BUILDING HTA CAPACITY IN BULGARIA

Prof. Rumen Stefanov, MD, PhD

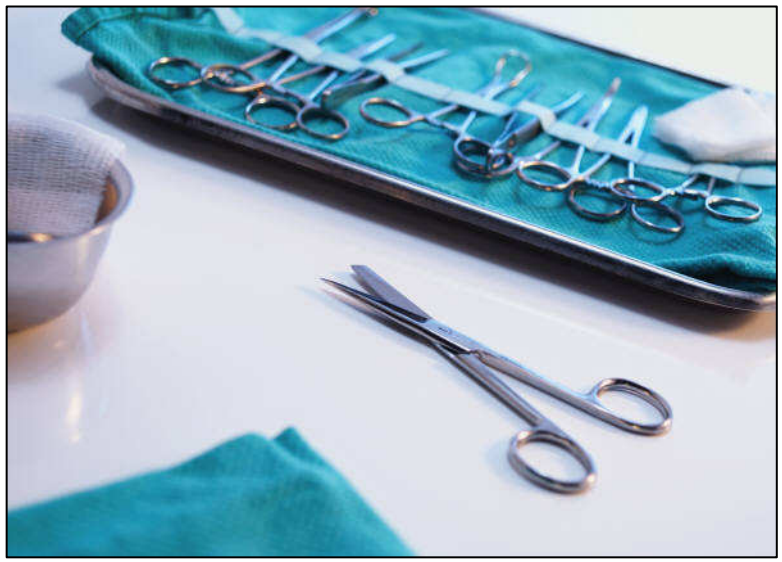
Dean, Faculty of Public Health, Medical University of Plovdiv

Director, Institute for Rare Diseases

HEALTH TECHNOLOGY

Health technology is the **practical application of medical knowledge**.

- **Material nature** (e.g., drugs, biologics, devices, equipment and supplies, medical and surgical procedures, organisational and managerial systems)
- **Purpose** (e.g., prevention, diagnosis, treatment, rehabilitation)
- **Stage of diffusion** (e.g., future, experimental, investigational, established, outmoded, abandoned)



HEALTH TECHNOLOGY ASSESSMENT (HTA)

A **multi-disciplinary process** of policy analysis that examines **the medical, economic, social and ethical implications** of the **incremental value, diffusion and use of a medical technology** in health care.

PURPOSE

Health policy decisions on use and coverage of health technologies are taken in **an informed and objective way** that is **transparent and open** to the society.

HTA is an aid to the decision-making process – it does not make decisions!

WHY HTA?

Today's challenges to public health:

- Management of health care costs
- Ethical dilemmas and societal expectations
- Support for research and innovations

PAST

«All EFFECTIVE treatments should be available to the population» *Prof. Archibald Cochrane (epidemiologist)*

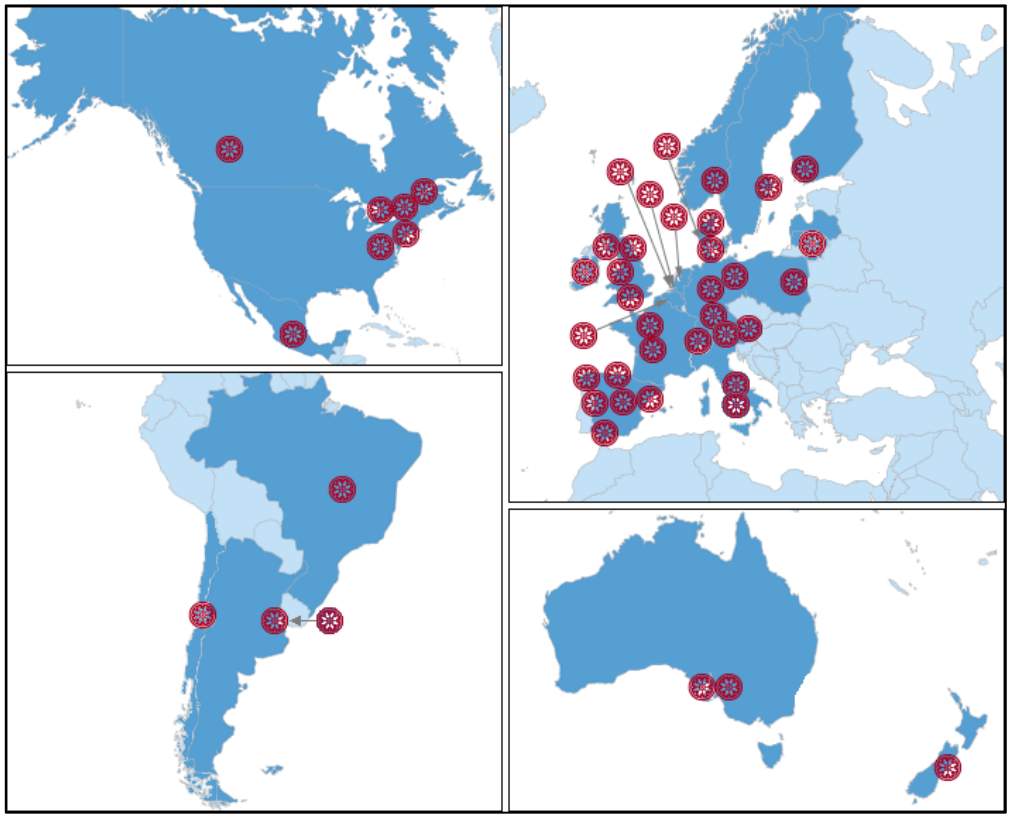
Cost containment health care reforms

Health care reforms oriented to quality and risk management

«All COST-EFFECTIVE treatments should be available to the population» *Prof. Alan Williams (health economist)*

PRESENT

HTA ON GLOBAL LEVEL
International Network of Agencies for Health Technology Assessment



INAHTA

Established in **1993** and expanded up to **57 member agencies** from **32 countries** by 2013

HTA IN THE EU
European Network for Health Technology Assessment

In **2004** the European Commission and the Council targeted HTA as **"a political priority", recognising "an urgent need for establishing a sustainable European network on HTA**".

A Commission call in 2005 led to the activities of the **EUnetHTA Project**. The consequent activities of EUnetHTA were organised through establishment of the EUnetHTA Collaboration 2009, the EUnetHTA Joint Action 2010-2012 and EUnetHTA Joint Action 2 2012-2015.

HTA IN THE EU
Organisational Dimension

MODEL	CHARACTERISTICS	COUNTRIES
Centralised and Integrated	One or more HTA bodies, operating in a national framework, integrated within the decision-making process	**UK, France, Germany, Sweden**
Centralised	One or more HTA bodies, supporting health authorities **without explicit integration in decision-making process**	**Norway, the Netherlands, Belgium**
Federal	Different HTA bodies, operating at national, regional or provincial level	**Spain**
Network	Different HTA bodies, cooperating at national, regional, provincial and local level, with a multilevel framework	**Italy**

HTA IN THE EU
Level of Powers

ROLE	CHARACTERISTICS	COUNTRIES
REGULATOR	HTA body is accountable to health authorities and is responsible for listing and pricing drugs, medical devices and other related services.	**UK, France, Sweden**
ADVISOR	HTA body makes reimbursement and/or pricing recommendations to national or regional health authorities.	**The Netherlands, Denmark**
COORDINATOR	HTA body coordinates HTA and produces reports (e.g., regional advisory bodies).	**UK, Spain**

HTA IN THE EU
Directive 2011/24/EU on Cross-Border Health Care

Article 15 Cooperation on HTA

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 HTA…
2. The objectives of the HTA network shall be to…
3. In order to fulfil the objectives set out in paragraph 2, the network on HTA may receive Union aid…
4. The Commission shall adopt the necessary measures for the establishment, management and transparent functioning of this network.

INTRODUCING AND IMPLEMENTING HTA IN BULGARIA

HTA SPECIFIC DEATH TRAPS

- ✓ LACK OF TRANSPERANCY
- ✓ MISAPPLIED ASSUMPTIONS
- ✓ OVERALL GENERALISATION
- ✓ INAPPROPIRATE CHOICE OF COMPARATORS
- ✓ PREDICTIVE ACCURACY

HTA FUNDAMENTAL PRINCIPLES

✓ **INDEPENDENCE**

- Status of an independent public body
- Financial autonomy
- Open and transparent management procedures
- Exclusion of competing interests

✓ **SCIENTIFIC RIGOUR**

- Decisions and recommendations are based on scientific research
- Decisions and recommendations are based on recent and reliable scientific evidence
- Clearly defined, rigorous and objective methodology of work

✓ **MULTIDISCIPINARY APPROACH**

- Use of wide range of scientific tools and concepts

IMPORTANT STEPS

- REGULATION OF HTA IN BULGARIA
- INSTITUTIONAL FRAMEWORK
- CAPACITY BUILDING
- ELABORATIONS OF HTA REPORTS
- criteria for designation of HTA bodies (public and private)
- transparency, accountability and appropriateness
- provision of independent assessment by third parties

The health of the people is really the foundation upon which all their happiness and all their powers as a state depend.

Benjamin Disraeli

THANK YOU FOR YOUR ATTENTION AND ENJOY THE WORKSHOP!