

# On pursue for EBHC - diversity of changes in basic benefit package

Dragana Atanasijevic

Local consultant for HTA

SHP Project-Ministry of Health of Serbia

# The objectives

- **Background or How to implement resources allocation in situation of limited funds**
- **Current situation in Serbia**
  - **Legal basis**
  - **HTA/SHP Project findings**
- **Project conclusions and recommendations**

# **Background or How to implement resources allocation in situation of limited funds**

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# EBM and BBP

How we might prioritize health care to provide a basic health care package that we can pay for?

We must use evidence-based medicine to find the most appropriate answers. We need to “know all there is to know ” which drugs are really essential and which of only borderline value.

# Types of evidence used in health care systems decisions

- **Colloquial evidence** (experts and professional opinion, political judgments, values and tradition, available resources)
- **Scientific evidence**
  - **Context free scientific evidence**
  - **Context sensitive scientific evidence**

# Structuring a basic benefit package in situation of limited resources is very difficult, even keeping EBM course

**Evidence** on daily aspirin use for the primary prevention of cardiovascular disease

- no risk factors present, the 5-year risk will be  $<1\%$  and the harm of using aspirin is greater than the benefit.  
Recommendation: “Don’t take an aspirin each day.”
- 2 or more risk factors present, the benefits are  $>3\%$  and the benefits will outweigh the harm. The conclusion is: “Take an aspirin each day.”

Shell we include aspirin in the basket of necessary basic drugs?

Rwanda, Cambodia...thresholds...

# A basic benefit package

“Minimum health services that should be generally and uniformly available in order to assure adequate health status and protection of the population from disease or that meet some other criteria or standard.”



A challenge in designing a basic benefit package is the difficulty of achieving consensus on its design.

# **Current situation in Serbia**

- **Legal basis**

# Documents



- Health Policy of Serbia
- Health care vision
- Laws on health care and health care insurance
- Poverty reduction strategy

All of them refer directly or indirectly to EBM  
in a number of terms,  
indicating a strong orientation of the drafters toward evidence

In addition, the Health Insurance Law states that the National Health Insurance Fund should define the content and scope of health care and should develop a list of indispensable medicines and indispensable medical devices.

# Compulsory health insurance includes

- insurance covering diseases and injuries not related to work;
- insurance covering work-related injuries or diseases.

Entitlements deriving from compulsory health insurance:

- right to health care;
- right to salary benefit for the period of temporary inability to work;
- right to transportation benefit relating to the use of health care services

# Right to health care includes:

- preventive health care and early-stage diagnosis measures;
- medical examinations and treatment of women relating to family planning, pregnancy, delivery and postnatal period up to 12 months after delivery;
- **medical examinations and treatment of the sick and injured;**
- prevention and treatment of dental diseases;
- medical rehabilitation of the sick and injured;
- medicines and medical supplies;
- prosthetic, orthotic and other devices for moving, standing and sitting, sight, hearing and speech devices, dentures and other supplementary and sanitary devices (medical-technical devices).

# Jeopardized accessibility

The contents and the scope of the right to the health care, funded from the Health Insurance Fund, includes **nearly all** health services.



Comprehensive network of state health care institutions assumes accessibility for all on the whole territory.

# Financial arrangements for services in BBP under compulsory health insurance

## Coverage

- 100%
- At least 95%
- At least 80%
- At least 65%



Drug  
reimbursement  
list

Primary  
health care

Preventive  
health care

Rehabilitation

Highly  
specialized  
procedures

Dental care

Medical  
devices

Occupational  
diseases

Emergency  
care

Transportation

Medical-  
technical  
devices



Hospital care  
(secondary  
/tertiary)

Sick leave

Abroad  
treatment

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- **HTA/SHP Project findings**

# List of issues, according to which the parts of BBP were searched and collected

- Name of BP,
- Typology of BP,
- Description of the elements,
- Definition,
- Legal foundations,
- Date of introduction to the system,
- Application for exclusion or inclusion to the BP,
- Decision-taking,
- Timeframe for changes,
- Inclusion criteria,
- Exclusion criteria,
- Indications,
- Application form (description),
- Appeal process,
- Payment method,
- Role of HTA in development.

# Drug reimbursement list



**A** - drugs which are prescribed and dispensed by medical prescription (100% reimbursement, patient paying the prescription premium)

**A1** - drugs which have alternatives in A category (10-75% participation of patients)

**B** - medicines which are for parenteral use, dispensed by health care institutions (medicines dispensed upon written order)

**C** - medicines with special regime of dispensing (only hospitals)

**D** - medicines which do not have Marketing Authorization in Serbia, and are necessary for diagnostics and therapy – non-registered medicines (in/out patient care)

- Type of BBP                      positive/defined
- Appealing process,              no specific form

# Description of the elements

- List A consists of 14 groups of medicines, list A1 of 13 groups of medicines, list B of 12 groups of medicines, list C of 3 groups of medicines and list D consists of 12 groups of medicines.
- For certain medicines from List of Medicines have been established limitations in dispensing in relation with:
  - Medical diagnosis set in accordance with ICD-10
  - Life years of insured person
  - Population group
  - Doctor's opinion with appropriate specialization which is valid up to four months or opinion of three doctors with certain specialization from a relevant health institution which is valid up to six months.

# Inclusion criteria

Managing Board of the HIF decides on two main criteria:

- Controlled clinical trials on pharmacotherapy (efficacy and safety) with the references;
- Pharmacoeconomic study, duration of the treatment and DDD costs and results of budget impact (the Board may ask for information about what kind of analysis should be submitted)

# Exclusion criteria

- OTC medicines (medicines for self treatment in other words medicines with mild action)
- magisterial formula and galena formula medicines (except when there is not industrial manufacturing);
- medicines which are used for treatment of functional disorders (like laxatives and others) and esthetics disorders;
- medicines which consist of several medicinal active substances (fixed combinations of medicine) except:
  - if the therapeutically effect of fixed combination is larger than the sum of effects of individual medicines
  - when the results of clinical study justify usage more than one medicine at the same time,
  - when the price of DDD of fixed combination of medicine is less than the sum of prices of DDD of single medicines,
  - when the dosage of the fixed combination can change within the majority of population taking the medicine;

# Decision-taking

- Managing Board of the Republic Institute of Health Insurance takes decision on the List of Medicines, according to the proposals made by the Central Expert Committee.
- Central Expert Committee makes decisions according to the opinion and assessment obtained previously by an Expert Subcommittee for Medicines for the areas defined by the ATC classification of medicines and the Committee for Pharmacoeconomics.

# Some examples of drugs from A & A1 Lists

|   | Unique classification drug code | Anatomical Therapeutic Chemical drug code | International Nonproprietary Name   | Brand name | Pharmaceutical formulation | Package and unit dose of medicine | Drug manufacturer  | State of manufacturer | Price of original drug package | Daily Defined Dose - DDD | Price for DDD | Co payment |
|---|---------------------------------|---|-------------------------------------|------------|----------------------------|-----------------------------------|--------------------|-----------------------|--------------------------------|--------------------------|---------------|------------|
| <b>caries profilaxia</b>  |                                 |   |                                     |            |                            |                                   |                    |                       |                                |                          |               |            |
| <b>A</b>  | 1120170                         | A01AA01                                   | natrium fluoride                    | FLUOROGAL  | Tablet                     | 250 by 0,25 mg                    | Galenika           | Republic of Serbia    | 1 Euro                         | 1.1 mg                   | 0.02 Euro     | 0.25 Euro  |
| <b>hormones of the anterior hypophysis</b>                              |                                 |   |                                     |            |                            |                                   |                    |                       |                                |                          |               |            |
| <b>A</b>  | 0044241                         | H01AC01                                   | Somatropin Synthetic Growth hormone | GENOTROPIN | Injection/capsule          | 5 by 16 i.j (5.3 mg/1ml)          | Pfizer Enterprises | Luxemburg             | 648 Euro                       | 2 i.j.                   | 16.5 Euro     | 0.25 Euro  |
| <b>Hypolipemics</b>   |                                 |   |                                     |            |                            |                                   |                    |                       |                                |                          |               |            |
| <b>A</b>  | 1104445                         | C10AA01                                   | simvastatin                         | ZOCOR      | Film tablet                | 28 by 40 mg                       | Merc Sharp & Dohme | Swiss                 | 10.7 E                         | 15 mg                    | 1.5 euro      | 0.25 euro  |
| familiar hyperlipidemia (E 78.4)  |                                 |   |                                     |            |                            |                                   |                    |                       |                                |                          |               |            |
| <b>A 1</b>  | 1104445                         | C10AA01                                   | simvastatin                         | ZOCOR      | Film tablet                | 28 by 40 mg                       | Merc Sharp & Dohme | Swiss                 | 10.7 E                         | 15 mg                    | 1.5 euro      | 60%        |
| in prevention of recidive myocardial and brain infarction (I 21 & I 63) |                                 |   |                                     |            |                            |                                   |                    |                       |                                |                          |               |            |

# Some examples of drugs from B,C &D Lists

|  | Unique classification drug code | Anatomical Therapeutic Chemical drug code | International Nonproprietary Name | Brand name              | Pharmaceutical formulation   | Package and unit dose of medicine | Drug manufacturer   | State of manufacturer | Price of original drug package | Daily Defined Dose - DDD | Price for DDD | Co payment |
|--|---------------------------------|---|-----------------------------------|-------------------------|------------------------------|-----------------------------------|---------------------|-----------------------|--------------------------------|--------------------------|---------------|------------|
| <b>Diuretics</b>   |                                 |   |                                   |                         |                              |                                   |                     |                       |                                |                          |               |            |
| <b>B</b>   | 0400140                         | C03CA01                                   | Furosemid                         | LASIX                   | injection                    | 5 by 20mg/2ml                     | Jugoremedia         | Republic of Serbia    | 0.5 euro                       | 40 mg                    | 2 Euro        | 0          |
| <b>Vaccines</b>  |                                 |   |                                   |                         |                              |                                   |                     |                       |                                |                          |               |            |
| <b>B</b>   | 0011712                         | J07BB01                                   | Influenza (Flu) vaccine           | Inactivated Flu vaccine | injection                    | 10 by 0.5 ml (1 dose)             | Torlak              | Republic of Serbia    | 25 Euro                        | -                        | -             | 0          |
| <b>Immunosuppressives</b>  |                                 |   |                                   |                         |                              |                                   |                     |                       |                                |                          |               |            |
| <b>B</b>   | 0034025                         | L01BB04                                   | Cladribin                         | LITAK 10 sol.           | Sol. for injection           | 5 by 10 mg/5 ml                   | Lipomed             | Swiss                 | 1.865 Euro                     | -                        | -             | 0          |
| <b>Antineoplastics</b>   |                                 |   |                                   |                         |                              |                                   |                     |                       |                                |                          |               |            |
| <b>C</b>   | 0039400                         | L01XC07                                   | bevacizumab                       | AVASTIN                 | Sol. for injection           | 1 by 16 ml (400mg/16 ml)          | F. Hoffman-La Roche | Swiss                 | 1.165 Euro                     | -                        | -             | 0          |
| <b>D - medicines which do not have Marketing Authorization in Serbia, and are necessary for diagnostics and therapy – non-registered medicines (in/out patient care)</b> |                                 |   |                                   |                         |                              |                                   |                     |                       |                                |                          |               |            |
|  | Unique classification drug code | Anatomical Therapeutic Chemical drug code | International Nonproprietary Name |                         | Pharmaceutical formulation   | Unit dose of medicine             |                     |                       | Unit price of Ph F             | Indications              |               | Co payment |
| <b>D</b>   | N002402                         | N02AA01                                   | morphine as morphine sulfate      |                         | Tablet with prolonged effect | 60mg                              |                     |                       | 1.25 Euro                      |                          |               | 0          |

# Medical devices



- Type of BBP
- Who makes the decision
- Indications
- Application form (description)
- Appealing process,
- Pricing,

positive/partly defined

No formal document was found describing detailed process of decision making, nor management nor transparency issues in respect to decision-making on the inclusions and exclusions to this BP.

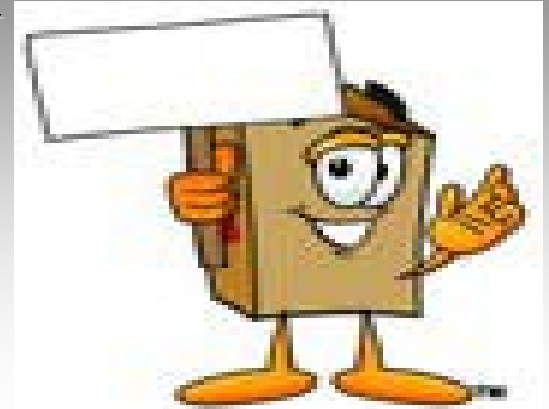
No detailed descriptions in respect to the specific indication was found

No formal document has been found

No information found

No detailed descriptions...

# Medical-technical devices



Positive / undefined (only general description, no listing of specific technologies)

No formal document was found describing detailed process of decision making, nor management nor transparency issues in respect to decision-making on the inclusions and exclusions to this BP.

Application form - No formal document has been found

Appealing process - No information found

No detailed descriptions in respect to the following issues were found:

1. Criteria for pricing
2. Process of setting prices (analysis, decision-making) – except article 41 for locally increased prices
3. Quality and transparency requirements in respect to calculations
4. Management of formal negotiations
5. Monitoring of prices of medical-technical devices in the international market

# And so on...



Primary  
health care

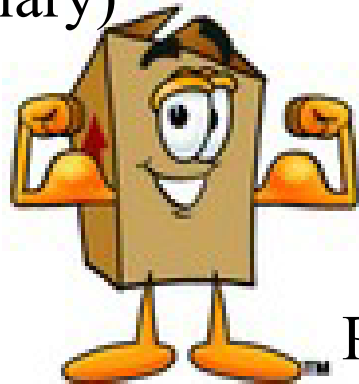


Transportation

Abroad treatment



Hospital care  
(secondary  
/tertiary)



Preventive  
health care



Emergency care ...

# Negative package examples

- **personal comfort** and special accommodation and personal care in hospital inpatient facilities...
- services related to treatment of **acute alcohol intoxication**...
- **cosmetic procedures** aiming to improve appearance without restoring body functions...
- pregnancy termination for non-medical reasons
- **non-compulsory immunizations** and immunizations related to traveling...
- diagnostic and **treatment of sexual dysfunction** or sexual inadequacy, including impotency, health care services, medicines and medical-technical devices relating to **sex change**...
- **surgical or invasive treatment** (including gastric balloon) **related to weight reduction**, except if medically needed...

**No criteria of exclusion from BBP**

# **Project conclusions and recommendations**

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# Development of basic benefit package and Transparency Directive of EU

## **„TRANSPARENCY” DIRECTIVE No 89/105/EEC**

**Assures transparency of measures regulating the pricing and coverage of medicinal products for human use and their inclusion in the scope of national health insurance systems** *(OJ No L 40 of 11. 2. 1989 p. 8)*

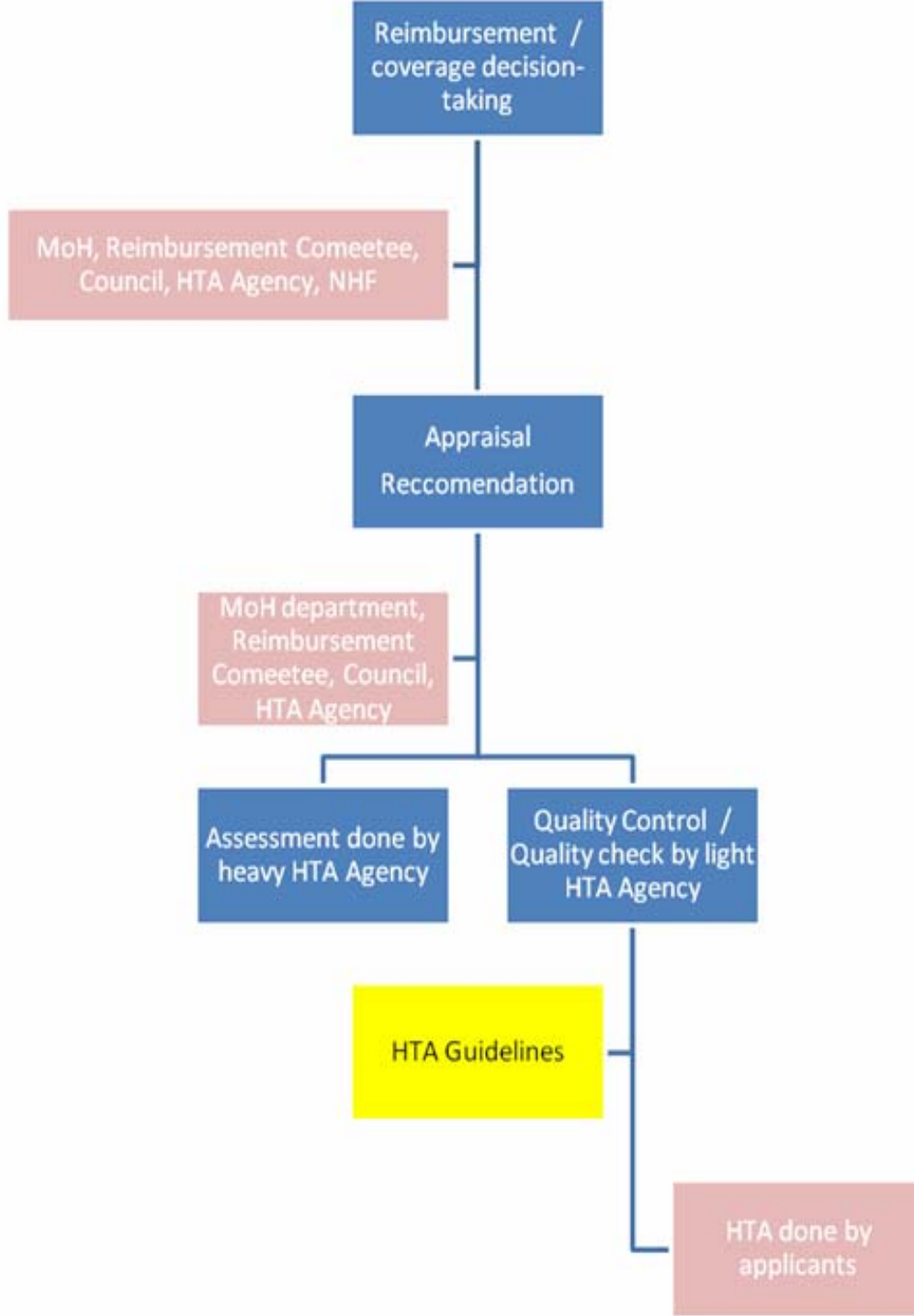
- Timeframe
- Transparent criteria based on rational (assuring repeatable decision-making and verification)
- Court supervision

# The definition of a benefit package contains the following essential elements:

- Referral to the health insurance of a specific type,
- Inclusion and exclusion criteria for components of the package,
- Management of inclusion and exclusion from the package (application, decision-making, decision-taking),
- Organization of services (including provision to patients) and method of payment to health care providers.

# Some Project conclusions based on findings

- Coverage decisions may be made and taken by different committees and/or different public authorities
- The role of particular state authorities and institutions with respect to specific areas of BBP, methods of regulation and requirements for new technologies should be clearly defined
- Criteria and processes should be transparent, precisely described and rooted in legal acts of the relevant importance.
- The higher the cost of the technology is, the more requirements in respect to evidence and restrictive process of assessment and appraisal should take place.



**Evidence based  
coverage  
decision-making**

# EBM and BBP

Appropriate use of EBM in decision making process requires a clear understanding of the diversity between basic components of each particular decision:

- scientific evidence and
- judgments applied to that evidence by individuals or organizations.

# Judgments applied to the evidence

A Physicist, a Marine Biologist and a Chemist are at the beach together.

The Physicist, upon seeing all the waves, gets very excited and runs into the water, disappearing.

The Marine Biologist, aware of tremendous variety of marine life in the ocean, also gets very excited, and runs into the water, disappearing.

The Chemist pulls out her notebook, and writes “The Physicist and the Marine Biologist are soluble in water”.

# To go beyond barriers

- Frequently changed governments
- Lack of tools and skills to interpret the evidence
- Negative attitudes towards scientific evidence
- Low quality of evidence (biased or no objective)
- Long, theoretical books without perception of relevance of evidence
- ...



Thank you for your attention

E-mail: [dratanas@yahoo.com](mailto:dratanas@yahoo.com)