HTA scientific network with HTA bodies, payers and patients



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Agencja Oceny Technologii Medycznych i Taryfikacji (AOTMiT) The Agency for Health Technology Assessment and Tariff System

From evidence to setting standards and improving quality



Best evidence available
Clinical Trials and Evidence Reviews

Health <u>Technology</u> Assessment

Clinical Guidelines / Disease Management

Care Quality Standards

System Quality measures

Agenda



- Health-care system of Poland at glance
- Network of stakeholders
- Role of HTA process in reimbursement of medicines and beyond
- Large-scale HTA-driven processes
- Summary

Poland in numbers

Total area: 312,679 km²

 Population: ca. 38,4 mln (December 2016)

- Member of the EU since 2004
- GDP per capita: 43 334 PLN (ca. 10 834 \$)
- About 7% of GDP allocated to health (4,5% comes from public sources)



Fundamentals of the health care system in Poland



- Poland's health care is based on a general health insurance system
- **Subsidized health services** are provided to Polish residents that are covered by the general health insurance. This can be either on a compulsory or a voluntary basis.
- Insured category usually means that those residents have their health insurance paid for by their employer, or are the spouse or child of an insured person
- Private healthcare use is very extensive in Poland
- **Private expenditure** (estimated as 30% of the total health expenditure) is mainly out-of-pocket payment with minor supplemental role of private insurance and quasi-insurance
- The **National Health Fund** (NFZ) the sole payer in the system is in charge of health care financing and contracts with public and non-public health care providers
- Around 70% of health expenditure came from public sources
- Compulsory health insurance covers 98% of the population and guarantees access to a broad range of health services
- However, the limited financial resources of the the three t





Launching AOTM by ordinance of MoH June 2009
Act on Health
Care Benefits
(HCB)

01 Jan 2012 Reimbursement Act

Reimbursement & HCB Acts update

2005 (in line with Dir 89/105/EEC*) coverage/ desinvestment rules per capita

eg. new task for AOTM – tariffication, guidelines, services

^{*}Council Directive 89/105/EEC of 21 December 1988 relating to the transparency of measures regulating the pricing of medicinal products for human use and their inclusion in the scope of national health insurance systems

Major players in the system

Ministry of Health



- Regulatory function
- Defining the guaranteed benefit basket
- Budget for highly specilized services (e.g. transplants) or obligatory vaccinations
- National health programmes

Agency for HTA and Tariff System



- HTA for
 - drugs
 - medical devices
 - other health care services
- Setting tarrifs for health care services
- Health care programmes assessment (governement, local authorities)

National Health Fund



- Head office and 16 regional branches:
- Planning and dividing budget
- Contracting health care providers
- Paying to health care providers
- Controlling the health services providers compliance with regulations

Stakeholders involvement in HTA assessment process





Others

- associations of health care providers (PFSz, WSCO, etc.)
- publishers of evidence-based translations (mp, viamedica, etc.)
- analytical institutes (CMJ, Łazarski, WUM, SGH, UJ, CMPK etc.)
- Consulting agencies

Transparency Council (TC)

 Members (20 people): medical experts, representatives of payer (NHF), The Office for Registration of Medicinal Products, The Commissioner for Patients' Rights

Responsibilities:

- a well justified statement, whether a drug, a food product for special dietary purposes or a medical device should/should not be financed of public funds;
- wording of detailed conditions for reimbursement :
 - · the proposed payment level,
 - proposals regarding inclusion to the existing or establishing a new limit group,
 - remarks and proposals to the description of a drug programme, if applicable,
 - remarks on proposal of risk-sharing instruments
- Transparency Council statements constitute the basis of AOTMiT's President recommendations

Council for Tariffs Affairs of AOTMiT (CTA)

- Launched in January 2015 The Act of Law (amendment to the Act on healthcare benefits financed from public funds) added new task related to setting the tariffs for health care services.
 According to Tariff Plan accepted by the Ministry of Health, the contracted products from the list of health care services under the benefit basket will be correspond to relative values (points), not in absolute values (PLN).
- In the area of creating the health care services tariff system, the activities of AOTMiT (in close cooperation with the CTA) consist of:
- Establishment of reference product/procedure/treatment/service,
- Establishment the relationship of particular medical product to the reference product/procedure,
- Cost calculation (outliers being rejected),
- Transformation of cost data onto tariff (point).



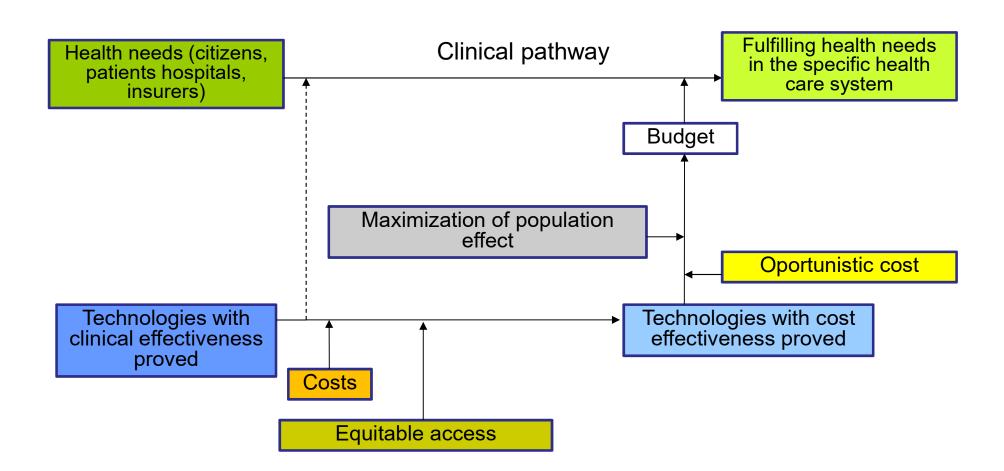
The Economic Committee



- The Economic Committee which is attached to the Ministry of Health and is responsible for negotiating with pharmaceutical companies the official sales prices for reimbursed drugs, levels of patient co-payments, and indications for reimbursement.
- Makes recommendations regarding:
 - the level of reimbursement (this can either be (a) 100% reimbursement with no patient co-payment, i.e. free of charge; (b) a flat fee; or (c) partial reimbursement – 70% or 50%), depending on the cost and duration of treatment;
 - differences in the reimbursement level, e.g. lower drug prices for certain population groups; and reimbursement period (2, 3 or 5 years).
- According to the Act, reimbursement decision has to be made on the basis of scientific evidence.

The place of HTA in health care systems





Model of health care services description (covering all the elements of a health services description)



Name of guaranteed service -Service code -Additional description of the service	I. Terms of entitlement to health service	
	Formal requirements	Referral issuer
		Required type and scope of referral
		Included medical tests
		Other conditions
	Inclusion criteria	ICD-10 code / other classification
		ICD-10 description / other classification
		Additional description
	Exclusion criteria	ICD-9/10 code and name / other classification
		ICD-9/10 description / description of the reason for
		exclusion
		Additional description
	II. Scope of service	
	ICD 9 code / other classification	
	ICD 9 description / other classification	
	Time frame for performance of the service	
	Accompanying services	
	III. Terms of services performance	
	Place of performance	
	Medical equipment supply	
	Medical personnel	
	Quality conditions for the performance of the service	
	Additional terms	
	IV. Networking criteria	
	Population criteria	
	Geographical criteria	
	V. Conditions for monitoring the effect of service	
	Indicators for monitoring the safety and effectiveness of diagnosis and treatment	
	Scope and form of rep	oorting or data reporting by healthcare providers

Analytical-consultative process in the qualification of health care services as guaranteed





Minister of Health

(commission) \downarrow

Stage I - Analytical process:

Agency for Health Technology Assesment and Tariff System



- 1. Decision problem analysis (scoping)
- 2. Clinical analysis
- 3. Economic analysis
- 3. Impact on the health care system analysis

Examples:

Stage II – Consultation process

- Working Stakeholders consultations
- Strategic consultations (optionally)
- Consultation of the full report (*obligatorily*)

Stakeholders organisations/ ---->
Providers





Main **institution** in the → health care system



► 1. National colsuntants

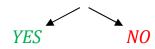
2. President of National Health Fund (NHF)



(submission of the report)

Stage III Transparency Council

Stage IV Recommendation of the Agency's President



Developing and implementing guidelines for health policy and clinical

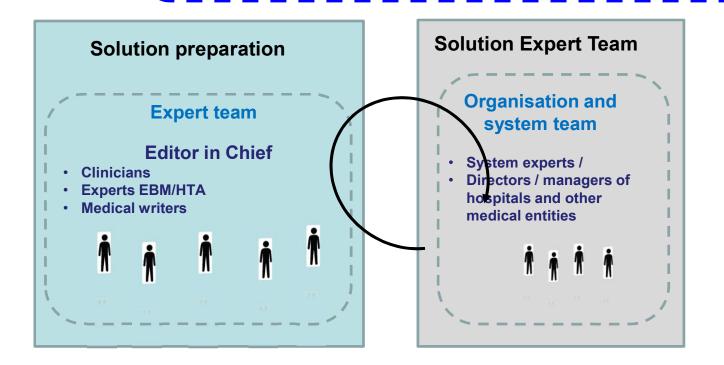




AOTMiT Project Team







Solution strategic consultations



- **National Health Fund**
- Professionals
- Patients

Organisation of work in the medical rehabilitation project

Structure concept of the team











Solution preparation

Experts team

- National Consultant
- Selected provincial consultants
- President of Polish Rehabilitation Society (PTReh)
- Professors

Analytical teams

 Clinicians with significant professional experience from different services providers

Solution stakeholders consultations

Organisation and system team

System experts / directors / managers of hospitals and other medical entities

Stakeholders organisations

- Association of Rehabilitation Physicians
- National Chamber of Physiotherapists

Solution strategic consultations

Steering Committee



- Department of Health Protection Organization
- Department of Drug Policy and Pharmacy
- Department of Health Insurance



National Health Fund

Social Insurance Institutions



State Fund for the Rehabilitation of the Disabled

Tasks:

Representing the strategic objectives of each institution, which should be included in the project's work
Assessing the feasibility of proposed changes implementation and developing an optimal path for them

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Dynamic and continuous process



Any knowledge that does not lead to new questions quickly dies out: it fails to maintain the temperature required for sustaining life.

Maria Wisława Anna Szymborska Polish literature Nobel Prize Winner

Summary



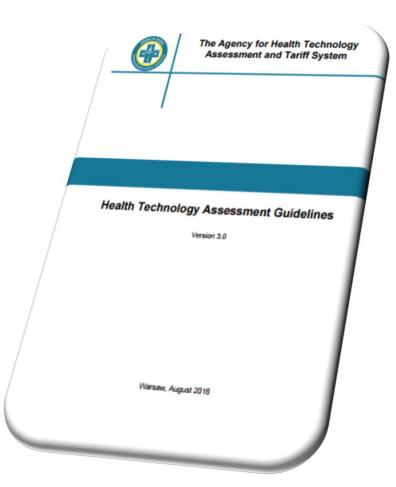
- To become a significant tool in shaping health care system:
 - HTA bodies have to achieve functional capability to carry-out strategic large-scale analytical processes
 - EBM way-of-thinking need to achieve level of understanding/internalization among critical stakeholders
- Reimbursement process for medicinal products across EU is generally based on- or supported by HTA – it's effectiveness can be used as a springboard for creation more information-driven HC system.

Polish Guidelines for HTA



- First guidelines were introduced in March 2007 (by the Ordinance of the Director of the Agency for Health Technology Assessment)
- The purpose was to indicate the principles and basic methods of performing Health Technology Assessment to ensure high quality of analyses and reliable results
- Revisions of the guidelines:
 - April 2009
 - August 2016 English version available on AOTMiT website

http://www.aotm.gov.pl/www/hta/wytyczne-hta/





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