RAPID REVIEW

Inclusion and exclusion criteria for guaranteed benefit packages in selected countries – possibility of application in Poland

Version 1.0
Krakow
2006

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This review was commissioned by the Agency for Health Technology Assessment in Poland (AHTAPol).

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INDEX OF ABBREVIATIONS

AHRQ	Agency for Healthcare Research and Quality
AHTAPol	Agency for Heath Technology Assessment in Poland
AMM	Autorisation de Mise sur le Marche
ARTG	Australian Register of Therapeutic Goods
ASMR	Amélioration du Service Médical Rendu
BBP	Basic Benefit Package
BC/BS	Blue Cross/Blue Shield
BIA	Budget Impact Analysis
BSV	Federal Social Insurance Office
CCOHTA	Canadian Coordinating Office for Health Technology Assessment
CBA	Cost – Benefit Analysis
CEA	Cost – Effectiveness Analysis
CFH	Commissie Farmaceutische Hulp
CMS	Centers for Medicare and Medicaid
COPD	Chronic Obturative Pulmonary Disease
CUA	Cost – Utility Analysis
DRG	Diagnosis Related Group
Dz.U.	Dziennik Ustaw (Journal of Laws)
EBM	Evidence Based Medicine
ECRI	Emergency Care Research Institute
EDI	Federal Department of Home Affairs
ELK	Federal Commission for General Health Insurance Benefits
EPC	Enhanced Primary Care
FFS	Fee For Service
FJC	Federal Joint Committee
FMH	Swiss Medical Association
HAS	Haute Authorité de Santé
HMO	Health Maintenance Organization
HTA	Health Technology Assessment
IQWIG	Institut für Qualitat und Wirtschaftlichkeit im Gesundheitswesen
KSV	Swiss Heath Insurers' Assossiation

KVG	Federal Law on Sickness Insurance
MBS	Medicare Benefits Scheme / Schedule
MSAC	Medical Services Advisory Committee
MH	Ministry of Health
NHF	National Health Fund
NHS	National Health Service
NICE	National Institute for Health and Clinical Excellence
NSF	National Service Frameworks
OTC	Over-The-Counter
PBAC	Pharmaceutical Benefits Advisory Committee
PBS	Pharmaceutical Benefits Scheme
PBS	Pracownia Badań Społecznych (a Polish company specialized in opinion polls)
PDC	Prostheses and Devices Committee
PKS	Parity Commission
QALY	Quality Adjusted Life Year
QoL	Quality of Life
RCT	Randomised Controlled Trial
RP	Rzeczpospolita Polska (Republic of Poland)
SHI	Statutory Health Insurance
SMR	Service Médical Rendu
TEC	Technology Evaluation Centre
TGA	Therapeutic Goods Administration
TK	Trybunał Konstytucyjny (Constitutional Tribunal)
TNO	Netherlands Organization for Applied Scientific Research
UK	United Kingdom
USA	United States of America
WHO	World Health Organization

GLOSSARY

Safety	Assessment of possible harmful effects of the intervention. Concerns type, severity and frequency of adverse events (for drugs) and complications (for non-drug technologies). Assessment of acceptable risk and possible harmful effects of the intervention. [10]
Evidence-Based Medicine (EBM)	A way of practicing medicine taking into account results of credible clinical trials, physician's experience and patient's preferences. [10]
Effectiveness	A term concerning both efficacy and safety. The term "effectiveness" is used only in relation to the actual population, in which the technology is applied in practice; in relation to results of a clinical trial the term "efficacy and safety" is used. [10]
Indirect cost	A cost that can not be meaningfully traced to a specific product, service or production process. [10]
Cost of a medical procedure	The sum of costs directly related to a specific medical procedure and a justified part of indirect costs (in terms of accountancy) related to performing of this procedure. [10]
Benefit package	A list of health care services or medical procedures: 1. which may be performed within health insurance of a specific type (regardless of the way the service is financed) or 2. which are excluded from a specific health insurance. [9]
Negative benefit package	A list of services or procedures excluded from the insurance of a specific kind. [9]
Undefined benefit package	A passively created package; includes all those services or procedures that were not put on the list of a defined package. Creation of one or more defined packages implicates "automatic" creation of an undefined package. [9]
Basic Benefit Package (BBP)	A list of health care services or medical procedures to which patients are entitled within basic health insurance. For obvious reasons a guaranteed package is a positive package. [9]
Positive benefit package	Contains services or procedures which may be performed and financed within health insurance of a specific kind. [9]
Supplementary benefit package	A list of health care services, which were not placed in the basic benefit package due to relatively insignificant effect on the health condition of the society, low efficacy and safety or unfavorable cost-effect relation as compared to optional health technologies, placed in the basic benefit package. [10] A list of health care services or medical procedures which may be performed within supplementary health insurance. [9]
Defined benefit package	Created actively by placing specific elements (health care services, medical procedures and other elements) on a finite list.

List of reimbursed drugs A list containing brand names of drugs and medicinal products used in ambulatory care and available for the insured either free of charge, for a fixed charge or partial payment, established by a regulation of the Minister of Health.

The purpose of the list of reimbursed drugs is to ensure availability of drugs of particular importance for the health condition of the society (or the insured), of proven efficacy and safety, most cost-effective among possible treatments and possible to finance within available patient's and payer's means. [10]

Negative package / negative list of non-drug technologies A list of diagnostic and non-drug therapeutic technologies of proven harmfulness in a specific indication. The list is created according to efficacy analyses based on systematic reviews or results of clinical trials or registers if these are alarming as to safety. [9]

Health Technology Assessment (HTA) An interdisciplinary branch of science employing scientific methods in health policy; combining information and methods of, among others, epidemiology, biostatistics, economy, law and ethics. HTA allows for making rational decisions, based on scientific evidence, concerning use and financing of health care services. HTA reports concern in the first place analyses of efficacy, safety and costs; they include systematic reviews and economic analyses, sometimes with recommendations concerning compared diagnostic or treatment options.

Health care Organized activity concerning care, services or supplies related to the health of an individual. Health care includes, but is not limited to preventive, diagnostic, therapeutic, rehabilitative, maintenance, mental health or palliative care and sale or dispensing of a drug, device, equipment or other item in accordance with a prescription. [10]

Cost-effectiveness See: "Cost-effective technology"

Fee for service (FFS) A method of financing of health care providers in the system. The provider receives a defined fee for each performed service. The provider's income depends on the number of performed services; this number may be limited or not. [10]

Primary endpoint The aim of prevention, treatment or diagnostics – the main, clinically significant health-related effect measured in phase III clinical trials. Primary endpoints are: mortality, prevalence or incidence (including adverse events and complications) and quality of life. [10]

Payer Any private or public institution which finances or provides means for health care of the insured. First-party payers are patients, second-party payers are health care providers, third-party payers are private and public health insurance institutions and governmental (administrative) units responsible for financing of specific health care services. [10]

Health needs Number and kind of health care services that should be ensured in order to maintain, restore or improve health condition of a specific group of patients (community). [12]

Medical procedure Any action concerning diagnostics, treatment, prevention, nursing, rehabilitation or certification, taking into account its indications, performed using specific health care infrastructure, medicinal products, medical devices and additional means. [14]

Medicinal product Any substance or combination of substances presented for treating or preventing disease in human beings or animals, or administered to a human being or an animal in order to establish a diagnosis or restitute, improve or modify physiologic functions of a human or animal organism. [15]

Systematic review

A method of search for information according to pre-defined inclusion and exclusion criteria, e.g. for clinical trials. A review of publications performed in order to solve a research problem may be called systematic if it contains:
(1) formal and complete process of search for credible publications;
(2) clearly defined *(a priori)* objective inclusion and exclusion criteria for clinical trials;
(3) statistical (quantitative) analysis of the results, including metaanalysis, if possible. [10]

Randomized Controlled Trial (RCT)

An experimental study designed in order to assess efficacy and safety in phase III trials or (seldom) effectiveness of interventions, in which patients are randomly assigned to groups (treatment or control) and their outcomes are then compared between groups. The treatment group receives the investigated intervention while the control group receives the standard intervention or placebo. [10]

Reimbursement

A part of payment for a health care service returned to the patient or incurred by a health insurance institution or the national budget. Reimbursement significantly lower than 100% implicates the patient's co-payment. [10]

Insurance premium

A defined amount of money paid to the insurance company (private or public) in exchange for coverage; the amount depends on the type of insurance, its length, risk and offered package or the amount of insurance. [10]

Efficacy

Assessment of beneficial (positive) effect of a technology or procedure. Efficacy is observed in clinical trials, while effectiveness is related to population, in which the technology is applied in practice. [10]

Standard of care

A legally defined standard concerning level and methods of care provided by most physicians in a specific clinical situation. In case of a charge of malpractice the physician's conduct is assessed as compared to accepted standards. [10]

Standard of technical equipment

A standard of equipment or methodology of program solution approved by an authorized standardizing institution or accepted by authorized specialists. [10]

Medical standards

Medical standards are sets of recommendations concerning all kinds of actions: preventive, diagnostic and therapeutic; sometimes the term is used interchangeably with "guidelines" – algorithms of management; standards are usually published by scientific associations or special government institutions as sets of recommendations; they have no legal force; should be based on current status of medical sciences and created according to principles of Evidence Based Medicine (EBM). [10]

Standards of health care services

Requirements concerning:

- medical personnel – minimum qualifications and so-called standards of employment,
- equipment used (certificates, quality and safety standards),
- medical equipment of defined kind, also related to the type of services; these may be minimum (defining minimum requirements for a particular type of services) or maximum standards (related to modern health technologies),
- the building – all norms that must be fulfilled in order to perform a particular type or range of services.

These are basically minimum standards, which must be fulfilled by every health care provider in order to perform specific medical procedures. [10]

Standardization of management

Identification and promotion of the best or preferred methods of management in specific conditions. [10]

Health care services

In this review the definition proposed by the AHTAPol Experts is used, in which a health care service is defined by at least 2 components: intervention and indication.

According to the health care institution act:

Any action intended to maintain, rescue, restitute or improve health or other medical activity related to treatment or defined by separate regulations concerning its performing, in particular related to: medical examination and consultation, treatment, psychological examination and therapy, rehabilitation, care of the pregnant woman and the fetus, delivery and puerperium, care of the newborn, care of the healthy individual, diagnostics (including medical analytics), nursing, care of the disabled, palliative and hospice care, certification concerning state of health, prevention of injuries and diseases by prophylactic means and vaccination, technical activities related to prosthetics and orthodontics, activities related to supply with orthopedic equipment and additional means. [10]

Supplementary health care service

An optional health technology which was not placed in the guaranteed benefit package due to insignificant effect on the health condition of the society, significantly lower efficacy and safety or unfavorable cost-effect relation as compared to a standard technology placed in the guaranteed benefit package. [10] (see also: supplementary benefit package)

Guaranteed service

A health care service financed exclusively from public means, in a way and according to rules defined in the appropriate act of parliament. [12]

Specialist service

A health care service related to a specific medical specialty, excluding services provided within general practice. [10]

Additional service

Accommodation and board in an all-day or day and night health care institution or ambulance service. [12]

Health care service

Any action intended to prevent diseases or maintain, rescue, restitute or improve health or other medical activity related to treatment or separate regulations concerning its performing. [12]

Material health care service

Drugs, medicinal products (including orthopedic equipment) and additional means related to treatment. [12]

Health care service provider

According to the health care financed from public means act of August 27th, 2004, (Dz. U. Nr 210, poz. 2135) a health care service provider is:

- a health care institution performing activities defined in its charter, a group medical practice, a group practice in nursing or midwifery, a medical professional working as a sole practitioner or a sole specialist practitioner,
- any person other than mentioned above, who achieved appropriate professional qualifications and provides health care services within conducted business activity,
- a unit created by the Defense Minister, the Minister of Internal Affairs or the Minister of Justice, financed from the national budget, containing within its structure an outpatients' surgery or infirmary or employing a general practitioner as defined by art. 50a of the health care institution act of August 30th, 1991 (Dz. U. Nr 91, poz. 408 with later amendments),
- any entity performing activities related to supply with additional means and medicinal products being orthopedic equipment. [12]

Effective technology

A health technology of efficacy and safety higher than that of placebo, proven in credible clinical trials according to the principles of Evidence-Based Medicine (EBM).

A technology of proven efficacy and safety (higher than that of placebo), with a favorable relation between efficacy and risk of adverse effects or complications. Assessment of the strength of intervention as compared to placebo or current standard intervention makes it possible to rank the technologies according to expected benefit and risk. [10]

Health technologies

Pharmacologic products and medical equipment, but also methods, algorithms and management strategies, applied in a specific indication in order to achieve a defined health-related effect. At least three elements are necessary to describe a health technology: population (indication), intervention and (health-related) effect. [10]

Drug technology

A medical procedure, the essential element of which is administration of a drug in a specific indication. Description of a drug technology contains: 1. intervention: the generic name, dose, formulation, way of administration; 2. population: characteristics of the sample of patients, who participated in phase III trials (indications) and 3. health-related effect which is to be achieved by the intervention or which is an adverse effect of the drug (primary endpoints). [10]

Non-drug technology

A procedure related to diagnostics or treatment, in which administration of a drug is not an essential element. Includes description of the intervention, population and health-related effect (benefit and complications). [10]

Cost-effective technology

A health technology, which, when applied, leads to favorable effect related to diagnostics or treatment, while cost of achieving of that effect is acceptable as compared to no treatment and equal to or lower than that of other methods applicable in a specific condition. [10]

Harmful technology

A health technology of efficacy equal or comparable to that of placebo and safety profile worse than that of placebo (risk of adverse events higher than that of placebo) or of relatively low efficacy as compared to risk of adverse events related to application of this technology. [10]

Health insurance

Health insurance in Poland is common and obligatory; was introduced by the common health insurance in the National Health Fund act of January 23rd, 2003 (Dz.U.03.45.391). The following persons are entitled to services within the insurance:

- Polish citizens living in the Republic of Poland,
- foreigners staying in the Republic of Poland with a residence visa for the purpose of work, a stay permit (for a specific time), residence permit or tolerated residence permit or granted the status of a refugee in the Republic of Poland or seeking temporary protection on its territory, if they are subject to obligatory health insurance or are voluntarily insured (art. 6 section 1 of the act),
- family members of the persons mentioned above, if they live in the Republic of Poland
- Polish citizens not living on the territory of the Republic of Poland, if they are subject to obligatory health insurance and are entitled to: pension insurance and disability pension insurance according to the social insurance system act of October 13th, 1998 or agricultural social insurance (art. 6 section 2 of the act),
- foreign students (including post-diploma students) who study in the Republic of Poland and graduates who perform obligatory training in the Republic of Poland – if insured voluntarily,
- foreigners – members of religious orders and alumni of clerical and theological seminaries, postulants and novices of monastic orders and their counterparts staying on the territory of the Republic of Poland with a visa or a residence or stay permit – if insured voluntarily (art. 7 section 1 of the act). [11]

Additional insurance A type of health insurance, which – in case of falling ill – entitles its owner to benefits not related to health care services or medical procedures; these are: financial benefits in case of falling ill, shortened time of waiting in the queue, higher hotel standard in the hospital etc. [9]

Supplementary insurance A type of health insurance, which entitles its owner (according to specific rules, e.g. with or without co-payment) to services and/or medical procedures not contained in the basic package, i.e. those placed in the supplementary package; not all supplementary insurances must offer all services and procedures placed in the supplementary package.

A supplementary insurance is related to the risk of falling ill and to possibility of obtaining specific medical assistance concerning services and procedures not covered by basic health insurance; a term related to function of the supplementary package. [9]

Indication The basis for initiation of a treatment for a disease or of a diagnostic test; may be furnished by a knowledge of the cause (causal indication), by the symptoms present (symptomatic indication), or by the nature of the disease (specific indication); the recommendations may be related to:

- diagnostics (type and frequency of tests),
- treatment (drugs and doses or non-pharmacologic treatments, including surgical interventions and procedures),
- prevention,
- control of treatment (control tests). [10]

Medical device Any instrument, apparatus, appliance, material or other article, whether used alone or in combination, including the software necessary for its proper application, intended by the manufacturer to be used for human beings for the purpose of:
- diagnosis, prevention, monitoring, treatment or alleviation of disease,
- diagnosis, monitoring, treatment, alleviation of or compensation for an injury or handicap,
- investigation,
- replacement or modification of the anatomy or of a physiological process,
- control of conception,
and which does not achieve its principal intended action in or on the human body by pharmacological, immunological or metabolic means, but which may be assisted in its function by such means. [10,12]

Range of insurance A list or set of health care services, to which patients are entitled within health insurance in defined conditions. [10]

Health 1. A state of a living organism, in which all functions are performed properly; complete physical and psychical fitness and well-being.

2. A state of complete physical, social and mental well-being, and not merely the absence of disease or infirmity. Other definitions, complementary to that formulated by the WHO, take into account general good feeling. [10]

1. INTRODUCTION

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The definition of a benefit package contains two essential elements:

1. health insurance of a specific type and
2. inclusion and exclusion criteria for components[1] of the package.

Transparent process of development of packages and supervision of the court (concerning also inclusion and exclusion of the drugs from the lists of reimbursed drugs) are required by the EU Transparency Directive[2] (Council Directive 89/105/EEC of December 21st, 1988). Possibility of appellation to the court, implicated by the Directive, is actual only if the court has the power to verify the authorities' decision using transparent criteria, which the authorities are obliged to observe.

The Directive concerns national health insurance system – its range, defined or undefined guaranteed benefit packages (also called basic or standard packages). Inclusion and exclusion criteria for medical procedures and services placed in the package are directly related to its function in the system.

The purpose of the guaranteed benefit package was defined and accepted by the Expert Group of the Agency for Health Technology Assessment in Poland (AHTAPol). The purpose of the guaranteed benefit package is to ensure availability of health care services or medical procedures, which are:

1. most important for health condition of the society,
2. of proven efficacy and safety,
3. most cost-effective of the optional or alternative and
4. possible to finance within available means of basic insurance.

All those criteria must, of course, be met simultaneously.

Necessity to limit arbitrary decisions – as required by the Transparency Directive – implicates development of detailed criteria, ensuring reproducibility of official decisions based on a defined amount of objective information. Reproducibility of decisions related to availability of objective information requires use of the results of credible, methodologically correct analyses and studies in the decision process.

On the other hand, practical aspects of development of the package are not to be neglected. Inclusion and exclusion criteria for the package components cannot therefore be too restrictive (especially when contents of the guaranteed package are defined for the first time), due to limited resources allocated for its creation – time as well as financial means and human

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1 The key problem is to distinguish between inclusion and exclusion criteria for components of the package and quality criteria (credibility and completeness) for the analyses attached to applications for placement in the package or other analyses, on which the decision concerning inclusion or exclusion of a service into/from the guaranteed benefit package will be made. This report concerns the former. Quality criteria for analyses of efficacy and safety, economic and financial analyses worldwide are accepted and published by Ministries of Health, HTA Agencies or Reimbursement Commissions, to which formal applications with attached analyses are submitted.

2 "COUNCIL DIRECTIVE 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** (89/105/EEC)"; http://tinyurl.com/zlmza

resources. Necessity to bring practical aspects together with formal requirements of the European Union was evident for the authors at every stage of the work[3].

According to the purpose of the guaranteed benefit package as defined by the AHTAPol Group, detailed criteria presented here are related to specific requirements of the purpose.

1.1. Need of a benefit package in Poland

In most of developed countries the system of reimbursement is based on a more or less defined benefit package (or packages). A list of basic services financed by the national budget or insurance institutions – depending on the system – is necessary due to:

1. limited means for financing of the health care services,
2. need to limit increase of health care costs (related, among others, to introduction of new health technologies),
3. existence of services and procedures characterized by:
    - lack of efficacy and safety,
    - low cost-effectiveness as compared to other available options (high cost / effect ratio),
    - relatively unimportant for the health condition of the society (e.g. procedures related to cosmetic surgery, some dental procedures and methods of psychotherapy),
    - proven harmful effect on the patients' health – such procedures should be eliminated by creation of so-called negative package.

Procedures and services, which are not placed in the package (due to economic reasons or low medical significance), may be offered within supplementary insurances and make an "area" for their free market competition. By creation of an offer addressed to people interested in services, which were not placed in the basic benefit package, they relieve the basic insurance system (which may lead, among others, to radical reduction of queues to services offered within basic insurance) and, introducing competition, serve as one of the most important quality-promoting factors in the system.

Nowadays people insured within basic health insurance (being *de facto* inefficient health care provision) in Poland do not know, to what services they are entitled. The unrealistic rule that "everyone is entitled to everything" remains in force, leading to general corruption and undue use of connections and privileges. In addition, the current system obviously does not fulfill the constitutional principle of equal access to medical procedures and services.

Development of supplementary insurances (which may exist only in the area not covered by basic insurance) is hindered not only by lack of the supplementary benefit package, but also by lack of the system stability. Legal regulations concerning health care underwent in recent years frequent, deep and mostly unpredictable changes. New laws and regulations introducing deep changes in the system were not based on performed *a priori* valid feasibility studies. In such situation serious investments and development of supplementary insurances are not to be expected. However, slow progress is observed in the area of additional insurances, entitling e.g. to higher hotel standard in the hospital. Additional insurances develop also in response to pathologies of the system, like "queue insurances" or insurances entitling to allowance in case of falling ill ("encouraging" to be sick and colloquially called "doctor's bribe insurances").

In the area of health care services there is obvious asymmetry of information between the producer and the customer. The customer in health economy is the official making decisions concerning reimbursement as well as the physician and the patient, especially in case of substantial co-payment. Lack of clear criteria and low production of valid analyses of efficacy

[3] Work on this report lasted less than a month (sic!), with scarce financial means available, therefore the title stresses its character (a rapid review). Fragments of other publications were used in this report; copyright laws and generally accepted rules of citation were observed. Im many places secondary documents (translations into English) were used as well as retrieved originals.

and safety as well as economic and financial analyses lead to a situation, in which the customer is unable to choose rationally the best of available services in a specific indication. [1] This in turn leads obviously to arbitrary decisions and is, as was forcibly demonstrated by the sentence of the Constitutional Tribunal (TK), contrary both to the Polish law and that of the EU. (chapter 1.3)

1.2. A "thorny and painful" way towards beginning of the work on the package

Introduction of a guaranteed benefit package in Poland was first considered in the beginning of the 90-ies. First attempts did not assume allocation of any real means for design of its structure, organization of its development or its placement in the system. Therefore no actual work began and no financial means were allocated for its implementation.

Subsequent attempts, not preceded by development of detailed plan of action, without defined aim or methodology of placement in the package, were made during works on so-called *"range of services guaranteed from public means".* However, the "guaranteed range of services act" was not enacted; only in the common health insurance act of 1997 (Dz. U. Nr 28, poz. 153) rights of the insured and obligations of the payer were formulated more precisely. Indirect attempts to define more precisely the range of the health insurance were made in 1999 during works on so-called "standards of health care services". The result was a document comprising 42 parts related to different medical specialties and explicitly listing medical procedures to be reimbursed by the patients' funds. [3]

All other attempts (e.g. 4 weeks of work on so-called "negative package" in 2004) may be considered chaotic and doomed to fail. They had no chance of success not only due to lack of prepared plan of action (and lack of allocated means for preparation of such a plan or development of the package), but also due to lack of defined inclusion and exclusion criteria, which should have been assumed before any attempts to place services in the package were made.

Before 2006 the best attempt to design the concept of the package and its position in the Polish system was conducted by the Dutch TNO on commission of the Ministry of Health. The work was financed by a World Bank loan. Although the conceptual work was successfully finished in 2001, election to the parliament, after which the rule was taken by politicians reluctant to the idea of the package, delayed the process for several years.

One of the issues more extensively discussed in the report prepared by the TNO is a proposal of methodology for creation of a list of guaranteed services. It must be stressed that the authors avoid clear answer as to the optimal model for Poland; they point out possible consequences of a given solution, however, they present no recommendations or purposeful conclusions. The main subject of the proposal is suggestion (but not recommendation) of a mechanism of assessment of services and procedures to be placed on the list and stress on cooperation between the HTA Agency and the Reimbursement Office as the basis of that mechanism. In the TNO's opinion both those institutions form the foundation of the process of creation of the list of guaranteed services or the reimbursement policy. Experience from analysis of national systems for creation of lists of guaranteed services allowed the authors for several remarks:

1. development of a list is a time-consuming process; in none of the countries the list is finished, although in some the lists are formally complete; the main difficulty is the vast number of medical services;
2. a part of services described as basic is easy to identify – this group contains pharmaceutical means and procedures related to prevention; other procedures are considered priority due to their efficacy or political importance;
3. in none of the countries were the services described in the whole perspective of medical and hospital services; for most procedures experimental efficacy and safety as well as actual effectiveness are taken as given. [4,5]

The authors point out two solutions, which may present an interesting starting point for development of regulations related to creation of a list of basic services (meaning reimbursed or guaranteed within basic health insurance):

- the Swiss model,
- the Dutch model.

Especially the Swiss model, mainly due to its relative simplicity and efficiency, seems worth imitation. Assessment of the procedures, although avoiding unnecessary methodological purism, remains transparent and scientifically rigorous. This simplified model of assessment of medical procedures placed in the basic benefit package consists of the following essential stages:

1. identification of technologies undergoing assessment performed or supervised by the HTA Agency or reimbursement institution (priority level is determined by the HTA Agency),
2. systematic review of the publications, including synthesis of available, credible data concerning:
   - safety,
   - efficacy,
   - social and ethical implications,
   - optional or alternative treatments,
3. often cost analysis, economic and financial analysis,
4. consideration of experts' consultations and development of final conclusions and possible recommendations,
5. the reimbursement proposal is based on conclusions of the synthesis of results and is accepted by an authorized body (a decision maker or an appropriate office). (see endnote [6])

A four-stage model of process of technology assessment and inclusion of the procedures into the basic package (importance for health condition of the society, efficacy and safety, cost-effectiveness and budget impact, ethical issues and other norms) functions in Switzerland and – as stated by the authors of the report – quite efficiently regulates the range of services available within basic health insurance. It seems that this simplified solution is suggested as the most efficient for Polish system, since:

- it allows for quick development of a system for assessment of the procedures and their inclusion into the lists of basic services,
- it constitutes a reasonable compromise between a rigorous system based exclusively on scientific evidence (mainly primary studies and HTA reports) and solutions that are arbitrary to a certain degree (experts' opinion, social expectations or the will of the decision makers),
- allows for contribution of scientific and expert circles to creation of the list. [5,6]

In 2006 works on creation of the benefit package in Poland began again. This was implicated not only by the political will declared by the Minister of Health, but also by the sentence of the Constitutional Tribunal, which obliged the legislator to define, to what services the patient is entitled within basic health insurance.

1.3. The sentence of the Constitutional Tribunal concerning the health act

An important fact for initializing of creation of the guaranteed benefit package in Poland was the sentence of the Constitutional Tribunal from January 7th, 2004 in which the health insurance act (Dz. U. Nr 45, poz. 391) was pronounced contrary to the Constitution of Poland.

The Constitutional Tribunal pronounced the following regulations contrary to art. 68 as related to art. 2 of the Constitution of the Republic of Poland:

1. organization and function of the National Health Fund (chapters 1 and 4),
2. regulations concerning health needs and organization of the health care system (chapters 5, 6, 7, 8),

3. financing of the system (chapter 9),
4. supervision and control over the National Health Fund (chapter 13). [7]

In the reasons of the sentence several essential issues, important for development of the package and the legal base of its function in the system, are presented. The judges of the Tribunal formulated it straight: **"The act cannot leave any doubt as to the range of services, to which patients are entitled within the public health care system, since there is an explicit constitutional order to define this matter"**. [7]. The sentence underlines that the authors of the Constitution, "being prepared for actual impossibility to provide free health care covering all services," made it possible (in art. 68 par. 2 sentence 2) to introduce free market competition in the area of supplementary services and demand that "conditions of providing and range of services thus financed should be defined by an act of parliament" [7]. At the same time the judges stressed that "The range of services, to which the citizens (and not only the insured) are entitled within the system financed from public means, was therefore considered a legal matter" [7]. Moreover, it is indicated that the demand to "precisely define the kind of services available »in exchange« is also implicated by the essence of the insurance" [7]. In several passages of the sentence the judges pointed out that the insured patients did not know to what services they were entitled, since "the act does not introduce the institution of so-called guaranteed benefit package" and "**according to demands of the Constitution (art. 68 par. 2) the act should define either the guaranteed benefit package or (negatively) the range of supplementary services to be financed from the patient's own means. If it is to be assumed that it is not possible (neither positively nor negatively), the act should at least introduce sufficiently clear and unambiguous formal criteria, according to which the range of services, to which an individual patient is entitled, will be established *in casu*, within an appropriate procedure defined by the act." [7]**

The sentence of the CT is important for works on the package for two reasons:

1. it declares that development of the benefit package concerning basic health insurance is implicated by the Constitution of the Republic of Poland itself,
2. it refutes the argument that the benefit package is contrary to the Constitution.

The benefit package may be one of the most important elements of policy concerning service supply and demand regulation (by increasing or limiting access), being at the same time the central mechanism of elimination of inefficacious and cost-ineffective services (as compared to alternative options in a specific indication). On one hand the package is therefore a development of the reimbursement system (being actually its designation); on the other, it is a pragmatic way to describe the purchasing power of specific "insurance units", which all the insured have at their disposal. [1]

2. HEALTH PRIORITY SETTING

Przemysław Ryś

2.1. Social aspects

Development of modern methods of diagnostics and treatment as well as continuously increasing demand for health care services (among others due to aging of the society) made it impossible for any country or system to ensure accessibility of all types of health care services available on the market. It is therefore necessary to reasonably limit access to services less important for the health condition of the society and thus improve accessibility of the most important services. In order to achieve this it is necessary to assume clear criteria for establishing of hierarchy of health care services.

Such a hierarchic list of health care services would make it possible to introduce priority financing for the "top" services and limit or resign from financing of those services which would be considered less important. Depending on the payer's available means it would be possible to extend (in case of availability of additional means) or limit (at times of worse economic situation) the range of health care services available within basic insurance. Criteria for health priority setting should also take into account social aspects.

Decisions concerning financing of health care services should be made taking into consideration social expectations and influence of the services on general health condition of the society, since proper diagnostics and treatment of some conditions is especially important for the society, both in long- and short-term perspective. These conditions include, among others:

1. infectious diseases (e.g. tuberculosis, venereal diseases),
2. certain chronic diseases,
3. pediatric diseases,
4. maternity care and (perhaps) treatment of infertility.

Financing of services concerning these areas should be a priority in every country and every health care system. An important, generally accepted issue in health priority setting is the **equity concept**. According to this concept modern health policy should be aimed at equalization of possible disproportions between individuals and populations. Presentation of different published theoretic models attempting at description and implementation of the equity concept exceeds the purpose of this report. [17]

In every health care system it must be decided, which interventions should be financed within basic health insurance and which should be excluded from such financing. This process is called **priority setting**. Making of such decisions is much easier when results of efficacy and safety analyses and cost-effectiveness analyses are taken into account. However, there are situations in which, due to social reasons, it is more important to finance procedures applied in treatment of serious conditions (e.g. cerebral stroke, myocardial infarction), even if they are less efficacious or less cost-effective than those applied in less important clinical problems (e.g. correction of abnormal bite). In many cases distinction between conditions more and less important for the health condition of the society is intuitive and presents no serious problems. However, efficient and transparent financing of the health care system requires clear and transparent criteria for assessment of different conditions – which of them are important for the health condition of the society and which should be assigned lower priority and (due to budget limitations) should be excluded from financing within the public health care system.

Methods of identification of the most important health issues, to which public means are allocated in the first place, are different in specific countries or systems. In further sections

examples of regulations concerning health priority setting in selected developed countries are presented.

2.2. Epidemiologic aspects

In epidemiologic approach identification of conditions that are most important for the health condition of the society is essential. This is usually based on rates of prevalence and incidence as well as causes of death. These indexes (especially trends observed over a long time) make it possible to determine, which disease entities, due to their prevalence, character or long-term complications, are major threats for the health of the whole population or its significant part. Such an approach made tuberculosis a leading health priority in many countries. At present, mainly due to civilization progress, the most often considered health priorities include:

1. cardiovascular diseases,
2. neoplastic diseases,
3. diabetes,
4. bronchial asthma and chronic obturative pulmonary disease (COPD),
5. mental diseases,
6. diseases of the musculoskeletal system, including arthritis,
7. prevention of traffic accidents and their consequences,
8. maternity care,
9. chronic pediatric diseases.

The priorities defined above are suggestions for decision makers and health politicians as to what disease entities require special effort and allocation of substantial means from public resources. Quite often to address these issues, apart from constant health care services (ambulatory and hospital care, reimbursement of specific drugs etc.), additional health care programs (concerning prevention, screening or treatment) are introduced; these are financed from the payer's budget, national budget or by local governments.

However, the method of health priority setting based on epidemiologic indexes, with possible consideration of social preferences, does not allow for hierarchization of health care services (an intervention in a specific population). This method makes it possible to determine strategic health issues requiring higher expenditures and divide them into two groups:

1. priority,
2. remaining.

Creation of a hierarchic list of all procedures and health care services is still not possible. The method of health priority setting by identification of strategic issues cannot therefore be used (at least not in its "pure" version) to define inclusion and exclusion criteria for placement of services and procedures in the package. However, it is possible to extend this method or combine it with other mechanisms in such a way as to make it useful for that purpose.

Epidemiologic approach to health priority setting is used in several European countries (e.g. in Spain) and in Australia. [21, 22] A similar (in a manner of speaking) method of health priority setting is also used for more than ten years in Polish reimbursement system. The list of reimbursed drugs contains medications available with a significant discount or free of charge for patients suffering from certain chronic diseases (e.g. diabetes, asthma, COPD, neoplastic diseases, glaucoma, selected neurological diseases, mental diseases etc.).

2.3. Oregon Health Plan

A widely known and practically proven system for health priority setting was introduced in 1990s in the state of Oregon (USA). The aim was to decrease the number of non-insured patients, who were therefore denied access to health care. It was assumed that the highest priority was

to ensure a minimum level of health care (according to current medical standards) for all patients and thus to guarantee them health safety.

In order to achieve this the Health Service Commission was instituted; its task was to develop a list of services ranked from the most to the least important for the health condition of the society. The Commission was to consist of 11 members, including 5 physicians, a nurse, a social worker and 4 representatives of patients. [19, 20]

Health priority setting was based on efficacy and safety of particular services[4] as well as their cost-effectiveness and (possible) availability. In the beginning assessment of efficacy and safety was based mainly on the experts' opinion (clinical experience). Over more than ten years, as the number of credible sources of medical information increased, the approach to assessment of efficacy and safety changed. Currently it is based mainly on data from clinical trials, efficacy and safety analyses and systematic reviews (Table 1). Certain exceptions are possible, especially in case of so-called rare diseases. The Health Service Commission also took into consideration costs of particular medical procedures (according to data from Medicaid and private insurances). [19, 20]

[4] by a health care service an intervention applied in a specific indication was understood

Table 1.
Sources of information concerning efficacy and safety used by the Health Service Commission

Basic sources of information	
BMJ Clinical Evidence	www.clinicalevidence.com
Evidence-Based Practice Centers (EPC)	www.ahcpr.gov
Cochrane Collaboration	www.cochrane.org
University of York	nhscrd.york.ac.uk
Agency for Healthcare Research and Quality (AHRQ)	www.ahcpr.gov
Health Technology Assessment Programme – United Kingdom	www.hta.nhsweb.nhs.uk
National Institute for Clinical Excellence (NICE) – United Kingdom	www.nice.org.uk
Canadian Coordinating Office for Health Technology Assessment (CCOHTA)	www.ccohta.ca
Blue Cross Blue Shield Technology Evaluation Center (TEC)	www.bcbs.com
Additional sources of information	
Bandolier	www.jr2.ox.ac.uk/bandolier
ECRI	www.ecri.org
National Guideline Clearinghouse	www.guideline.gov
Institute for Clinical Systems Improvement	www.icsi.org
CMS Medicare Coverage Advisory Committee	www.cms.hhs.gov

Development of the ranking list of health care services, to which the citizens of the state of Oregon were to be entitled within the Medicaid system, required also consideration of social expectations. In order to achieve this, the following studies were performed:

1. 12 intensified interviews, during which information concerning the citizens' health preferences was collected,
2. ca. 50 focus studies performed at different sites in the state of Oregon,
3. a poll of 1001 citizens, in which effect of different clinical problems on general health condition was assessed.

In the beginning the ranking list of health care services was to be based on the results of cost / benefit analysis. Cost / benefit rates, calculated separately for each health care service, were to determine the position on the list of health care services. The list created using this method turned out controversial. According to that list relatively high priority was assigned to some modestly expensive and very efficacious interventions applied in trifling conditions, while more costly and relatively less effective procedures used in more serious diseases were placed much lower in the ranking. Thus the list was contrary both to social expectations and the opinion of the Commission members. It was therefore not introduced in practice. Instead, the Commission decided to classify health care services in 17 main categories, which were ranked according to their importance as related to social expectations (Table 2). [19, 20]

Table 2.
Categories of health care services as defined by the Health Services Commission of the state of Oregon

Category	Characteristics
Category 1	Acute fatal conditions; treatment prevents death, with full recovery
Category 2	Maternity care
Category 3	Acute fatal conditions; treatment prevents death, without full recovery
Category 4	Preventive care for children
Category 5	Chronic fatal conditions; treatment improves lifespan and quality of life
Category 6	Reproductive services (excepting maternity care and treatment of infertility)
Category 7	Palliative care in conditions, in which death is imminent
Category 8	Preventive dental care
Category 9	Preventive care for adults; procedures of proven efficacy and safety
Category 10	Acute non-fatal conditions; treatment causes return to previous health status
Category 11	Chronic non-fatal conditions; one-time treatment improves quality of life
Category 12	Acute non-fatal conditions; treatment without return to previous health status
Category 13	Chronic non-fatal conditions; repetitive treatment improves quality of life
Category 14	Self-limiting conditions; treatment expedites recovery
Category 15	Treatment of infertility
Category 16	Preventive care for adults; less effective procedures
Category 17	Fatal and non-fatal conditions; treatment causes minimal or no improvement in quality of life

First nine categories were considered essential and their financing was guaranteed by the state legislature. Four further categories were described as “very important” and financed depending on available means. The last four categories were considered less essential for the society. [9]

Services within each category were ranked according to their efficacy, safety and generated costs. The list is periodically verified (every 2 years) – certain procedures may be shifted up or down the list depending on fresh data concerning their efficacy and safety or costs.

Even the best ranking system (regardless of the principles of ranking itself) may prove fallible in certain situations, since it is not possible to put the whole reality into a frame of points and formulas. The Oregon Health Plan is a good example. In case of doubts concerning the position of a particular service on the list (according to the rules described above), the Commission may perform an additional assessment in order to find out whether the position of that service was appropriately determined and whether it reflects actual efficacy and safety of the procedure as well as actual social expectations. To achieve this additional studies are carried out, mostly among clinicians. They can express their opinion as to health effects of the service itself as well as its importance for the patients. The results of the assessment may contribute to “manual” adjustment of the position of a particular service on the list.

The Oregon list of health care services is a good example of health priority setting based on various factors, impossible to evaluate with a single measure. Classification of procedures into seventeen importance categories and subsequent ranking of services in each category based on the results of efficacy and safety analyses and cost analyses allowed for creation of a reasonable system for health priority setting. If the position of a specific service on the list developed according to assumed methodology becomes controversial, there is an "emergency" procedure – a kind of a "safety valve".

However, influence of the list of priorities on monthly costs *per capita* was moderate. It was estimated that costs for the cut-off point set at the level of 560 would amount to 90% of the costs that would be generated if the cut-off point was shifted to the level of 720. [20]

2.4. Slovenian system for evaluation of health care programs [18]

A different solution concerning financing of health care programs was applied by the decision makers in Slovenia. Increasing number of applications for financing of health care programs made it necessary to develop system solutions, which would allow to rank them according to their importance for the health condition of the society, efficacy, safety and costs. For this purpose the Committee for Assessment of New and Improved Health Care Programs was instituted; its task was to develop criteria for prioritization concerning implementation and financing of health care programs.

Prioritization is based on characteristics of health care programs (interventions or algorithms of management in a specific indication) considering four essential aspects:

1. **Criterion 1: clinical condition and effect of treatment**

   Reflects severity of the clinical condition and efficacy and safety of a specific intervention. In general, the more severe is the disease and the higher expected benefit from the intervention, the higher is the score for the assessed program. Some groups of patients (pregnant women, mentally ill) are treated in a particular way – they are privileged as to access to health care services. Therefore programs addressed to these groups are scored relatively higher for this criterion.

2. **Criterion 2: costs and economic aspects**

   Final (planned) method of economic assessment of programs is the cost-utility analysis. This method makes it possible to calculate the cost of gaining of one additional quality-adjusted life year (QALY). Although this measure has certain drawbacks and is difficult to assess, it is at present one of the methods most widely used to compare efficacy and safety of different programs, especially if they concern different indications. However, calculation of QALY values in applications for financing was not mandatory; therefore for the time being a different cost measure is used: "the sum required for one patient".

3. **Criterion 3: social aspect**

   Within this criterion the experts' opinion and social expectations concerning the assessed program are taken into account. Programs supported both by the experts and the society are graded higher than those assessed ambiguously or negatively.

4. **Criterion 4: population**

   This criterion concerns size of the population, to which a specific health care program is addressed. The larger is the group of potential beneficiaries, the higher is the score.[5]

Each program is independently evaluated and scored for each criterion. The sum of points for all four criteria reflects importance of the program for the health condition of the society. The higher is the total score, the higher is the priority assigned to the program.

[5] Consistency of this criterion with the principle of equal access to health care services within public health insurance may raise certain doubts. It seems justified to recommend application of exactly the opposite rule to that introduced in Slovenia.

Table 3.
Principles of health priority setting – evaluation of health care programs in Slovenia [18]

Priority	Characteristics	Weight
Criterion 1: clinical condition and effect of treatment		
1.	a. Acute fatal condition; treatment leads to full recovery or prolongs life without full recovery (e.g. malignancies, cardiovascular diseases) b. Maternity care (in pregnancy and childbirth) c. Programs extended by the Ministry of Health	50
2.	a. Treatment of psychoses	40
3.	a. Chronic fatal disease; treatment improves lifespan and quality of life b. Preventive care for children, including preventive dental care c. Treatment of infertility d. Palliative care	30
4.	a. Acute non-fatal condition; treatment may cause return to previous health status (i.e. as before acute symptoms occurred – e.g. symptomatic treatment of pain) b. Preventive care for adults; methods of proven efficacy c. Treatment of mental diseases other than psychosis	20
5.	a. Chronic non-fatal conditions; one-time or repetitive treatment improves quality of life b. Acute non-fatal conditions; treatment without return to previous health status c. Conditions, in which treatment expedites recovery	10
6.	a. Preventive care for adults; less effective procedures b. Fatal or non-fatal conditions; treatment may cause minimal or no improvement in quality of life	5
Criterion 2: economic aspects (in Slovenian currency units; 100 SIT = ca. 1.7 PLN)		
1.	Under 100,000	20
2.	From 100,001 to 500,000	15
3.	From 500,001 to 1,000,000	10
4.	From 1,000,001 to 1,500,000	5
5.	Over 1,500,001	0
Criterion 3: social aspect		
1.	Positive opinion of experts and the society	15
2.	Positive opinion of experts and neutral opinion of the society	11
3.	Positive opinion of the society and neutral opinion of experts	7
4.	Neutral opinion of experts and the society	3
5.	Negative opinion of experts and the society	0
Criterion 4: population		

Priority	Characteristics	Weight
1.	Over 2,000 patients	15
2.	From 1,000 to 1,999	11
3.	From 500 to 999	7
4.	From 50 to 499	3
5.	Under 50	0

3. INCLUSION AND EXCLUSION CRITERIA FOR THE COMPONENTS OF THE BENEFIT PACKAGE USED IN SELECTED COUNTRIES [9]

Agnieszka Nadzieja

3.1. Australia

In Australia detailed criteria for assessment of the services to be placed in the package (on the lists) are defined in the National Health Act. Inclusion and exclusion criteria for the components of the benefit package are presented in Table 4.

Table 4.
Inclusion and exclusion criteria for the components of the package in Australia

Assessing institution	Assessed technologies	Safety	Internal efficacy	External efficacy	Cost-effectiveness
TGA	Drugs and other medicinal products	YES	YES	x	x
MSAC	Medical procedures other than drugs and medical devices	YES	x	YES	YES
PBAC	Drugs	YES	YES	YES	YES
PDC	Certain medicinal products and prostheses	x	YES	x	x

Source: Productivity Commission 2005, Impacts of Medical Technology in Australia, Progress Report, Australian Government, Melbourne, April.

In general, all medicinal products must be registered in Australian Register of Therapeutic Goods (ARTG) before they are introduced into the market.

All reimbursed health care services (excepting reimbursed drugs in ambulatory care) and their prices are presented in the Government's Medicare Benefits Schedule (MBS). New procedures, diagnostic methods, medicinal products etc. may be placed on the Schedule depending on the decision of the Medical Services Advisory Committee (MSAC), based on restrictive, evidence-based assessment of:

1. safety,
2. actual benefit for the patient (efficacy),
3. comparative analysis of cost-effectiveness of the optional methods.

Drugs

Certain limitations concerning selected indications or groups of patients are introduced in order to achieve better control of costs of pharmacotherapy, especially costs generated by very expensive medications.

PBAC (Pharmaceutical Benefits Advisory Committee) recommends drugs as limited services:

1. for economic reasons, if a drug is considered cost-effective only in some of its registered indications (e.g. fentanyl reimbursed in treatment of severe pain);
2. for medical reasons (e.g. azithromycin may be reimbursed only in cases of decreased risk of development of bacterial resistance towards other antibiotics);
3. additional criteria concern patients' qualification for treatment – e.g. before a statin is introduced, the patient must fulfill defined personal and diagnostic criteria, if the drug is to be reimbursed within the PBS (Pharmaceutical Benefits Scheme).

After the drug is registered by the TGA, the sponsor of phase III trials (the manufacturer) or the distributor may submit an appropriate application to the PBAC, with attached efficacy and safety analysis and economic analysis in comparison with the most important optional treatments – these requirements are defined in the amended National Health Act from 1987.

The PBAC express these requirements more precisely in its guidelines. The PBAC suggests the amount of sales and may recommend restrictions, e.g. limitation of reimbursement to certain defined conditions.

Non-drug technologies

Apart from efficacy and safety analysis the MSAC requires presentation of a cost analysis and a cost-effectiveness analysis for non-drug technologies. The MSAC guidelines present all requirements concerning range and methodology of such analyses. In the first place it is recommended to perform analyses from the social point of view. The MH chooses priorities for selection of applications to be assessed by the MSAC. Main criteria of selection are:

1. clinical need for introduction of a particular service in Australia;
2. assessment of possibility of financing of the service within the MBS (Medicare Benefits Scheme / Schedule).

The assessed medicinal product must be registered by the TGA (Therapeutic Goods Administration). When these criteria are fulfilled, the MSAC performs:

1. safety assessment,
2. analysis of efficacy and safety,
3. cost-effectiveness analysis.

Depending on the results, the MSAC recommends to the Ministry of Health classification of the medicinal product into one of three categories:

1. results of credible analyses strongly recommend placement of the technology on the MBS list,
2. not recommended for the MBS,
3. the results are ambiguous, but suggest that the technology may be safer, more efficacious or more cost-effective than alternative options; in this case the MSAC may commission its own analyses.

3.2. Switzerland

The process of definition and creation of the benefit package in Switzerland began in mid-1980s. Since 1992 a manual concerning quality criteria and completeness of comparative efficacy and safety analyses and economic analyses of health technologies has been created.

A positive list of services was created and all diagnostic and therapeutic procedures placed on that list were financed, if they were proven as:

1. efficacious and safe,
2. necessary to apply,
3. cost-effective (in a comparative analysis).

Otherwise the procedures were placed on the negative list.

In 1999 services of alternative and complementary medicine were conditionally placed in the basic benefit package. After complex assessment of the procedures of alternative medicine only selected procedures in specific indications were left in the basic package. [the author's information]

The basic package does not list all the procedures explicitly, while the negative package is defined clearly and in details. All diagnostic and therapeutic procedures (including drugs) used in hospital and ambulatory care are therefore reimbursed unless they were excluded due to:

1. lack of proven effectiveness,
2. "inappropriateness" or lack of cost-effectiveness.

Inclusion and exclusion criteria for services (drug and non-drug technologies assessed as compared to optional or alternative technologies in a specific indication) concern:

1. effectiveness
2. safety,
3. necessity of application,
4. cost-effectiveness (economic and financial analysis taking into account size of the population and delivery of the services).

Along with the application for placement in the positive package the manufacturer must submit a HTA report. The analyses attached to applications must be prepared according to precise and transparent guidelines (quality criteria concerning credibility and completeness of the analyses) – the Manual for the Standardization of Clinical and Economic Evaluation of Medical Technology. The manual was formally accepted in 1998 and updated in 2000. The document was prepared by the BSV on the commission of the ELK; it contains clear description of all stages of the procedure of application for reimbursement and its consideration (acceptation or refusal). The description of administrative proceedings is complete and illustrated with examples.

Analyses of efficacy and safety are based on systematic reviews; in many cases data from registers or clinical trials are used to assess effectiveness. Some registers and clinical trials are conducted by public institutions and financed from public means; in other cases they are commissioned by the applicants and financed from their own resources. Analyses of efficacy and safety and economic and financial analyses are performed by public institutions as well as other Swiss and foreign companies and institutions, appointed by public tender or commissioned to external experts. Most analyses are financed from public means by the Federal Coverage Committee.

In order to place a procedure on the positive list (in the positive package) consent of a federal institution is necessary (e.g. Federal Social Insurance Office – BSV); its assessment is consulted with various federal committees and commissions.

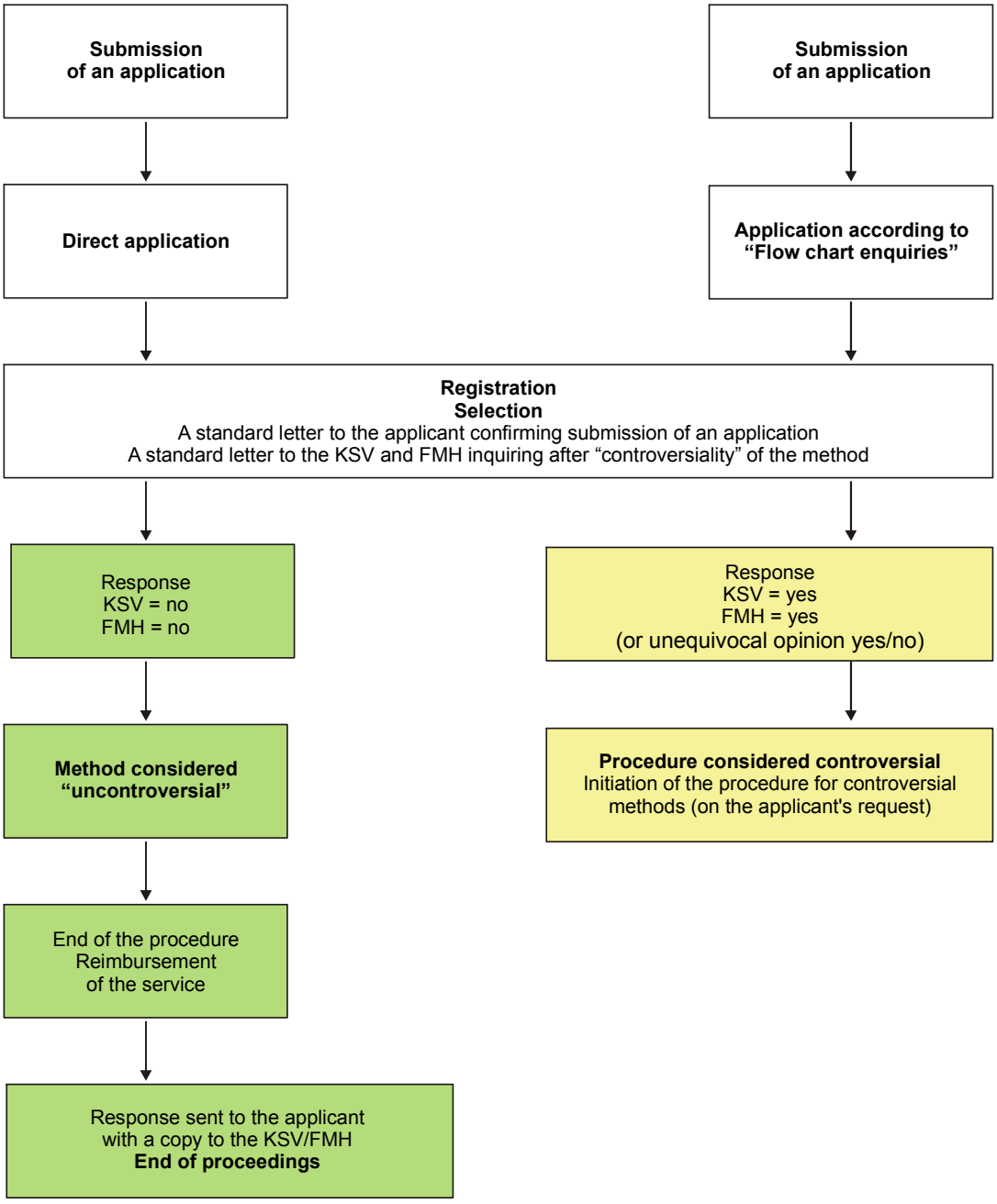
The supplementary package (larger than the basic package – "the second group of procedures is the larger one") contains procedures performed in ambulatory and hospital care which are not or do not need to be financed within basic insurance and may be offered in various configurations by supplementary insurances. The following procedures are (or may be) excluded:

1. procedures that are not reimbursed or may be reimbursed conditionally within basic insurance, for which the ELK conducted:
   - assessment of effectiveness,
   - assessment of utility in clinical practice and cost-effectiveness;
2. procedures, for which studies or analyses (concerning effectiveness, utility in practice and cost-effectiveness) are continued may nevertheless be conditionally reimbursed within basic insurance in precisely defined indications and groups of patients, within limited budget (in a way similar to therapeutic programs in Poland),
3. very expensive procedures or those requiring special skills or specialist equipment are financed within basic health insurance provided that they are performed by qualified specialists in defined circumstances.

Procedure of application for placement in the positive package (reimbursement) for services (including drugs) and medical procedures

The procedure is initiated on request of the applicant. The BSV decides whether to forward the application for reimbursement to the EDI after consulting the Swiss Health Insurers' Association (KSV) and the Swiss Medical Association (FMH).

Figure 1.
Procedure of consideration of applications for placement of services and procedures in the basic package in Switzerland



Source: BSV manual

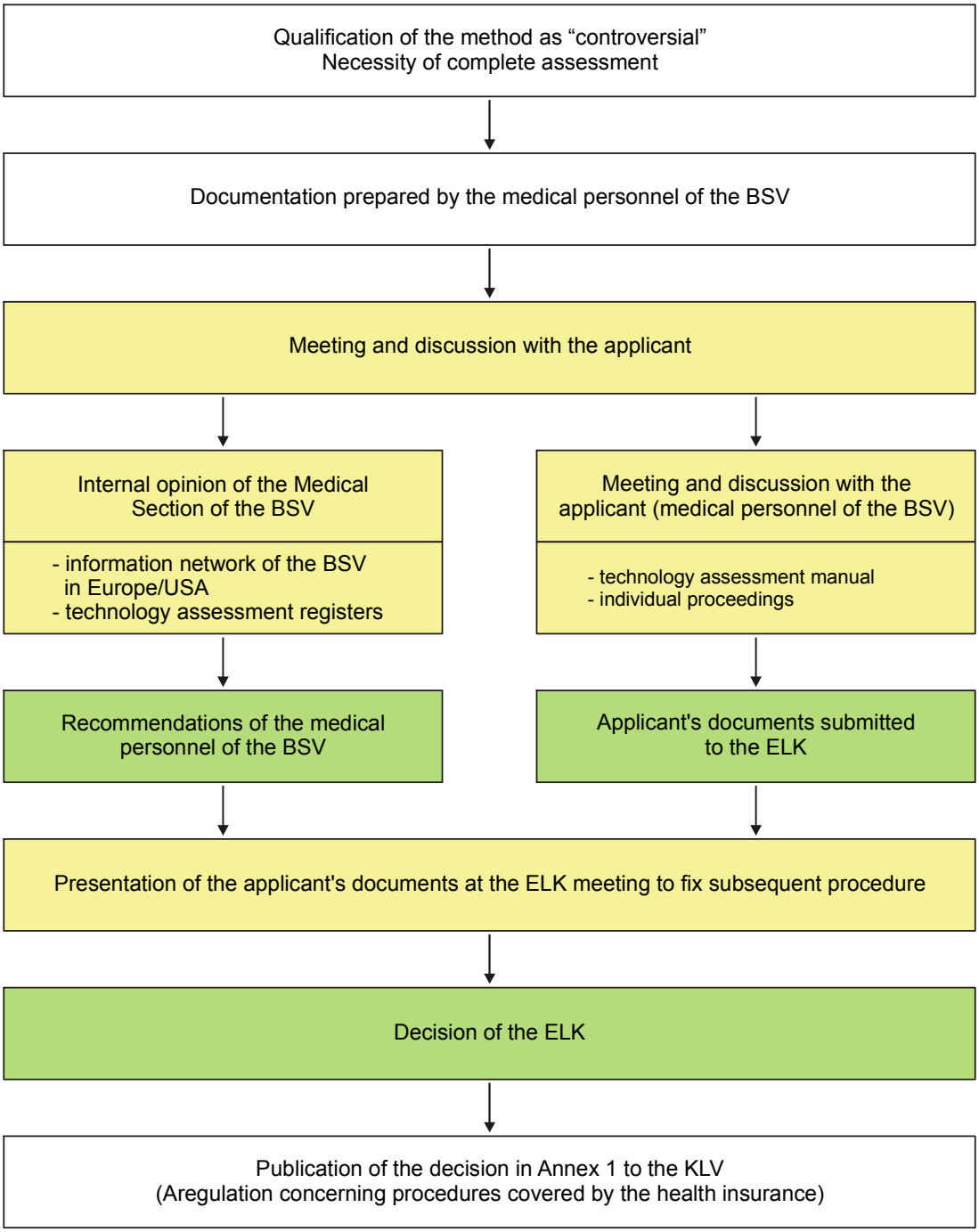
Further procedure for applications concerning procedures and services considered controversial at the first stage of assessment

If a treatment is considered "controversial", further assessment of this treatment is necessary.

The ELK investigates effectiveness, necessity of use and efficiency of the "controversial" procedure and presents its recommendations to Federal Department of Home Affairs (see art. 32, par. 1, 2 and 3 of the KVG, art. 33 of the KLV). The ELK makes decisions concerning

recommendations taking into consideration documents submitted by the applicant and written opinion of the BSV.

Figure 2.
Further procedure for services and procedures considered controversial



Source: BSV manual

Economic assessment

The next step towards obligatory reimbursement, i.e. placement in the basic package, is comparative economic analysis and financial analysis. Assessment of cost-effectiveness of compared methods should be based on cost analysis according to guidelines of the PKS (Parity Commission).

3.3. The Netherlands

In 1985 it was assumed that efficacy, safety and cost-effectiveness of all future health technologies will be assessed before the technologies are placed in the benefit package. In 1985 assessment of three technologies was initiated: heart transplantation, liver transplantation and *in vitro* fertilization. Projects financed from special budget for health care research could concern new technologies or those already introduced – their efficacy, safety and cost-effectiveness as well as social, ethical and legal implications. In practice mainly new technologies were assessed before application for placement in the benefit package.

A report of the Governmental Committee titled “Choices in Health Care” (1992) defined the following criteria for the services to be placed in the guaranteed benefit package:

1. necessity (from medical point of view),
2. efficacy,
3. efficiency and
4. the services must not depend on individual responsibility.

In general, inclusion and exclusion criteria concern efficacy, safety and costs. For drugs the criteria are cost-effectiveness and impact on the payer’s budget. There are no formally established criteria for medicinal products other than drugs. Choice of a product may depend on costs and preferences of patients.

In assessment of a new drug it must be first taken into account whether generic substitutes of this drug are available. Drugs having a similar mechanism of action and administered in a similar way, without significant differences in their clinical characteristics, are classified in the same group (cluster) and form Category 1A. Otherwise the drug may be classified in Category 1B (see below).

Since mainly drugs belonging to Category 1B contribute to increase of expenses on drugs in general, additional assessment of their cost-effectiveness and therapeutic importance is performed – the procedure is more restrictive than in case of the 1A drugs.

Analyses concerning therapeutic importance, efficacy and safety and significance for the health condition of the society are supplied by the manufacturer. An opinion based on these analyses is submitted to the Minister; however, decision of the Minister may be different from the opinion since it is the Minister who decides if the drug is important for the health condition of the society. Budget impact and severity of the disease are also considered. The CFH and the CVZ assess credibility of the received analyses and their results and prepare a special report containing recommendations (an opinion for the Minister), which is published in the internet. If the Minister, according to the CFH report, decides that the drug should be placed in the package, the drug is classified in Category 1B.

Since January 2005 pharmaceutical companies are obliged to demonstrate cost-effectiveness of new drugs. Formal requirements include pharmacoeconomic analysis and budget impact analysis (in years 2002-2004, being an intermediate period, pharmacoeconomic analysis was not required). This procedure is required for drugs without generic equivalents (1B).

In years 1993-1998 Category 1B was temporarily closed. Only drugs used in first-line pharmacologic treatment in indications that were not considered so far were assessed. At that

time the health care system was restructured. Since 1999 the drugs of prices higher than those of their substitutes may be reimbursed only if they are more efficacious and safer. Reimbursement limits for each group are set by Farmatec. If the price of the drug is higher than reimbursement limit granted for this drug, the difference in costs is incurred by the patient.

3.4. Great Britain

Inclusion and exclusion criteria for the benefit package are presented in the tables below.

Table 5.
Inclusion and exclusion criteria for the components of the benefit package

Range of services	Criteria
Services in ambulatory care	• requirement • efficacy and safety • costs
Drugs	• efficacy, safety and effect on quality of life (without relation to other, already registered drugs) • assessment of the amount and value of sales • importance from medical point of view

Table 6.
Negative package – exclusion of services

Negative package	Excluded services	Exceptions
NHS Trust purchasing contracts	cosmetic surgery (e.g. tattoo removing, buttock lift, breast enlargement)	in exceptional circumstances
"Black list" of drugs	a list of excluded drugs (OTC drugs, perfume, food, beverages)	-
"Grey list" of drugs	a list of drugs of doubtful safety or low cost-effectiveness	exceptional clinical cases
NICE reports	exclusion of specific drugs or procedures (e.g. extraction of wisdom teeth)	in defined indications
Decisions of British National Screening Committee / NSF	screening concerning: • prostate cancer, • in pregnant women: chlamydiae, cystic fibrosis, type C hepatitis, diabetes, • in neonates: Duchenne dystrophy, autoimmunologic thrombocytopenia, neuroblastoma • in children: autism, arterial hypertension, speech retardation, sideropenic anemia, lead poisoning, obesity, vision defects, • in adults: Alzheimer disease; rectal, pulmonary, ovarian and gallbladder cancer, depression, type C hepatitis, osteoporosis, Vaccinations: smallpox, single vaccinations against measles, mumps and rubeola.	x
Others	spectacles for employed adults	a criterion depending on age and income

In many hospitals HTA reports or pharmacoeconomic analyses are taken into consideration in decision making concerning inclusion into or exclusion from the formulary.

Since in the UK profits of pharmaceutical companies are controlled by the state, for prescription drugs the criterion of budget impact (BIA analysis) is not taken into account.

3.5. France

Primary purpose of creation of the benefit package in France was elimination of ineffective procedures.

Basic criteria, according to which decisions of placement of a service on the positive list are made, concern:

1. safety,
2. efficacy,
3. costs.

Drugs

Placement of a drug on the list of reimbursed drugs depends on two issues:

1. the drug must improve treatment (as compared to other drugs in the same therapeutic group)

   or
2. lower the costs of treatment.

Criteria of assessment of therapeutic value of a drug (SMR, Service Médical Rendu) taken into consideration by the Transparence Commission concern:

1. efficacy and safety profile,
2. role in treatment as related to available optional and alternative methods of treatment,
3. severity of the disease to be treated,
4. features concerning causal, preventive or symptomatic treatment,
5. importance for the health of the society.

For each of these criteria the assessment is made on a five-degree scale. Therapeutic value for each criterion may be described as:

1. very high,
2. high,
3. moderate,
4. low,
5. insufficient.

The last grade (“insufficient”) disqualifies the drug from placement on the positive list and therefore from reimbursement.

Granting of the status of the reimbursed drugs is based on three elements:

1. definition of health-related benefit of the drug, called “Service Médical Rendu” (SMR),
2. assessment of the intervention described by the SMR as related to the “gold standard” and alternative interventions, called “Amélioration du Service Médical Rendu (ASMR)”,
3. identification and definition of a treatment strategy for the reimbursed drug.

Since 1972 the procedure of drug registration is based on the assessment of its quality, efficacy and safety. Exceptions are made e.g. for homeopathic drugs. Assessment of these parameters is a task of the AMM commission.

If a specific drug is to be granted the status of a drug reimbursed by the insurer (Caisse Nationale d'Assurance Maladie), it must be assessed by the Transparence Commission (CT) as to its:

1. efficacy and safety,
2. innovativeness,
3. benefits related to its introduction onto the market and reimbursement.

Efficacy and safety of all registered drugs (and other medicinal products) is assessed by Amélioration du Service Médical Rendu (ASMR). The ASMR gives opinions concerning drugs and other medicinal products taking into consideration opinions of experts of Commission de la Transparence and Agence du Medicament.

Every drug registered by the ASMR is classified into one of 6 categories:

1. an innovative drug of proven effectiveness,
2. an effective drug – clinical efficacy prevails over the risk of adverse effects (an acceptable safety profile)
3. an equivalent of a medicinal product already present on the market and registered in France, of relatively proven efficacy,
4. a probably efficacious drug of low clinical utility,
5. a drug of unproven efficacy (it is still possible to place such a drug on the list of reimbursed drugs),
6. a drug not to be placed on the list of reimbursed drugs due to negative opinion.

There are different levels of reimbursement for specific drugs:

1. irreplaceable or very expensive drugs are completely reimbursed – 100%,
2. drugs used mainly in treatment of not serious disorders – 35% (labeled with blue tags – “vignettes bleues”),
3. other drugs used in most frequent diseases – 65% (labeled with white tags – “vignettes blanches”),
4. prescription drugs and products listed on the official list of drugs – 65%.

Medicinal products other than drugs

Medical devices and medicinal products other than drugs may be placed on the positive list of products and related services. The list contains also reference prices of products and services. The list is constructed on the national level. It consists of 4 sections, as follows:

1. therapeutic medicinal products, including those related to first aid,
2. corrective devices,
3. medical implants and grafts,
4. wheelchairs.

For each product the criterion for inclusion into or exclusion from the package is its utility, assessed as related to another product, already placed on the list.

The HAS performs assessment of efficacy and/or safety of the procedure under consideration and defines conditions, on which it may be placed on the list.

The opinion of the HAS concerning a medical procedure is based on:

1. scientific evidence concerning efficacy and/or safety of the procedure,
2. comparison with procedures placed in packages or lists in other countries:
   - USA – Current Procedure Terminology,
   - Australia – Medicare Benefit Schedule Book,
   - Belgium – Nomenclature of Health Care Services,
   - Switzerland – the list of reimbursed procedures,

3. opinion of specialists in the field,
4. opinion of health care providers, developed within a meeting of the working group.

3.6. Germany

In Germany inclusion and exclusion criteria for the components of the benefit package are based on diagnostic and therapeutic benefit, medical necessity and cost-effectiveness.

Table 7.
Inclusion and exclusion criteria for the components of the package in Germany

Package	Description: level of detail	Components of the package [medicinal goods or services, indications (i.e. procedures understood as relations between an indication and an intervention) or relation to an indication]	Update	Inclusion criteria for the benefit package				
				Necessity	Costs	Efficacy and safety	Cost-effectiveness	Budget impact
SHI GBR	1; 2	X	When necessary	+	X	X	X	X
SHI FJC general directives	2	X	When necessary	+	+	+	(+)b	X
SHI FJC special directives: positive	2; 3	Products, services, indications	When necessary	+	+	+	(+)b	X
SHI FJC annexes to directives: negative	3	Products, services, indications	When necessary	+	+	+	(+)b	X
SHI DRG	3	Services	Annually	+	+	+	X	X
SHI EBM	3	Services	When necessary	+	+	+	X	X
SHI BEMA	3	Services	When necessary	+	+	+	X	X
SHI BEL-II	3	Products	When necessary	+	+	+	X	X
Legal long-term care insurance: GBR	1	X	X	X	+	X	X	X

1 – all necessary; 2 – area of care; 3 – specific services or procedures; b – concerns all medicinal products

In Germany CE analyses or other economic analyses are exceptionally taken into account in creation of packages or reimbursement.

The DRG system, introduced by the “SHI Reform Act” (GKV 2000), is based on the results of health technology assessment and stresses the role of guidelines.

One of the institutions responsible for the package is the Federal Joint Committee. Directives issued by so-called Plenary, a central decisive body of the FJC, may set priorities in health technology assessment as related to inclusion or exclusion of technologies to/from the SHI benefit package.

In January 2004 the government of Germany announced foundation of the IQWiG (Institut für Qualität und Wirtschaftlichkeit im Gesundheitwesen), the purpose of which is to provide

information to assist in the process of appraisal based on health technology assessment. The task of the Institute is to supply HTA analyses, on which decisions of the FJC and the Ministry of Health and Social Care concerning reimbursement will be based. The first 6 conditions assessed by the IQWiG were: bronchial asthma, COPD, arterial hypertension, depression, dementia and diabetes.

3.7. USA

The Oregon Health Plan

In 1994 a project concerning creation of a relatively complete list of services available in the state of Oregon was started. The aim was to create a list of guaranteed services and to decrease the number of non-insured patients, who were therefore denied access to health care. The intention of the Oregon Health Plan was to reduce the list of Medicaid services to a set of services most important and necessary to maintain the health condition of the society.

The list was constructed by assigning treatment procedures to specific conditions and creation of a list of codes of guaranteed medical procedures.

All elements of the list were arranged in a hierarchic order, taking into account additional criteria, e.g.:

1. life expectancy,
2. quality of life,
3. cost-effectiveness of the procedure,
4. availability of the service.

The following hierarchy of the procedures was set:

1. life-saving services leading to full recovery,
2. maternity care,
3. life-saving services not leading to full recovery,
4. services causing minimal or no improvement in quality of life.

The final list consisted of more than 700 positions. The proposed system allowed for annual reduction or increase of the number of financed procedures, according to available budget.

Table 8.

Stages and criteria of creation of the package of the Oregon Health Plan

Plan	Action: characteristics and stages	Criteria
1	• construction of a list of 709 so-called condition-treatment pairs (CT), assessed by physicians as to their incremental treatment benefit and net health-related benefit as measured by a weighted scale (Quality-of-Well-Being-Scale), • calculation of the cost-benefit ratio for each CT pair • ranking of the pairs according to calculated ratio	• cost / benefit ratio, • Quality of Life (QoL)
2	• creation of 17 categories of services, each containing one CT pair, • calling of public meetings in order to gather opinion and assess social expectations, • identification of 3 aspects of social expectations: value for the society, value for an individual, necessity in primary health care, • ranking of 17 categories based on the results of social expectations assessment, • classification of categories into 3 groups: essential, very important, important for specific individuals, • rearrangement of CT pairs within each category based on net health-related benefit, • adjustment of the list to social expectations and assigned values	• effect on the health of the society, • costs related to treatment, • public opinion
3	• the list was shortened to 688 pairs – QoL was not taken into account in assessment of treatment results	• probability of death, • probability of return to asymptomatic state • costs of avoiding of a death
4	• final correction of the list	-

In the USA Oregon is treated as the reference state for comparisons concerning limitation of range of Medicaid services.

Information concerning the Oregon system is also presented in the chapter concerning health priority setting. (Chapter 2.3)

Organizations of managed care, due to their competitiveness, set their own inclusion and exclusion criteria for the components of the package. Exclusion criteria play a special role. These criteria concern mainly so-called experimental technologies and services not considered essential from medical point of view.

According to definition published in Health Benefit Plans (Rule R590-165) concerning basic principles of the insurance in HMO-type units, an experimental technology is a treatment, procedure, drug or medical device, which does not fulfill all of the following conditions:

1. the technology must be finally accepted by all appropriate regulative governmental organs,

2. the technology must be assessed in a significant number of external clinical trials or other studies,
3. available studies concerning the technology must allow for assessment:
   - if the technology is both necessary from medical point of view and appropriate for an insured patient,
   - if the technology is efficacious and safe,
   - if – and with what probability – its application in an insured person will bring health-related benefit;
4. the technology must be considered appropriate by the regional medical community.

Blue Cross defines an experimental technology as a procedure which does not fulfill generally accepted medical standards concerning efficacy and safety of treatment in specific circumstances.

Tradition of exclusion of experimental technologies from services covered by the insurance dates back to 1974 (Federal HMO Act, Regulations 1974). Even then inclusions of such technologies into the benefit package depended on decisions of particular HMOs.

The Kaiser health plan excludes every service that, after consultations with the medical group, was considered experimental and was not classified according to medical standards as efficacious and safe in a specific case or requires permission of appropriate government bodies.

Services are excluded depending on the criterion concerning experimental technologies or medical necessity. For instance, the procedure of implantation of an artificial disc in degenerative disease of the spinal column (spondylosis) was excluded from the Blue Cross package until credible evidence concerning its efficacy and safety is published. Blue Shield insurance does not cover such services as bariatric surgery, abdominal plastic surgery, mammoplasty, magnetic resonance imaging (MRI) of the chest or mastopexy.

4. CRITERIA RELATED TO THE HEALTH CONDITION OF THE SOCIETY

Przemysław Ryś

Due to limited time for creation of the guaranteed benefit package it seems necessary that solutions concerning the effect on the health condition of the society should for the time being be simple, clear and easy to implement. In the following years they may possibly undergo more or less thorough modifications, according to the situation.

As it was stated in the chapter concerning health priority setting, epidemiological approach does not take into account all aspects of the health condition of the society. Although specific target groups requiring special treatment may be identified, it is not possible to consider that all remaining patients will be excluded from the system of financing.

Implementation of a system inspired by the Oregon Health Plan would probably bring good results, but would require several years of preparation – the time necessary for creation of a similar list would be much longer than 18 months (the time appointed for development of the package in Poland). However, assuming that the process of update and modification of the package contents will be continuous, it is possible that Oregon experience will prove helpful in the future.

The Slovenian system was designed for assessment of health programs and does not concern all services possible to perform within basic insurance; therefore it contains criteria that should not be taken into consideration in decisions concerning reimbursement in Poland. This is true, for example, for the criterion of the target population size. Considering basic assumptions for the package in Poland, it is not possible to promote services related to frequent diseases and limit or reluctantly finance services in relatively rare diseases. Slovenian methodology of priority setting has certain advantages, although implementation of such methods would require specific simulations, which in turn would require time and appropriate financing.
Thus it seems that for the time being the benefit package should fulfill the following requirements related to the criterion of the health condition of the society:

1. **The basic package should contain at least one intervention for each disease entity (each indication).**

   This rule results from social solidarity understood in such a way, that for each insured person who requires treatment (regardless whether the disease is severe or not, is placed on the list of socially important diseases or not, whether the patient can afford a supplementary insurance or is treated only within basic insurance) access to a method of diagnostics or treatment of proven efficacy and safety should be ensured. Exceptions from this rule are defined below (rule 2).

2. **It will be necessary to define a negative list of disease entities.**

   Not all clinical conditions are important enough for the society as to finance their treatment from public means and take them into account on defining the range of basic insurance. Contemporary medicine offers, apart from many interventions improving quality of life and/or lifespan, also interventions applied for cosmetic reasons or in conditions, in which the criterion of medical necessity is not fulfilled. In a situation, in which limitation of expenses related to health care is necessary, resignation from such interventions would entail relatively insignificant social consequences.

   Finally, there are diseases and conditions which do not require treatment or in which the treatment is relatively quick and cheap – they require no insurance. This concerns mainly trifling conditions in young people, without concomitant diseases. It seems that the negative list may contain certain drugs used in herpes, pharyngitis or even uncomplicated peptic ulcer. Treatment of these conditions is short, relatively cheap and bearable for most citizens.

These considerations suggest that definition of a negative list of disease entities and indications, in which treatment will not be financed from the payer's budget, would be a justified solution.

Development of such a list would require consensus of representatives of: medical professionals, the MH and patients as well as AHTAPol experts and other interested parties. It seems reasonable that the list should contain only these disease entities and conditions that:

1. are not life-threatening (either directly or indirectly, e.g. by increasing the risk of other conditions – fatal or worsening quality of life),
2. do not cause permanent health impairment,
3. are transient and short in duration and their treatment costs are relatively low and may be covered by the citizens from their own means (e.g. uncomplicated influenza, pharyngitis),
4. their treatment is not considered priority in Poland (Table 9).

Examples of clinical conditions that may be placed on the negative list are presented in Table 10.

Table 9.
A list of disease entities considered health priorities in Poland (a proposal)

Health priorities in Poland
1. cardiovascular diseases
2. neoplastic diseases
3. diabetes
4. bronchial asthma and chronic obturative pulmonary disease
5. mental diseases
6. diseases of the musculoskeletal system, including arthritis
7. prevention of traffic accidents and their consequences
8. maternity care
9. chronic pediatric diseases

Table 10.
Examples of health care services that may be placed on the negative list (more precise definition of indications and exceptional situations is recommended)

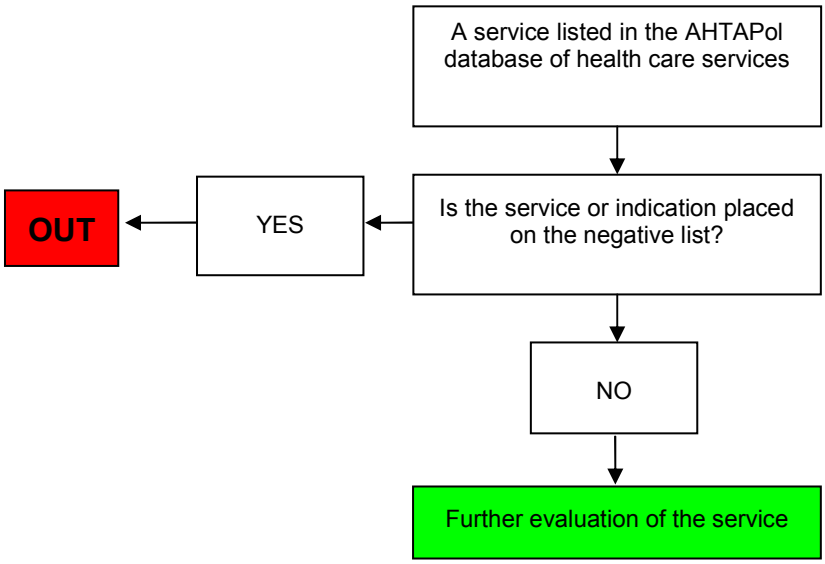
Negative list of health care services in Poland
1. contraception
2. plastic surgery
3. contraceptive means
4. sex change operations
5. juvenile acne
6. alopecia in men
7. trifling upper respiratory infections (not requiring long-term treatment – expected time of spontaneous recovery shorter than 7 days)
8. trifling food poisoning (not requiring long-term treatment – expected time of spontaneous recovery shorter than 7 days)

The criteria described above ensure financing of at least one technology for each indication, treatment of which is important for the health condition of the society. At the same time these rules exclude financing of certain (few) services of minor clinical and social significance. Considering that means allocated for health care are limited it is obvious that these means must not be spent on treatment of conditions, which are neither socially important nor constitute a threat to life or health. Financing of certain services (e.g. plastic surgery without medical indications) with simultaneous limitation of means spent on diseases such as diabetes, asthma,

neoplasms or heart diseases would be unethical[6] and unreasonable, considering interest of the state and the society.

Health care services related to diseases placed on the negative list are not included into the basic benefit package and therefore are excluded from further assessment according to the package inclusion and exclusion criteria.

Figure 3
Stage I – Health condition of the society



[6] the resources are limited and their allocation for treatment of one condition (X) implicates decrease of means used for treatment of another condition (Y)

5. CRITERIA OF EFFECTIVENESS

Robert Plisko

Krzysztof Łanda

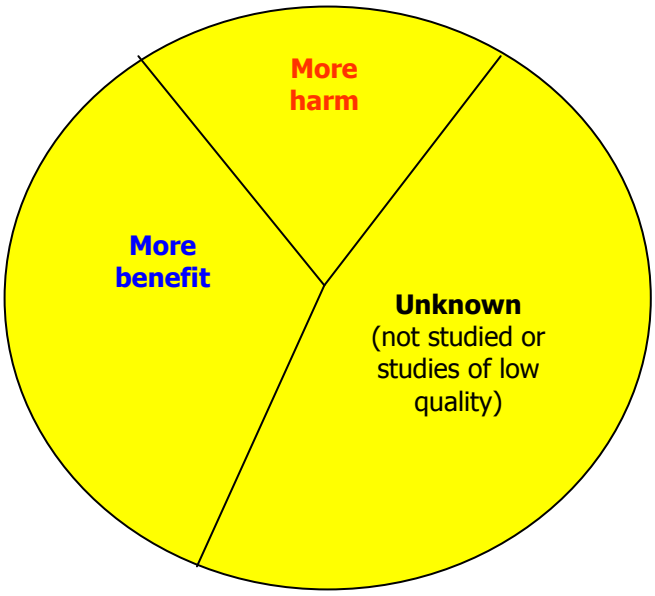
Criteria of efficacy and safety concern only services related to conditions that were not placed on the negative list (see: criteria related to the health condition of the society). In other words interventions performed in conditions placed on the negative list do not undergo further assessment according to the inclusion and exclusion criteria – they were excluded from the guaranteed benefit package at the previous stage of assessment.

5.1. Analysis of efficacy and safety

Both the guaranteed benefit package and the supplementary benefit package may contain only services of proven efficacy and safety.[7] Services of proven harmfulness in a specific indication should be placed in the negative package, which means that they should be prohibited both within basic and supplementary insurance. Services of doubtful or unknown efficacy and safety may be placed only in the supplementary benefit package.

The diagram below, prepared by prof. Sir Muir Gray, illustrates efficacy and safety of health care services performed within health care systems worldwide. In developed countries services of proven efficacy and safety comprise less than 50% of all performed services; other services (not necessarily financed by the insurance) are those of proven harmfulness or of unknown efficacy and safety (not proven in properly designed and performed clinical trials). Two last categories raise the most doubt.

Figure 4
Efficacy and safety of health care services performed within health care systems worldwide.



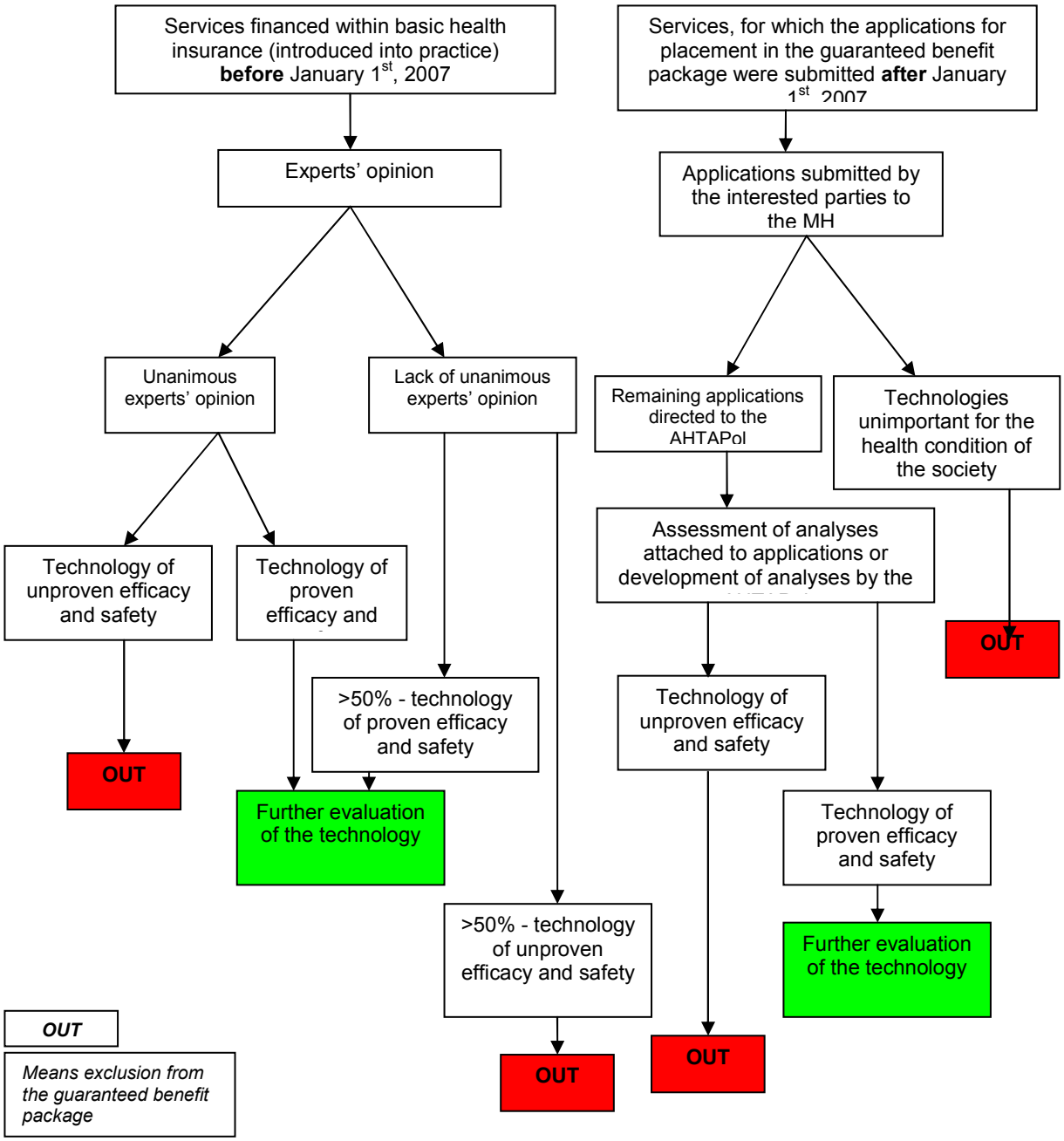
[7] Because resources would always be limited, they should be used to provide equitably those forms of health care which had been shown in properly designed evaluations to be effective – Prof. Archie Cochrane

The basic rule of inclusion into the guaranteed benefit package is inclusion of **at least one service** of proven efficacy and safety for each important indication. This principle is based both on social solidarity and the citizens' rights contained in the Polish Constitution (equal access).

Different criteria concerning efficacy and safety are presented for two groups of health care services:

1. for services currently (in 2006) financed within health insurance (present on the lists of services, the lists of reimbursed drugs etc.),
2. for services, for which application for inclusion into the guaranteed benefit package will be submitted on January 1st, 2007 or on a later date.

Figure 5
Stage II – Efficacy and safety



Criteria concerning efficacy and safety for currently financed services

Only services of proven efficacy and safety will be investigated at further stages of evaluation.

Assessment of efficacy and safety will be based on unequivocal opinion of the experts – arbitrary as it is, the experts' opinion should be based on scientific evidence. In case of unequivocal opinion concerning lack of efficacy and safety in a specific indication, the service will undergo no further assessment and will be excluded at this stage from the guaranteed benefit package (marked “OUT” on the diagram). If efficacy and safety of the service remains doubtful, the service will undergo further assessment.

The expert group may formulate the following statements concerning efficacy and safety of each considered health care service:

1. an unequivocal positive opinion – the service is considered efficacious and safe and proceeds to further stages of evaluation (according to subsequent criteria);
2. an unequivocal negative opinion – due to lack of proven efficacy and safety the service is excluded from the guaranteed benefit package (OUT);
3. the expert group was unable to formulate an unequivocal opinion:
    A. more than 50% votes for the service being efficacious and safe – the service proceeds to further stages of evaluation (according to subsequent criteria);
    B. more than 50% votes against the service – due to lack of proven efficacy and safety the service is excluded from the guaranteed benefit package (OUT).

Criteria concerning efficacy and safety for services submitted for evaluation as to possible inclusion into the guaranteed benefit package after January 1st, 2007

All inclusions concerning:

- drug or non-drug health technologies,
- diagnostic or therapeutic health technologies,
- registered health technologies or those introduced into practice outside the registration system,

may be made exclusively after submission of the appropriate application and consideration of this application according to defined principles and established procedure.

The AHTAPol, depending on the results of the analyses of efficacy and safety, evaluates the services as those:

1. of proven efficacy and safety – the services undergo further evaluation,
2. of unproven efficacy and safety – the service is not included into (or is excluded from) the guaranteed benefit package and undergoes no further evaluation (OUT).

In the annex (chapter 12) hierarchy of publications concerning efficacy and safety proposed by the Oxford Centre for Evidence-based Medicine is presented; this may be accepted by the AHTAPol.

A credible efficacy and safety analysis should always be based on a systematic review. This makes presentation of selected publications containing results favorable for the service (and the applicant’s interest) impossible. The advantage of a systematic review is high reproducibility of the results; it means that a systematic review repeated by a different institution brings results identical or very similar to those of the primary review.

The efficacy analysis should include all optional health care services possible to apply in a specific clinical condition (in a specific indication). The new technology should be compared to the most important options.

A credible analysis of efficacy and safety should fulfill the following criteria:

1. takes into account all options, i.e. all methods of treatment applicable in a specific clinical situation,
2. contains description of all technologies and reasons of inclusion and exclusion of specific methods of treatment into/from the analysis,
3. presents searched databases, search strategy for clinical studies and combinations of key words,
4. includes all studies assessed as credible, regardless of their results,
5. evaluates (and scores in points) credibility of the clinical studies included in the metaanalysis.

The review may be called systematic if it fulfills 4 of these 5 criteria (Cook et al.).

The links presented below lead to manuals concerning conduct and assessment of efficacy and safety analyses:

1. Great Britain: http://www.york.ac.uk/inst/crd/report4.htm
2. Cochrane Collaboration: http://www.cochrane.org/resources/handbook/

Guidelines concerning quality of the analyses of efficacy and safety should be presented by the AHTAPol, if the Agency will be responsible for quality of the analyses used in decision making.

The main purpose of the guidelines is to ensure transparency[8] and reproducibility of decisions and – at the further stage – objectiveness of the results of economic analyses based on credible and complete analyses of efficacy and safety (mainly due to hierarchization of methods). Guidelines *per se* are an element of standardization and therefore should lead to limitation of arbitrariness and to hierarchization of methods; this implicates recommendation of the best methods wherever such methods are applicable.

Apart from transparency the most important purpose of the guidelines is to ensure reproducibility of the results of analyses, i.e. if different investigators would independently work on the same subject according to the same guidelines they should obtain the same or very similar results. **The measure of quality of guidelines or credibility criteria is their ability to ensure reproducible results of the analyses.**

[8] „Towards Transparency in Health Technology Assessment. A checklist for HTA Reports", David Hailey; International Journal of Technology Assessment in Health Care, 19:1 (2003), 1-7

6. SIMPLIFIED BUDGET IMPACT ANALYSIS

Marcin Gąsiorowski

Krzysztof Łanda

Simplified[9] budget impact analysis (BIA) is performed for health care services which were considered efficacious and safe at the previous stage of the assessment and were introduced into practice before January 1st, 2007. Health care services introduced into practice after January 1st, 2007 undergo complete economic analysis and the payer's budget impact analysis (chapter 7) – therefore this stage of the assessment does not apply to them.

The purpose of simplified payer's budget impact analysis is to identify these services of proven efficacy and safety, for which one-time or annual costs of treatment are relatively high and therefore may be a factor seriously limiting their availability. Relatively high unit costs of health care services are one of the most important causes[10] of limited availability of the services and of the very existence of health insurances.

A simplified (due to practical reasons) BI analysis should be performed for each service currently performed and financed within basic insurance, which is to be placed in the guaranteed package. This concerns all drug and non-drug interventions, both diagnostic and therapeutic, in every significant indication – especially in indications related to registration – within the range of the defined, positive[11] guaranteed benefit package.

Depending on the results of threshold analysis (alpha, beta, phi) the services to be placed in the guaranteed benefit package will be identified, according to unequivocal opinion (proven efficacy and safety), as well as those services, for which complete economic and financial analyses for the most important treatment options will be necessary (provided that such options exist and there is no doubt as to their efficacy and safety – see assumed rules).[12]

Two kinds of information are necessary for simplified budget impact analysis (for practical reasons precision of both estimations may be limited at this stage of work on the package):

1. unit cost of the service or annual cost of treatment (the values may be taken from the NHF list of services, IMS data, assessment of the AHTAPol or they may be estimated values according to agreed opinion of members of the Expert Groups assessing particular services) and
2. number of services performed annually or number of patients undergoing continuous treatment in the whole country (according to the NHF data, epidemiological data or estimated data according to agreed opinion of members of the Expert Groups assessing particular services).

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9 An example of a simplified BI analysis required for application (submitted to Australian Pharmaceutical Benefits Advisory Committee) for placement on the PBS list is available at: http://tinyurl.com/pzmx4 or http://www.health.gov.au/internet/wcms/Publishing.nsf/Content/health-pbs-general-pubs-guidelines-part3.htm (section 4 - Estimated extent of use and financial implications).

10 (along with necessity to decrease differences between productive age and the age at which most diseases begin and expected progress in medicine)

11 According to assumptions made by the Ministry of Health and observed by the AHTAPol and the Expert Group

12 In case of significant patient's co-payment the perspective of the analysis should take into account costs incurred directly by the patients or their families – in case of co-payment availability of the services depends both on the level of reimbursement and costs incurred by the patient. Even with significant reimbursement high absolute cost related to co-payment may constitute an obstacle, which may limit availability of the service even to zero.

The first criterion for inclusion into the guaranteed benefit package at this stage of evaluation is the number of different procedures available in a particular indication. According to assumed rules:

1. if in a specific indication there is only one procedure of proven efficacy and safety, this service is "automatically" included into the guaranteed benefit package,
2. if in a specific indication there is more than one optional procedure (more than one method of treatment of similar efficacy and safety in this indication), inclusion into the guaranteed benefit package or further evaluation will depend on the results of simplified BI analysis and obtained values as related to assumed thresholds (see below).

The rules presented below concern the second situation, in which in a specific indication there is more than one optional procedure, i.e. more than one method of treatment of similar efficacy and safety in this indication. Threshold values will be set by appropriate authorities, taking into consideration means available within basic insurance and number of services with specific results of budget impact analyses (this will probably require actuarial consultations after the list of services of proven efficacy is prepared, taking into account results of simplified budget impact analyses).

Alpha1 and alpha2 thresholds

The α threshold determines limit value for the unit cost of the procedure (alpha1 threshold) or annual cost of treatment for one patient (alpha2 threshold).

Values of a1 and a2.

Estimated value for the unit cost of the procedure (a1 value) or annual cost of treatment for one patient (a2 value).

Beta threshold

This threshold concerns number of procedures performed annually in the whole country or the number of patients undergoing the service annually in the whole country.

b value

Estimated number of procedures performed annually in the whole country or estimated number of patients undergoing the service annually in the whole country.

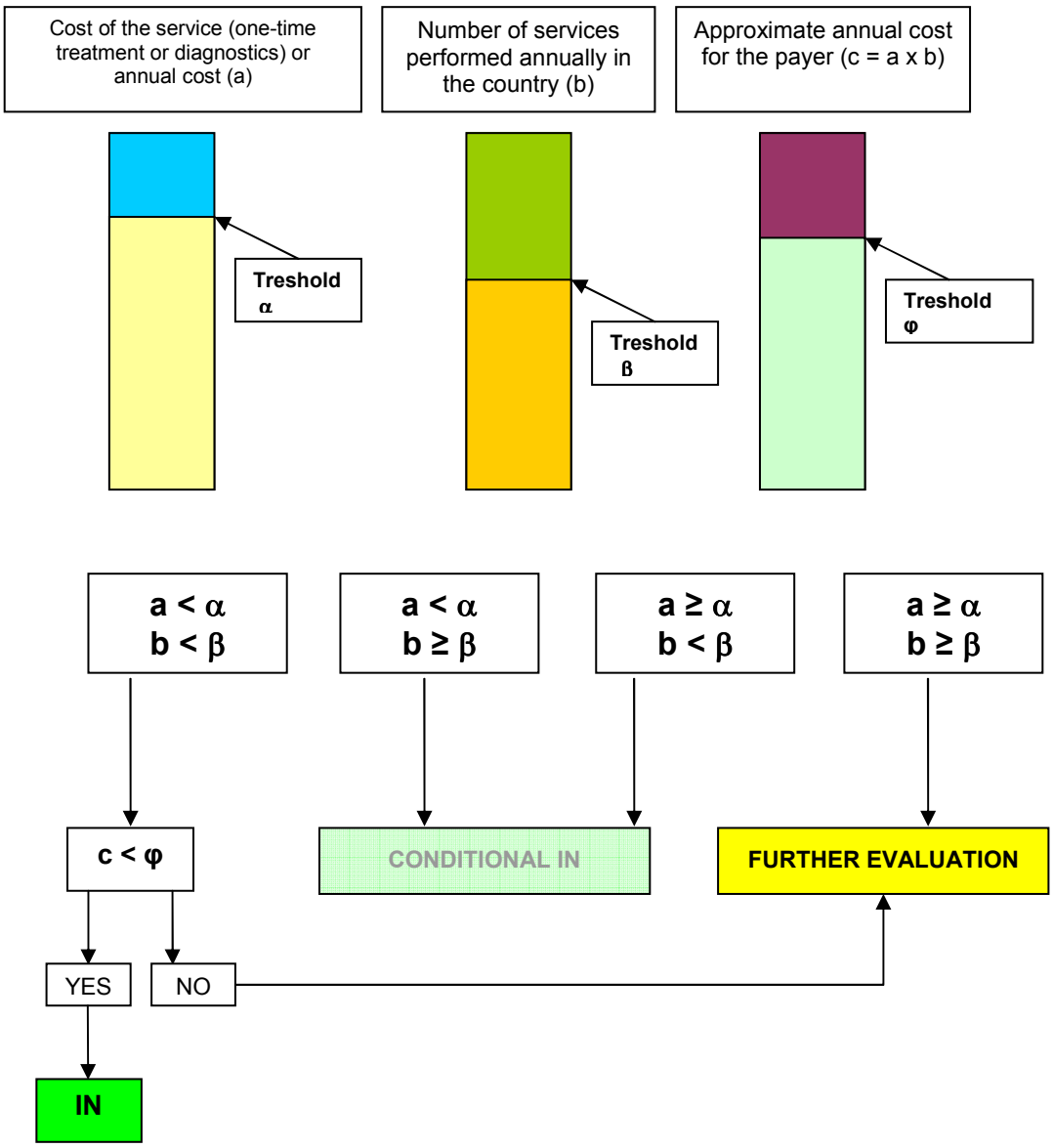
Phi threshold

Threshold value for the product of the values a and b.

c value

The product of values a and b calculated for a specific service in the simplified budget impact analysis.

Figure 6
Stage III – Simplified budget impact (BI) analysis



Possible decisions based on values and results achieved in simplified budget impact analyses:

IN[13]

If the a value is lower than the alpha threshold (a<α), the b value is lower than the beta threshold (b<β) and the c value is lower than the phi threshold (c<φ), then the service is **placed** in the guaranteed benefit package, provided that majority of the opinions of the Expert Group members is positive.

If the a value is lower than the alpha threshold (a<α), the b value is lower than the beta threshold (b<β) and the c value is equal to or higher than the phi threshold (c≥φ), then the service **undergoes further evaluation** based on the results of complete economic and financial analysis.

CONDITIONAL[14] IN

If the a value is lower than the alpha threshold (a<α), but the b value is equal to or higher than the beta threshold (b≥β), then the service is **conditionally placed** in the guaranteed benefit package, provided that majority of the opinions of the Expert Group members is positive.

If the a value is equal to or higher than the alpha threshold (a≥α), but the b value is lower than the beta threshold (b<β), then the service is **conditionally placed** in the guaranteed benefit package, provided that majority of the opinions of the Expert Group members is positive.

FURTHER EVALUATION

If the a value is equal to or higher than the alpha threshold (a≥α) and the b value is equal to or higher than the beta threshold (b≥β), then the service **undergoes further evaluation** based on the results of complete economic and financial analysis.

A decision concerning conditional placement of a procedure in the guaranteed benefit package must, after a specific time (e.g. after 2 or 3 years), undergo verification based on complete analysis of direct and indirect costs (in terms of accountancy), complete comparative economic analysis for the most important options and financial analysis. If these analyses are not submitted within appropriate period of time, the conditionally placed service is automatically removed from the guaranteed benefit package (in exceptional situations the period of conditional placement may be prolonged, but the reason must be announced to the public). Within three years from the date of conditional placement in the guaranteed benefit package companies interested in permanent placement (or the AHTAPol from public means) are obliged to prepare and submit to decision makers complete economic and financial analyses, with positive opinion concerning their quality. In case of prolongation of placement in the guaranteed benefit package, presentation of complete economic and financial analyses should be the duty of the applicant whenever it is considered appropriate by the Minister of Health or other authorized person; such decisions should be based on transparent criteria taking into account public interest and financial benefits achieved from a specific service by for-profit organizations.

[13] inclusion into the guaranteed benefit package

[14] conditional placement means that it is made for a specific period of time, during which complete economic and financial analyses for the most important options must be submitted.

7. ECONOMIC AND FINANCIAL ANALYSIS

Robert Plisko

Services introduced into medical practice (including registered services) before January 1st, 2007

For health care services introduced into medical practice before January 1st, 2007, for which the conditions taken into account in the simplified payer's budget impact analysis, i.e.

1. the number of services performed annually in a specific indication above the β threshold or
2. the service unit cost above the α threshold

are fulfilled, the expert should consider to require complete economic and financial analyses for the most important optional methods of treatment.

If the c value is equal to or higher than the φ threshold, the decision concerning placement should always be based on the results of complete and credible economic and financial analyses for the most important optional methods of treatment – **this is consistent with the constitutional right to equal access to health care services in a situation of limited financial means.**

The threshold values (α, β, φ) should be defined by the Minister of Health or another authorized decision maker depending on the results of simulations performed with use of data from the list of services created by the AHTAPol and databases containing cost data for all services currently performed and financed within basic insurance.

For selected services (of extremely high α, β and φ values) the AHTAPol should prepare (or demand submission of) comparative economic and financial analyses at the early stage of work on the guaranteed benefit package. In many cases it is possible to use economic analyses as well as efficacy and safety analyses prepared in other countries, often by governmental HTA Agencies, which may be relatively simply adjusted to Polish circumstances. Certainly for majority of the services, for which the c values will be higher than the φ threshold, systematic reviews and HTA reports prepared in other countries may be retrieved.

Services being the only ones of proven efficacy and safety in particular important indications (see stage I – criteria related to the health condition of the society) are unconditionally placed in the guaranteed benefit package. They remain in the guaranteed benefit package until placement of another optional service of better cost/benefit ratio is proposed.

Services introduced into medical practice (including registered services) after January 1st, 2007 [12.2]

All inclusions concerning:

- drug or non-drug health technologies,
- diagnostic or therapeutic health technologies,
- registered technologies or those introduced into practice outside the registration system,

introduced into practice (including registration) after January 1st, 2007 may be made exclusively after submission of the appropriate application with attached required analyses and consideration of this application according to defined principles and established procedure.

Along with main applications analyses of efficacy and safety based on systematic reviews, complete economic and financial analyses or applications to the AHTAPol for preparation of

such analyses (financed from public means) should be submitted. The AHTAPol assesses (for a defined fee or free of charge) quality of analyses attached to applications for placement in the guaranteed benefit package according to transparent criteria (published and easily accessible), performs appropriate analyses on its own within available means or commissions the analyses to other institutions by tender. The list of applications submitted by interested parties should be overt and published successively on the webpage of the Ministry of Health or the AHTAPol.

Applications for placement in the guaranteed benefit package may be submitted by any individual or legal entity. It is suggested that administrative fee (according to overt price list) should be charged for submission of an application. The fee will perform two functions: firstly, it should discourage from submission of applications concerning services having little chance to be placed in the guaranteed benefit package; secondly, it will contribute to financing of the process of verification of applications and analyses, should these be attached by the applicants.

Applications submitted by the interested parties to the Minister of Health undergo initial verification before being directed to the AHTAPol. Applications negatively verified by the MH are rejected (without further consideration by the AHTAPol). The list of rejected applications along with reasons of rejection should be published on the webpage of the MH or the AHTAPol.

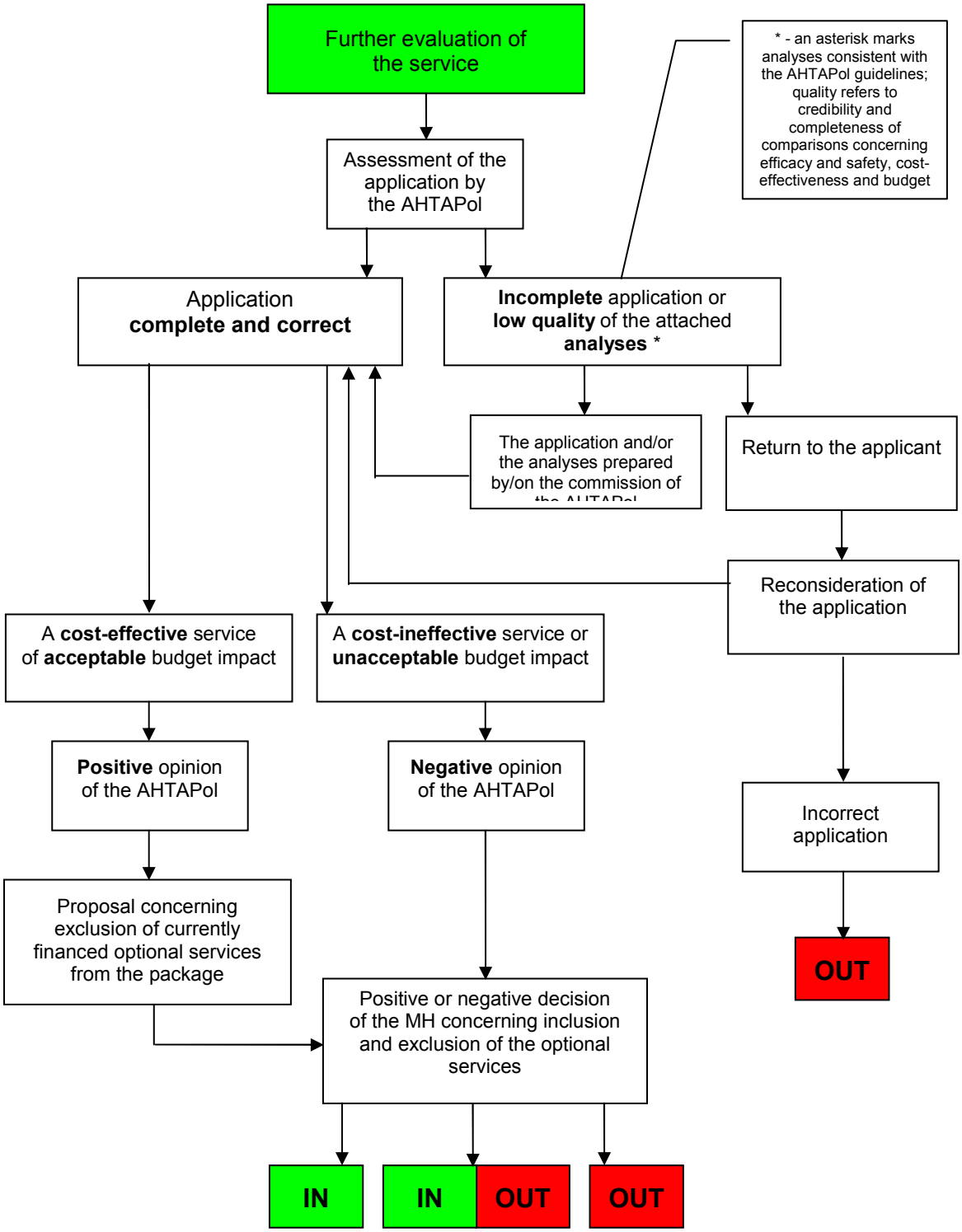
Applications verified positively by the Ministry of Health are directed to the AHTAPol:

1. The AHTAPol will prepare formal requirements to be fulfilled by the applications (contents, quality criteria [credibility, completeness], examples of documents, forms etc.).
2. The AHTAPol assesses analyses attached to applications for placement in the guaranteed benefit package according to published criteria concerning quality of analyses submitted for the purpose of reimbursement.
3. In case of public interested parties, associations of patients etc., which did not submit appropriate analyses, the AHTAPol conducts such analyses on its own or commissions them to other institutions, according to analytic priorities accepted by the MH – this is related only to diagnostic and therapeutic non-drug technologies.
4. If the application is submitted by a manufacturer of drugs or medical devices (a for-profit organization, which expects financial benefit from placement of the service in the guaranteed benefit package), the cost of preparation and submission of the required analyses is incurred by the interested party and only in exceptional situations by the AHTAPol.
5. In case of doubts concerning quality of the analyses attached by the interested parties to applications for placement in the guaranteed benefit packages (this will usually concern for-profit organizations) – the AHTAPol asks the applicants to complete or correct the analyses.
6. The AHTAPol or the MH will also define so-called fast path, i.e. possibility of conditional placement (for a specific time) in the guaranteed benefit package, based on incomplete analyses, if there are justified reasons.

Appropriate analyses of efficacy and safety and economic analyses must compare the new service (technology) with the most important optional methods of treatment in a specific indication.

Depending on the analyses prepared and published by the AHTAPol or the analyses positively verified as to their quality by the AHTAPol, the decision makers would make appropriate placements and exclusions of services – often inclusion of a procedure in a specific indication would mean exclusion of an optional method of treatment in this indication, placed up to that moment in the guaranteed benefit package.

Figure 7
Stage IV – Complete economic and financial analyses



Guidelines concerning economic and financial analyses

If AHTAPol is to be responsible for high quality of economic and financial analyses, it should present guidelines concerning development and quality requirements for such analyses. AHTAPol may use available, published guidelines.

Apart from transparency the most important purpose of the guidelines is to ensure reproducibility of the results of analyses, i.e. if different investigators would independently work on the same subject according to the same guidelines they should obtain the same or very similar results. **The measure of quality of guidelines or credibility criteria is their ability to ensure reproducible results of the analyses.**

The guidelines should undergo analysis and assessment concerning consistency with standards in other countries, performed by Polish and foreign experts from governmental HTA agencies, the Cochrane Collaboration or scientific journals, e.g. La Revue Prescrire, Evidence Based Medicine; opinions of other experts, who would like to take part in discussion, should also be taken into consideration.

Polish guidelines cannot be contrary to guidelines concerning economic analyses accepted in developed countries, especially to guidelines developed by other governmental HTA Agencies worldwide. Hierarchy of credibility of clinical studies and preferences concerning cost studies should be clearly presented. It should be stressed that efficacy analyses should be based on primary endpoints, which should be assessed in the first place. Secondary endpoints (surrogates) should be analyzed only if no clinical studies concerning primary endpoints are available and there is correlation (well documented in credible publications) between the effect of the intervention on surrogates and on primary endpoints. An economic analysis based on one, selected “best” clinical study without a systematic review must not be recommended, since selection of the “best" clinical study is possible only after comparison of all available studies, retrieved by means of a systematic review carried out according to guidelines of the Cochrane Collaboration or NHS Centre for Reviews and Dissemination.

Examples of guidelines concerning economic analyses:

1. Canada: http://www.cadth.ca/media/pdf/186_EconomicGuidelines_e.pdf
2. Australia: http://www.health.gov.au/internet/wcms/publishing.nsf/content/health-pbs-general-pubs-guidelines-index.htm
3. Italy: http://www.diahome.org/content/Abstract/2001/dij1570.pdf
4. Baltic states: http://www.zca.gov.lv/docs/new2002/doc24-1.pdf
5. WHO; http://www.who.int/choice/publications/p_2000_guidelines_generalisedcea.pdf

Selected links to various guidelines worldwide are available at:
http://www.ispor.org/PEguidelines/index.asp.

Remarks concerning application of economic and financial criteria

Presentation of exemplary procedures of inclusion into specific packages for optional treatments in a particular indication **exceeds** the purpose of this report. Members of Expert Groups working on inclusions into and exclusions from the guaranteed benefit package should be additionally trained with regard to this issue.

Experts preparing recommendations for the decision makers in this field should have profound **knowledge, skills and experience** in conduct and assessment of primary and secondary studies. Among others, their knowledge and skills should include:

- assessment of methodology and results of clinical studies,
- assessment of quality of reviews of scientific publications,
- assessment of the results, credibility and completeness of efficacy and safety analyses,
- assessment of quality and results of cost analyses,

- assessment of quality and results of economic analyses,
- assessment of quality and results of BI analyses.

Such experts should also be skilled in search of publications and their selection, including use of medical and economic databases.

8. SUMMARY

The services which were not placed in the guaranteed benefit package may be included into the supplementary package or the negative package; anyway, they cannot be provided within basic insurance.

The process of decision making as related to the criteria concerning services introduced into practice before January 1st, 2007:

1. exclusion of services concerning diseases and conditions placed on the negative list related to health care priorities,
2. exclusion of services of unproven efficacy and safety (as considered by the experts),
3. inclusion of services of proven harmfulness into the negative package,
4. mandatory inclusion into the guaranteed benefit package if the procedure is the only one of proven efficacy and safety in a specific indication,
5. conditional inclusion of services generating high costs for the system – individual or annual – and/or procedures performed very often,
6. for conditionally included services additional analyses are mandatory: efficacy and safety analyses based on systematic reviews, economic and financial analyses concerning the most important optional technologies,
7. "natural" verification of the package – analyses attached to applications for inclusion concerning services introduced into practice after January 1st, 2007 will include comparative analyses of efficacy and safety as well as economic analyses concerning services already placed in the package, which will make it possible to verify earlier inclusions.

The process of decision making as related to the criteria concerning services introduced into practice after January 1st, 2007:

1. submission of the application for inclusion (according to defined procedures),
2. rejection of incomplete applications as well as those concerning procedures and indications placed on negative lists by the Ministry of Health,
3. transfer of positively considered applications to the AHTAPol,
4. quality assessment of attached analyses by the AHTAPol; should such analyses be missing, their financing from public means will be considered (according to assumed analytic priorities),
5. decision to include a technology into the guaranteed benefit package will be based on high quality comparative efficacy and safety analyses as well as economic and budget impact analyses concerning the most important optional technologies in a specific indication,
6. inclusion of a new technology into the guaranteed benefit package will make it possible to exclude less efficacious and safe or less cost-effective technologies.

9. LIMITATIONS

Work on this report lasted less than a month (sic!), with scarce financial means available, therefore the title stresses its character (a rapid review). Fragments of other publications were used in this report; copyright laws and generally accepted rules of citation were observed. In many places secondary documents (translations into English) were used as well as retrieved originals.

Search for publications concerning criteria introduced in other countries was not systematic; due to the type of the report (rapid review) and limited means intensified interviews with authors of the criteria described here were not performed.

According to the rules concerning numeration of subsequent versions of the reports (efficacy and safety analyses, HTA reports and other documents) prepared by the CEESTAHC, version 1.0 is the final version of a document before any evaluations were made by external auditors. The final version evaluated by “external” experts is numbered 2.0.

10. REFERENCES

1. K. Łanda, J. Siwiec, „Mechanizmy Antykorupcyjne w Ochronie Zdrowia – Przejrzystość, Transparentność", http://www.ozzl.org.pl/akt/MechnizmyAntykorupcyjne.doc.
2. K. Łanda, „Koszyk potrzebny od zaraz, Med-info, styczeń 2006,
3. A. Kozierkiewicz, „Koszyk świadczeń – doświadczenia krajowe i zagraniczne", dostępny na www: http://www.qcm2.quicksilver.pl/img/27/Referat%20Adam%20Kozierkiewicz.pdf
4. H.D. Banta, Zakres świadczeń nabywanych w ramach narodowego systemu ubezpieczeń zdrowotnych, dla osób ubezpieczonych, Raport TNO – 1, 2001 rok.
5. H.D. Banta, Zakres świadczeń oraz warunki jego wykonywania (standard produktu) w ramach systemu powszechnego ubezpieczenia zdrowotnego, Raport TNO – 7, 2001 rok.
6. H.D Banta, K. Łanda, „Opracowanie propozycji listy świadczeń gwarantowanych z określeniem grupy świadczeń o najlepszych i najgorszych parametrach", Raport TNO – 6, 2001 rok.
7. Wyrok z dnia 2004-01-07, sygn. K 14/03, Konstytucyjność ustawy z dnia 23 stycznia 2003 r. oo powszechnym ubezpieczeniu w Narodowym Funduszu Zdrowia Z.U. 2004 /1A / 1 Dz.U. 2004.5.37 z dnia 2004-01-15
8. Badanie opinii społecznej „Refundacja świadczeń zdrowotnych - preferencje Polaków", Wykonane przez PBS Sopot na 1074 osobowej, reprezentatywnej grupie Polaków w wieku 15 lat i więcej w dniach 05-06 listopada 2005r., na zlecenie: Ogólnopolskiego Związku Zawodowego Lekarzy. Dostępny na www: http://www.ozzl.org.pl/akt/PBS.pdf
9. M. Władysiuk-Blicharz K. Łanda A. Nadzieja M. Gąsiorowski M. Dziadyk, „Podstawowe cechy i zasady tworzenia koszyków świadczeń zdrowotnych w wybranych krajach - opracowanie wstępne." (Opracowanie w przygotowaniu do druku)
10. K. Łanda, M. Blicharz, J. Siwiec, „Słownik podstawowych terminów EBM", Dokument w przygotowaniu do wydruku)
11. Dane ze strony: http://www.mz.gov.pl/wwwmz/index?mr=m111111&ms=&ml=pl&mi=&mx=0&mt=&my=0&ma=0245
12. Słownik do ustawy z dnia 27 sierpnia 2004 r o świadczeniach opieki zdrowotnej finansowanych ze środków publicznych (Dz.U. Nr 210, poz. 2135), Dostępny na www: http://www.mz.gov.pl/wwwmz/index?mr=m111111&ms=&ml=pl&mi=&mx=0&mt=&my=0&ma=0340
13. K. Łanda, „Ocena technologii medycznych", Problemy Zarządzania 4/2004 Uniwersytet Warszawski,Tekst dostępny na www: http://www.hta.pl/dok/otn_ost.pdf
14. Ustawa z dnia 27 sierpnia 2004 r. o świadczeniach opieki zdrowotnej finansowanych ze środków publicznych. (Dz.U. z 2004 r. Nr 210, poz. 2135) dostępna na www: http://www.abc.com.pl/serwis/du/2004/2135.htm
15. Ustawa z dnia 6 września 2001 r. - Prawo farmaceutyczne. (Dz.U. z 2001 r. Nr 126, poz. 1381) dostępna na www: http://www.abc.com.pl/serwis/du/2001/1381.htm
16. Ustawa z dnia 14 maja 2004 r. o zmianie ustawy o zakładach opieki zdrowotnej (Dz. U. z dnia 4 maja 2006 r.), dostępna na www: http://www.abc.com.pl/serwis/du/2006/0518.htm
17. Hauck K, Smith PC, Goddard M. The Economics of Priority Setting for Health Care: A Literature Review. World Bank 2003
18. Novak M, Toth M, Marušič D. Proposed method of introducing new or supplemented health care programmes in the Republic of Slovenia
19. A Brief History of Health Services Prioritization in Oregon. http://egov.oregon.gov/DAS/OHPPR/search.html 2004
20. Prioritization of health services. A Report to the Governor and the 73rd Oregon Legislative Assembly.
21. Health Priorities. Australian Government – Department of Health and Ageing. http://www.health.gov.au/internet/wcms/Publishing.nsf/Content/Health+Priorities-1
22. Health Plan for Catalonia. www.gencat.net/salut
23. Produced by Bob Phillips, Chris Ball, Dave Sackett, Doug Badenoch, Sharon Straus, Brian Haynes, Martin Dawes since November 1998. http://www.cebm.net/levels_of_evidence.asp
24. Canadian Task Force on the Periodic Health Examination: The periodic health examination. CMAJ 1979;121:1193-1254.
25. Sackett DL. Rules of evidence and clinical recommendations on use of antithrombotic agents. Chest 1986 Feb; 89 (2 suppl.):2S-3S.
26. Cook DJ, Guyatt GH, Laupacis A, Sackett DL, Goldberg RJ. Clinical recommendations using levels of evidence for antithrombotic agents. Chest 1995 Oct; 108(4 Suppl):227S-230S.
27. Yusuf S, Cairns JA, Camm AJ, Fallen EL, Gersh BJ. Evidence-Based Cardiology. London: BMJ Publishing Group, 1998.

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12. ANNEX

12.1. Hierarchy of publications concerning assessment of efficacy and safety

Table 11
Oxford Centre for Evidence-Based Medicine Levels of Evidence (May 2001) [23]

Level	Therapy/ Prevention, Aetiology/ Harm	Prognosis	Diagnosis	Differential diagnosis/symptom prevalence study	Economic and decision analyses
1a	SR (with homogeneity*) of RCTs	SR (with homogeneity*) of inception cohort studies; CDR† validated in different populations	SR (with homogeneity*) of Level 1 diagnostic studies; CDR† with 1b studies from different clinical centres	SR (with homogeneity*) of prospective cohort studies	SR (with homogeneity*) of Level 1 economic studies
1b	Individual RCT (with narrow Confidence Interval‡)	Individual inception cohort study with ≥ 80% follow-up; CDR† validated in a single population	Validating** cohort study with good††† reference standards; or CDR† tested within one clinical centre	Prospective cohort study with good follow-up****	Analysis based on clinically sensible costs or alternatives; systematic review(s) of the evidence; and including multi-way sensitivity analyses
1c	All or none§	All or none case-series	Absolute SpPins and SnNouts††	All or none case-series	Absolute better-value or worse-value analyses ††††
2a	SR (with homogeneity*) of cohort studies	SR (with homogeneity*) of either retrospective cohort studies or untreated control groups in RCTs	SR (with homogeneity*) of Level >2 diagnostic studies	SR (with homogeneity*) of 2b and better studies	SR (with homogeneity*) of Level >2 economic studies
2b	Individual cohort study (including low quality RCT; e.g., <80% follow-up)	Retrospective cohort study or follow-up of untreated control patients in an RCT; Derivation of CDR† or validated on split-sample§§§ only	Exploratory** cohort study with good†††reference standards; CDR† after derivation, or validated only on split-sample§§§ or databases	Retrospective cohort study, or poor follow-up	Analysis based on clinically sensible costs or alternatives; limited review(s) of the evidence, or single studies; and including multi-way sensitivity analyses

Level	Therapy/ Prevention, Aetiology/ Harm	Prognosis	Diagnosis	Differential diagnosis/symptom prevalence study	Economic and decision analyses
2c	"Outcomes" Research; Ecological studies	"Outcomes" Research	x	Ecological studies	Audit or outcomes research
3a	SR (with homogeneity*) of case-control studies	x	SR (with homogeneity*) of 3b and better studies	SR (with homogeneity*) of 3b and better studies	SR (with homogeneity*) of 3b and better studies
3b	Individual Case-Control Study	x	Non-consecutive study; or without consistently applied reference standards	Non-consecutive cohort study, or very limited population	Analysis based on limited alternatives or costs, poor quality estimates of data, but including sensitivity analyses incorporating clinically sensible variations.
4	Case-series (and poor quality cohort and case-control studies§§)	Case-series (and poor quality prognostic cohort studies***)	Case-control study, poor or non-independent reference standard	Case-series or superseded reference standards	Analysis with no sensitivity analysis
5	Expert opinion without explicit critical appraisal, or based on physiology, bench research or "first principles"	Expert opinion without explicit critical appraisal, or based on physiology, bench research or "first principles"	Expert opinion without explicit critical appraisal, or based on physiology, bench research or "first principles"	Expert opinion without explicit critical appraisal, or based on physiology, bench research or "first principles"	Expert opinion without explicit critical appraisal, or based on economic theory or "first principles"

Users can add a minus-sign "-" to denote the level of that fails to provide a conclusive answer because of:

1. EITHER a single result with a wide Confidence Interval (such that, for example, an ARR in an RCT is not statistically significant but whose confidence intervals fail to exclude clinically important benefit or harm)
2. OR a Systematic Review with troublesome (and statistically significant) heterogeneity.
3. Such evidence is inconclusive, and therefore can only generate Grade D recommendations. (Table 13)

Table 12
Signs used in Oxford Centre for Evidence-Based Medicine Levels of Evidence (May 2001) [23]

*	By homogeneity we mean a systematic review that is free of worrisome variations (heterogeneity) in the directions and degrees of results between individual studies. Not all systematic reviews with statistically significant heterogeneity need be worrisome, and not all worrisome heterogeneity need be statistically significant. As noted above, studies displaying worrisome heterogeneity should be tagged with a "-" at the end of their designated level.
†	Clinical Decision Rule. (These are algorithms or scoring systems which lead to a prognostic estimation or a diagnostic category.)
‡	See note #2 for advice on how to understand, rate and use trials or other studies with wide confidence intervals.
§	Met when all patients died before the Rx became available, but some now survive on it; or when some patients died before the Rx became available, but none now die on it.
§§	By poor quality cohort study we mean one that failed to clearly define comparison groups and/or failed to measure exposures and outcomes in the same (preferably blinded), objective way in both exposed and non-exposed individuals and/or failed to identify or appropriately control known confounders and/or failed to carry out a sufficiently long and complete follow-up of patients. By poor quality case-control study we mean one that failed to clearly define comparison groups and/or failed to measure exposures and outcomes in the same (preferably blinded), objective way in both cases and controls and/or failed to identify or appropriately control known confounders.
§§§	Split-sample validation is achieved by collecting all the information in a single tranche, then artificially dividing this into "derivation" and "validation" samples.
††	An "Absolute SpPin" is a diagnostic finding whose Specificity is so high that a Positive result rules-in the diagnosis. An "Absolute SnNout" is a diagnostic finding whose Sensitivity is so high that a Negative result rules-out the diagnosis.
‡‡	Good, better, bad and worse refer to the comparisons between treatments in terms of their clinical risks and benefits.
†††	Good reference standards are independent of the test, and applied blindly or objectively to applied to all patients. Poor reference standards are haphazardly applied, but still independent of the test. Use of a non-independent reference standard (where the 'test' is included in the 'reference', or where the 'testing' affects the 'reference') implies a level 4 study.
††††	Better-value treatments are clearly as good but cheaper, or better at the same or reduced cost. Worse-value treatments are as good and more expensive, or worse and the equally or more expensive.
**	Validating studies test the quality of a specific diagnostic test, based on prior evidence. An exploratory study collects information and trawls the data (e.g. using a regression analysis) to find which factors are 'significant'.
***	By poor quality prognostic cohort study we mean one in which sampling was biased in favour of patients who already had the target outcome, or the measurement of outcomes was accomplished in <80% of study patients, or outcomes were determined in an unblinded, non-objective way, or there was no correction for confounding factors.
****	Good follow-up in a differential diagnosis study is >80%, with adequate time for alternative diagnoses to emerge (eg 1-6 months acute, 1 - 5 years chronic)

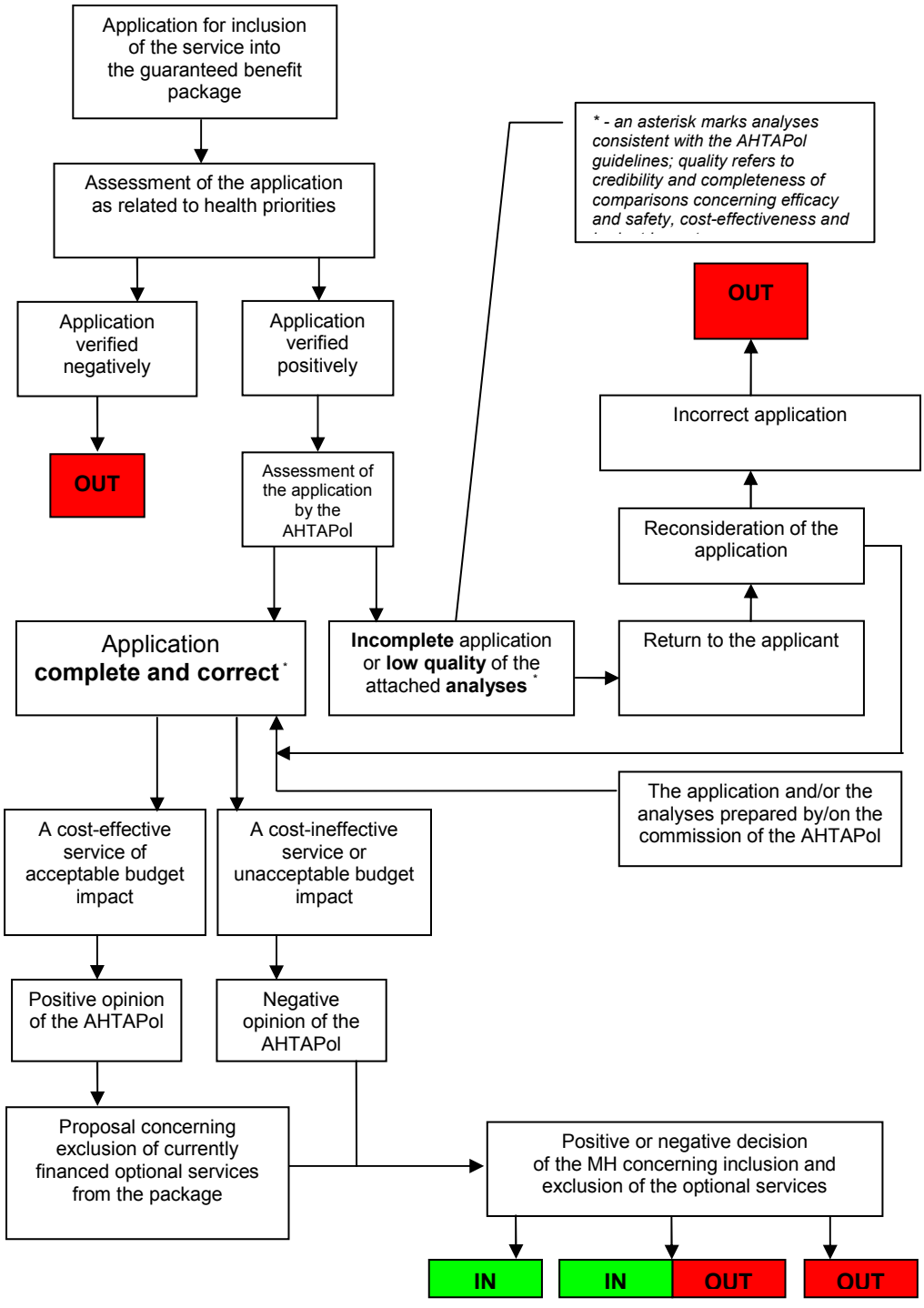
Table 13
Grades of recommendation

A	consistent level 1 studies
B	consistent level 2 or 3 studies ***or*** extrapolations from level 1 studies
C	level 4 studies ***or*** extrapolations from level 2 or 3 studies
D	level 5 evidence ***or*** troublingly inconsistent or inconclusive studies of any level

"Extrapolations" are where data is used in a situation which has potentially clinically important differences than the original study situation. [24, 25, 26, 27]

12.2. Consideration of applications for inclusion into the guaranteed benefit package submitted after January 1st, 2007

Figure 8
Algorithm of consideration of applications concerning inclusion into the guaranteed benefit package submitted after January 1st, 2007



„**IN**" means inclusion into the guaranteed benefit package
„**OUT**" means exclusion from the guaranteed benefit package or refusal of inclusion
„**IN-OUT**" means inclusion into the guaranteed benefit package and exclusion of the optional services

12.3. Ranking of health care services – a method of creation of the package using assignment of weights

The following proposal concerning assignment of weights is presented in the annex as not recommended at this stage due to practical reasons. Use of weights may prove troublesome and time-consuming and therefore inapplicable, considering short time remaining for development of a defined positive guaranteed benefit package in Poland.

Methodology concerning assignment of weights and ranking of the health care services was based on the Slovenian methodology, appropriately modified in order to adjust the list to conditions of function and the purpose of the package in Poland.

Criterion 1: condition and effect of treatment

The first criterion was largely based on the Slovenian solution. Severity of the condition and expected effect of treatment were taken into account and groups of patients requiring special care were identified. In addition high priority was assigned to conditions, for which no method of treatment has been placed in the package yet (provided that the condition was not placed on the negative list). This postulate is implicated by the assumed general rules (at least one intervention of proven efficacy and safety for each condition).

Criterion 2: cost-effectiveness

Apart from clinical importance, results of economic analysis should be taken into account in decisions concerning order, in which the applications will be considered. Public interest requires that dominant (more efficacious and cheaper) interventions should be placed in the package as soon as possible; applications concerning such interventions should therefore be considered in the first place. However, more efficacious and more expensive interventions require consideration whether benefits are worth additional costs. This makes definition of thresholds of cost-effectiveness necessary. Such strategic decision will be made by the AHTAPol or the MH. For example, the thresholds may be set as follows:

1. the first threshold of cost-effectiveness – cost of one year of life equal to ½ of the cost of one year of treatment with dialysis;
2. the second threshold of cost-effectiveness – cost of one year of life equal to the cost of one year of treatment with dialysis.

If the comparison of cost-effectiveness was made for endpoints other than mortality, two solutions are possible. One is more difficult and complicated: the AHTAPol should publish a list of endpoints for particular disease entities along with respective thresholds of cost-effectiveness (not higher than thresholds for mortality). The other, simplified way would be arbitrary statement that thresholds of cost-effectiveness for other endpoints (excluding surrogates) are equal to ½ of those established for mortality. The second solution should be regarded as temporary, until the first solution is implemented.

Criterion 3: available budget

From the social point of view it is important to promote these health care services, which will bring the same benefit and at the same time make it possible to lessen (or at least not increase) the burden on the payer's budget.

Criterion 4: experts' opinion

Similarly to the Slovenian criteria, the experts' opinion was taken into consideration in assessment of the applications. At the same time it was clearly defined, whose opinion may be treated as "expert's". Due to expected problems with assessment of the opinion of the society, this factor was not taken into account.

Table 14.
Criteria of ranking of health care services using appointed weights

Priority	Characteristics	Weight
Criterion 1: condition and effect of treatment		
1.	• Acute fatal condition; treatment prevents death with or without full recovery (e.g. malignancies, cardiovascular diseases) • Maternity care • A service concerning a condition, for which no intervention of proven efficacy and safety has been placed in the package yet • Programs extended due to an intervention of the Minister of Health	50
2.	• Treatment of psychoses	40
3.	• Chronic fatal condition; treatment improves lifespan and quality of life • Preventive care for children, including dental care • Treatment of infertility • Palliative care	30
4.	• Acute non-fatal condition; treatment may cause return to previous health status (i.e. as before acute symptoms occurred – e.g. symptomatic treatment of pain) • Preventive care for adults; methods of proven efficacy • Treatment of mental diseases other than psychosis	20
5.	• Chronic non-fatal conditions; one-time or repetitive treatment improves quality of life • Acute non-fatal conditions; treatment without return to previous health status • Conditions, in which treatment expedites recovery	10
6.	• Preventive care for adults; less effective procedures • Fatal or non-fatal conditions; treatment may cause minimal or no improvement in quality of life	5
Criterion 2: cost-effectiveness of the program (according to the results of the attached cost-effectiveness analysis)		
1.	**Dominant procedure** The results of the cost-effectiveness analysis indicate that the service is dominant (more efficacious and cheaper) as compared to the service present in the guaranteed benefit package	20
2.	**CE ratio < 1st threshold of cost-effectiveness** The results of the cost-effectiveness analysis indicate that the service is highly cost-effective as compared to the service present in the guaranteed benefit package	10

Priority	Characteristics	Weight
3.	**CE ratio < 2nd threshold of cost-effectiveness** The results of the cost-effectiveness analysis indicate that the service is slightly more cost-effective as compared to the service present in the guaranteed benefit package	5
4.	**CE ratio > 2nd threshold of cost-effectiveness** The results of the cost-effectiveness analysis indicate that the service is poorly cost-effective as compared to the service present in the guaranteed benefit package	0
5.	**Dominated procedure** The results of the cost-effectiveness analysis indicate that the service is dominated (less efficacious and more expensive) as compared to the service present in the guaranteed benefit package	-20
Criterion 3: available budget		
1.	The results of the BI analysis indicate that placement of the service in the package may result in reduction of the payer's expenses	15
2.	The results of the BI analysis indicate that placement of the service in the package will have no effect on the payer's expenses	11
3.	The results of the BI analysis indicate that placement of the service in the package may result in increase of the payer's expenses	0
Criterion 4: experts' opinion		
1.	Positive opinion of the national consultant in the field and recognized medical associations (of physicians or nurses)	15
2.	Positive opinion of the national consultant in the field; no other opinions	11
3.	Positive opinion of the national consultant in the field; neutral opinion of other consultants or recognized medical associations (of physicians or nurses)	7
4.	Neutral opinion of the national consultant in the field and recognized medical associations (of physicians or nurses)	3
5.	Negative opinion of the national consultant in the field and recognized medical associations (of physicians or nurses)	0

12.4. Algorithm of the process of decision concerning inclusion into or exclusion from the guaranteed benefit package

Figure 9
Algorithm of the process of decision concerning inclusion into or exclusion from the guaranteed benefit package