

**President of the Russian ISPOR
Chapter**

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**Health Technology Assessment:
15 Years Searching for Road
Map**

**For the first time the issue of
informed choice of medical technology
was discussed in terms of the
development of the health
standardization system by the
Ministry of Health, Federal Agency
on Technical Regulating and
Metrology and the Federal
Mandatory Health Insurance Fund
in 1997**

**One of the basic principles of health
standardization**

**Obligatory evidence in the
development of regulations**

It has become clear that

- **Evidence-based medicine is not an abstract science, it is a health technology assessment tool**
- **Along with clinical assessment economic evaluation is required**

**Russian RSPOR branch was held
in 1998**

**For the first time in
Russia clinico-economic
analysis has been used
for Health Technology
Assessment**

**The basic regulations which development
required Health Technology Assessment**

- **Patient management protocols**
- **List of Essential Medicines**

**Principles and rules for the selection of
medical technology were found to be similar**

- **Three levels of the evidence for effectiveness**
- **Negative evidence of inefficiency or 2 levels of risk**
- **Evaluation of "cost / effectiveness" for comparison of medical technologies**
- **Transparency of procedures**
- **Consensus decision-making**

**All these principles were used in four health standards
(1999-2002)**

**Standard for clinico-economic analysis was the first
one in Eastern Europe!**

**Prior to 2004 principles of health technology
assessment were implemented in**

- **Development of the Formulary Committee**
- **Development of the Russian Ministry of Health Council for Health Standardization**
- **Development of more than 20 patient management protocols**
- **The overall review of the List of Essential Medicines before 2000 with introduction of entirely new groups of drugs: anti-cancer, antithrombotic, psychotropic drugs, modern antibiotics, antiviral drugs, etc.**
- **Development of the State Register of Medicines and model clinical and pharmacological articles for all drugs**
- **Development of Medicines Handbook of the National Formulary Committee**

To some extent the principles of Health Technology Assessment were used in

- Establishment of the system of medical activity licensing in 2002-2006.
- Development of the system of quality management in health (Panel of the Russian Health Ministry, 2003)

In the first half of the 2000s

- Independent pharmacoeconomic laboratories and groups has began to appear
- Pharmacoeconomic studies of drugs
- Articles in pharmacoeconomics and evidence-based medicine were issued
- Several books on clinico-economic analysis were published
- Pharmacoeconomics has become a subject for teaching

All these principles

met resistance of:

- Expert community (views of key opinion leaders disaccord with the evidence)
- Officials (it has become more difficult to make corruptive decisions)
- Pharmaceutical business (the system has been built on the different, non-transparent principles)

2004 was a turning point

- No one was ashamed of corruption
- Formulary committee and the Council for Health Standardization were removed from the Russian Ministry of Health
- All the principles of the regulations have been emasculated and de facto abolished
- Formulary Committee was self-dissolved and removed to the Russian Academy of Medical Sciences (RAMS)
- Council for Health Standardization evolved into the Committee # 466 "Medical Technology" of the Russian Federal Agency on Technical Regulating and Metrology

Step by step the following organizations were dispelled

- **Group for medical activity licensing**
- **All the elements of the system of health quality management**

But before 2007

There was cooperation with the Russian Ministry of Health

Systems of essential drug supply (DLO, the monetization of benefits) were established
Special program for "orphan" diseases ("7 Nosologies") with its own standards of care and the need for medications was developed
700 standards of medical care were developed

Ascension of the Health Minister Golikova in 2007 marked with expulsion of all staff and ideas from the Russian Ministry of Health

- **Health standardization has been completely dissolved - any standard has not being approved since 2007**
- **Approved standards of care - patient management protocols, have been dissolved**

Since 2007 there has been an imitation of activity in the Russian Ministry of Health and Social

Development

- **Approved "Procedures for providing medical care" are not feasible - it is a quasi-standard**
- **Thousands of experts are involved in the development of these procedures**
- **Any standard has not being approved**
- **Several Chiefs of the Health Standardization Committee of the MoHSD have already retired**
- **The regularly issued list of medications does not include antineoplastic agents, but there is Actovegin, Cerebrolysin and more than 40 "placebo" in it**

**In three approved federal laws –
on drugs, on health insurance and on
health**

- **There is nothing about the Health Technology Assessment**
- **Transparency of the procedures is not discussed at all**

Medical Community

- **Criticized the law**
- **Required not to approve the law**
- **Halt urgent adoption of the law and made more than 200 amendments to it**
- **There is no mention of Health Technology Assessment in the law still**

Formulary Committee

- **Involved experts from different regions of Russia**
- **Developed and approved the Standard of Health Technology Assessment**
- **Both general approach and a brief assessment of technologies for health organizations were included in the Standard**

Basic unresolved issue

- **Who and what for needs it in Russia**
- **How to motivate authorities to implement Health Technology Assessment**