA Strategy

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Strategic objectives

1. Regulatory embedding, ensuring legitimacy of HTA
2. Organization of HTA: institutionalization + financing, national coordination
3. Quality assurance of HTA: transparency in processes and products
4. Capacity building: national activities and European collaboration
Regulatory embedding, ensuring legitimacy of HTA 1/2

Recommendations

- Bring existing HTA regulations to life, and to analyze obstacles for their implementation
- Prioritization according to transparent criteria
- HTA closer to actual payers (NHIF)
- Governance structures to safeguard independence
Regulatory embedding, ensuring legitimacy of HTA 2/2

Activities

- Minister of Health approves HTA Strategy with order
- Analysis of obstacles to implementing existing HTA regulations
- List of pending program or policy decisions, prioritization for HTA
- Separation of functions (policy/ funding, regulatory, HTA)
Organization of HTA: institutionalization + financing, national coordination 1/2

Recommendations

- HTA Coordinator with defined tasks and responsibilities, accountabilities
- Stable, long term funding (position in HC budget)
- Stepwise integration of all national HTA activities
- Enforce HTA at SMCA, develop HTA for planning of specialized services
Organization of HTA: institutionalization + financing, national coordination 2/2

Activities

- Continued funding of EU project staff at SHAA, IoH
- Define task of HTA Coordinator in support of MoH HTA Committee, annual reporting
- Build up HTA-unit at SMCA – EUnetHTA submission templates
- Involve academia: Identify local HTA champions for challenging projects (evidence-based planning)
Quality assurance of HTA: transparency in processes and products 1/2

Recommendations

- Implement transparent HTA process
- Wide communication and inclusion of stakeholder (clinicians, public, media)
- Implement quality criteria
- Implement clear criteria for topic priorities
- Minister of Health reports to public on implementation of HTA recommendations
Quality assurance of HTA: transparency in processes and products 2/2

Activities

- National HTA methods handbook, cross-reviewing within all HTA-groups, peer-review standards/-database etc.
- Public websites with all HTA reports (from all institutions)
- Action plan for communicating and implementation of results for each HTA report
- Monitoring of international HTA activities and reporting to MoH, NHIF
Capacity building: national activities and European collaboration 1/2

**Recommendations**

- Keep trained expert in public sector and in LT
- Stay up to date on current HTA projects (EUnetHTA POP-database)
- Actively participate in international HTA collaborations
- Capacity building for teaching and research at LT universities
Capacity building: national activities and European collaboration 2/2

Activities

- Train in-house capacity: 1-2 seniors per institution to guide juniors in each institution doing HTA
- International exchanges of staff
- Offer 1 day courses for Hospital Manager, Clinical Managers, NIHF-Manager, etc.
- Introduce Evidence-based medicine and HTA in the basic curriculum of medical schools
Implementation of HTA Strategy

Success of HTA Strategy: health sector stakeholders increasingly take ownership

Prerequisite: HTA champions need to begin with „sexy (controversial) projects“
- Media and young clinicians as collaborators

But: Change of culture takes time and has to overcome resistance
Eventually transparent, reliable and replicable HTAs develop their own convincing language and begin to speak for themselves.
Questions, Discussion, Ideas!
Contact

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