CEESTAHC Krakow

Dr. med. Pedro W. Koch-Wulkan
PPP technique by M. Baeriswyl

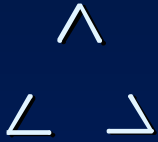
Goals of Swiss Federal Law of Sickness Insurance (KVG) 18.3.1994

- Reinforcing of solidarity between insured persons (per equation of the of disease risk and, within limits, of economic conditions).
- Guarantee for all health services of quality at supportable financial conditions

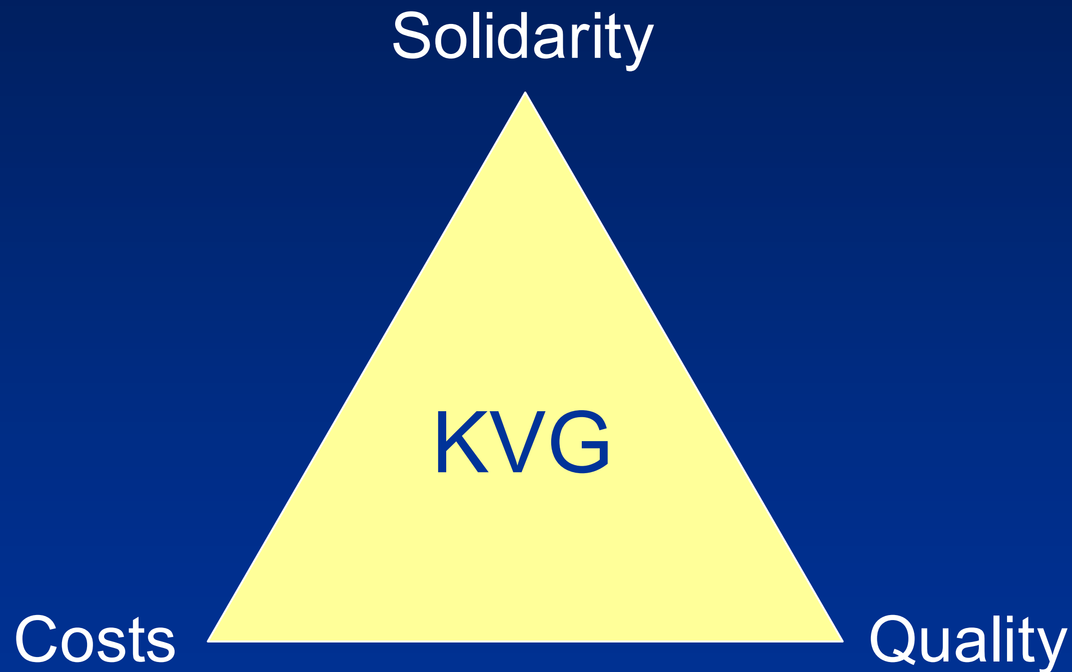
Goals of Swiss Federal Law of Sickness Insurance (KVG) 18.3.1994

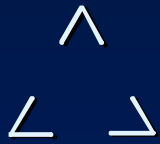
- To extend coverage for health care services (Compulsory Insurance)
- As contribution to diminish the cost evolution in Health Care, addressing divers health care actors, introducing coordination mechanisms, true concurrence and cost control.

(Publication Swiss Federal Office of Social Security, 2001)



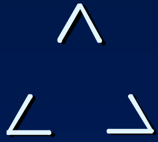
KVG Triangle





Health care services
Legal Principles

- The Basic Sickness Insurance Package reimburses Services in cases of:
  - Sickness
  - Maternity
  - Accident (subsidiary)
  - Congenital diseases (till 20 years age, subsidiary)



Delivers of Services are

- Admitted:
  - Physicians
  - Pharmacists
  - Physiotherapists
  - Occupational therapists
  - Speech therapists
  - Chiropractors
  - Midwives
  - In and outpatient care by independent nurses or nursing facilities
  - Specialised centres for diabetics
- Not admitted:
  - Psychologists (apart from „delegated psychotherapy“)
  - Podiatry
  - Psychomotor therapists
  - Complementary medicine therapists
  - Neuropsychologists

Definition of the Health Care Services to be introduced in Basic package:

Composition of Federal Committees (ELK,EAK, ALK, MIGELK, GK)

- Delivers of Services (private and public)
- Insurers (sickness funds)
- Patient Organisations and Consumers
- Other Federal Authorities
- Cantonal Health Authorities
- FC Principles: ethics / FCM and FCMA: industry

Definition of the Health Care Services to be introduced in Basic package:

Health Care Services

- Insurance-based national HTA mandate through the Swiss Federal Law on Sickness Insurance (KVG) of 1994
- Art. 32 KVG explicitly demands the procedures (e.g. technologies) offered in Basic Sickness Insurance Coverage to be EAE (WZW)

Effective	Appropriate	Efficient
E	A	E

Definition of the Health Care Services to be introduced in Basic package:

Health Care Services

- Effectiveness to be proved by scientific methods
- EAE of procedures to be periodically reviewed
- Art. 58 KVG, 1 demands the procedures (e.g. technologies) offered in Basic Sickness Insurance Coverage to be of quality

Definition of the Health Care Services to be introduced in Basic package:

Health Care Services

- Are reimbursed:
  - All services
    - Non Controversial or not having being declared not to be reimbursed by the Federal committees
    - The Delivers must adjust professional effort to appropriate Services
- Are not reimbursed:
  - All controversial services, or services being declared to be non WZW by the Federal Committees

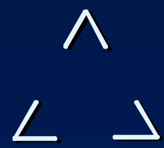
Definition of the Health Care Services to be introduced in Basic package:

Health Care Services

- Services ordered by a physician and delivered by a non medical professional (transparent 7)
- For to be reimbursed the services have not only to be WZW, but to be explicitly included in a Service Package List :
  - Drug List (SL)
  - Laboratory Analysis List (AL)
  - Medical Devices List (MiGeL)
  - Prestations listed in the Ordinance Concerning Diagnostic and Therapeutic Procedures (Krankenpflege Leistungs Verordnung KLV)

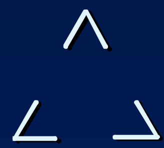
Evaluation
Assessment Procedure: Legal Basis

- Within Swiss Government the Medical Technology Unit (MTU), the Unit I headed, prepares the implementation of Art. 33, 34 and 58 of the Federal Law on Sickness Insurance (KVG) through the Federal Department of Home Affairs
  - The tool is HTA based Handbook
  - The goals are
    - to introduce „good“, HTA evidenced new procedures
    - quickly and complete in order to avoid a „two class medicine“ in Switzerland



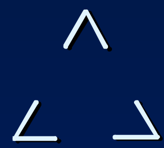
Established Definition of Health Technology Assessment (HTA)

- **Healthcare technology** is defined as prevention and rehabilitation, vaccines, pharmaceuticals, and devices, medical and surgical **procedures**, and the **systems** within which health is protected and maintained.
- **Technology assessment in health care** is a multidisciplinary field of policy analysis. It studies the medical, social, ethical, and economic implications of development, diffusion, and use of health technology.



OECD Definition of Health Technology Assessment (HTA)

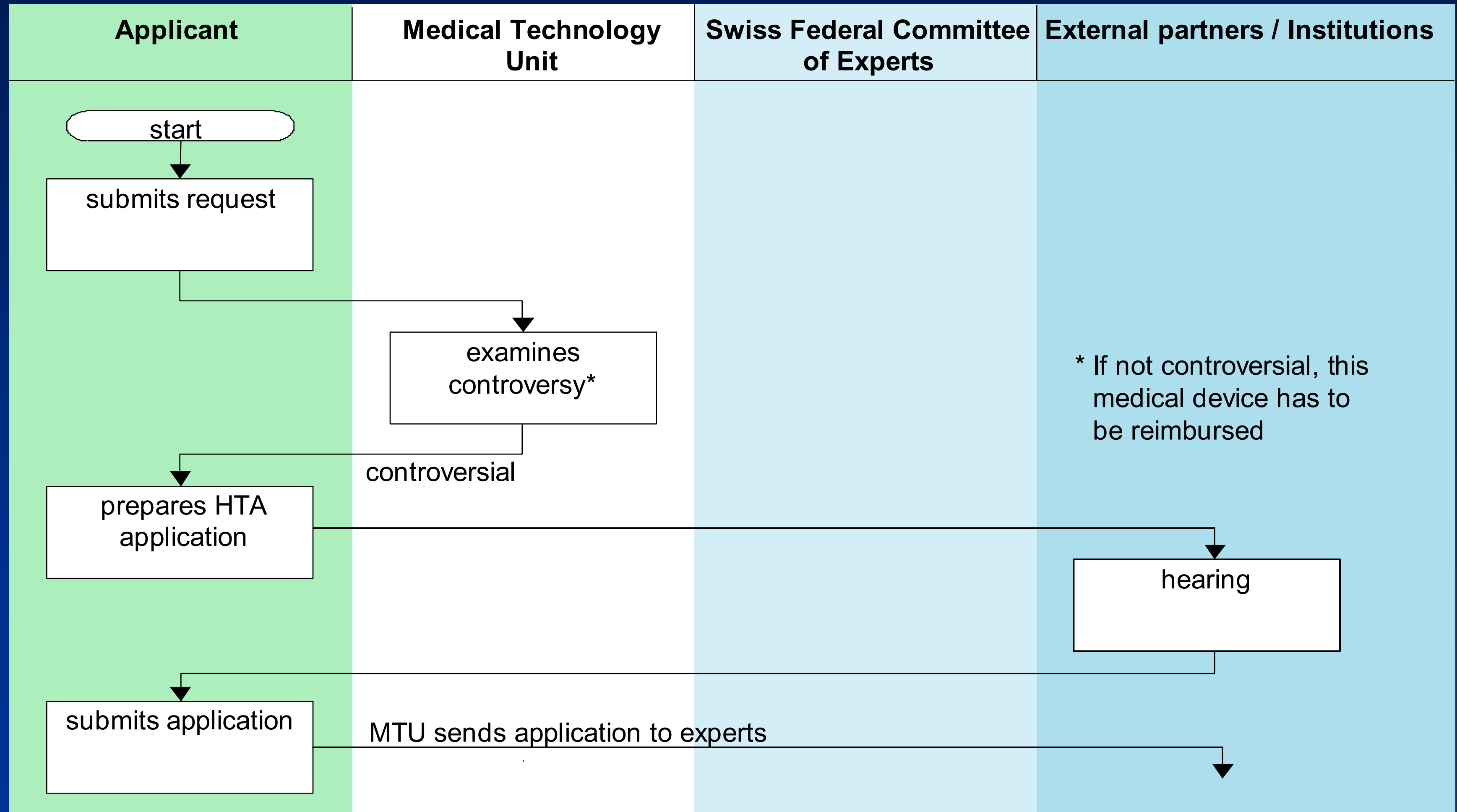
- HTA as a “scientific exercise” is very much linked to Decision making. Decisions in health care take place on various levels. For simplification many authors use the following 3 levels:
  - Macro or political level (marketing approval / financing / reimbursement)
  - Intermediate or institutional level (investment)
  - Micro or individual level (patient with a particular health problem seeking help from a health care professional)



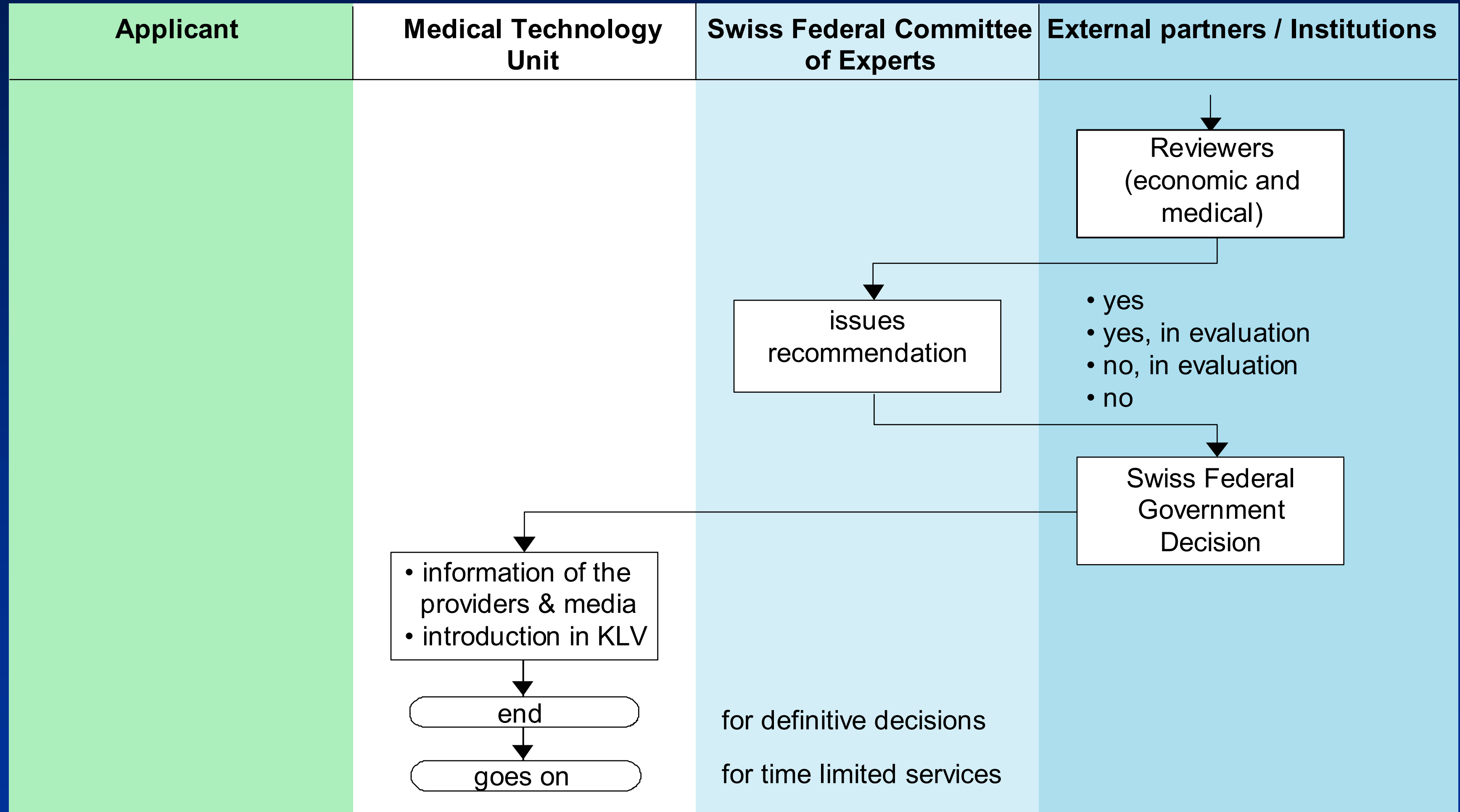
OECD Definition of Health Technology Assessment (HTA)

- Usually, the term HTA is used only in the context of decisions on the macro and intermediate level. The (very similar) process of assessment and appraisal of the scientific literature for application the individual level is usually integrated in the process of guideline development.

Evaluation
Assessment Procedure: Work Flow

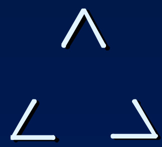


Evaluation
Assessment Procedure: Work Flow



Evaluation – Assessment Procedure: Application with Dossier

- Conform to:
  - “Manual of the Standardisation of Clinical and Economic Evaluation of Medical Technology”
  - Supplement “Cost Consequences introducing a new Technology”



Poster presented at ISTAHC Meeting 1995 (?) Swiss Handbook

Standardisation of Medical Technology Assessment for Coverage and Reimbursement Decisions

The new sickness insurance law enacted January 1st 1996 allows the Swiss Federal Office of Social Security (SFOSS) to regulate the assessment of new technologies, the reassessment of old ones and the prospective reimbursement – on a project basis – for the evaluation of emerging technologies.

In order to assure the standardisation of medical and economic evaluation of controversial medical technologies the SFOSS has developed a manual for the preparation of the medical and economic documentation required for demonstrating effectiveness, appropriateness and efficiency of diagnostic, preventive or curative medical procedures.

The Federal Services Commission for General Health Insurance Services decides on the basis of the presented documents whether the obligatory reimbursement of a service should be granted and addresses a corresponding proposal to the Federal Department of Home Affairs.

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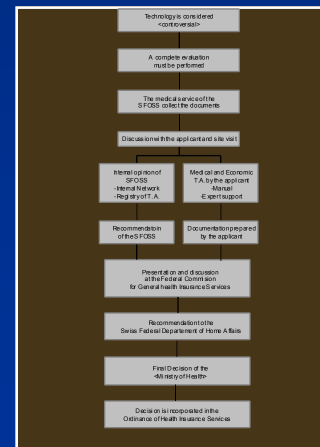
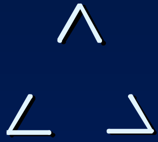


Flow Chart for the Evaluation of Medical Technologies

Evaluation – Assessment Procedure: Yes, in Evaluation

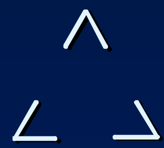
For services apt to be reimbursed under «Yes in Evaluation»

- Establishment of an Evaluation project comprising:
  - The evaluation design
  - The organisation
  - The financing



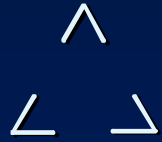
in dubio pro reo

- KVG Reimbursement YES, but
- Time limited
  - Within attached tasks and conditions for evaluation



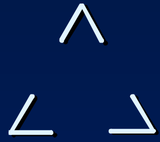
Evaluation – Assessment Procedure: Follow up

- Trimestrial information
  - From the centers or delivers of services admitted to participate
- Annual Rapports presenting
  - Data gathered during evaluation time
  - Partial preliminary rapport



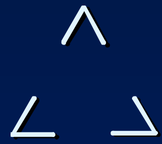
Final Rapport concerning services having benefited from «Yes in Evaluation»

- Outcomes of Evaluation data
- Actualized Application Documentation
  - Evolution of knowledge since first Application at international and national level
  - Evidence that WZW criteria are achieved



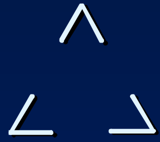
Yes or No?

- Definitively admitted in the Benefit Package
- Refusal of continuing the time limited reimbursement
- Exceptionally: Prolongation of “Yes in Evaluation”
- Total between 1994 and 2004
  - 38 prestations in evaluation
  - Of them 1/3 definitively refused



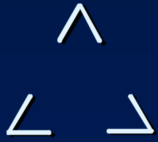
KVG from 2005 on
Quo vadis?

- Rigorous measures: examination of the Services Package to sort services out, transferring the costs to the patients
- Increase of patients cost participation
- Raising demand for private insured Services with disadvantages: reserves, exclusions, elevation of fees etc.



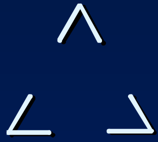
Examples:

- Refusal of continuing the time limited reimbursement for complementary medicine (PEK)
- Announcement of restrictions concerning Basic Package Services for aged persons
- Psychotherapy delivered by psychologists continuous to be excluded
- Announcement of restrictions concerning Rehabilitation Medicine



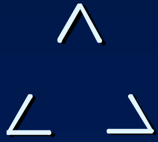
The case of PEK

- The Program Evaluation Complementary Medicine (PEK) Process from the point of view of the President of Steering Committee
- A goal centered enterprise of Swiss Government (EDI) to clear the benefit (WZW) of Complementary medicine in Switzerland



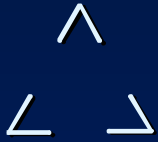
EDI Resolution 1998:

- Elaboration of criteria and principles to demonstrate the benefit of Complementary Medicine by an Expert Group. Discussion in a Workshop in 1998.



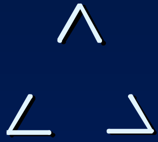
EDI Resolution 1998:

- Acceptance of the special criteria by EDI and introduction into Handbook.
- The Federal Committees have from now on to base their decisions of Complementary Medicine Services beside the classic criteria of Evidence Based Medicine (above all RCT's), **with equal value**, on other Clinical Evidence as Casuistic, Patient interviews, Cohort studies etc. (pgs 30/31Handbook 2000).



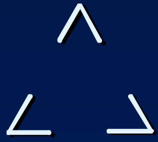
EDI Resolution 1998:

- ***On this setting*** recommended the Federal Committee the definitive introduction of Acupuncture and time limited of Anthroposophy Medicine, Homeopathy, Neural therapy, Phytotherapy and Traditional Chinese Medicine in the Basic Package.
- EDI followed the advice and with resolution of 9.7. 1998 the Complementary Medicine was introduced in KLV.



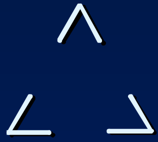
PEK Strategy:

- Conditions to be fulfilled in the Evaluations program:
  - Independent financing: with EDI money (6,5 Million Swiss Francs).
  - To be carried equally by CM Physicians and School medicine: Consensus finding 1998 to 2000.
  - Based on Scientific Standards: Decision of Evaluation in Switzerland on Quality of delivered Services (Observational Studies at General Practitioners Offices) and Literature Research.



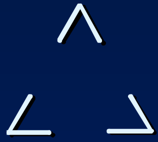
PEK Operational:

- Organisation structure with PEK Steering Committee, Experts group, Review-Board) 2000 started 2001 realised.
- Program adjustment at development of evaluation Protocols and announcement for Observational Studies at General Practitioners Offices and Literature Research.



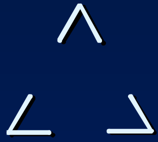
PEK Operational:

- PEK had opportunity to include questions about use and satisfaction grade of CM on the statistic inquiry of the Swiss Population 2000.
- Practical carrying out Observational Studies at General Practitioners Offices 2002 und 2003 (Components I und II).
- Component III, also a Observational Studies at General Practitioners Offices was not permitted by Cantonal Ethic Commission Bern (KEK). A discussion with KEK showed, that they expected the rules of Good Clinical Practice to be followed, even for a non interventional Study!



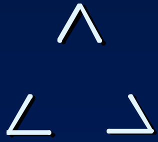
PEK Operational:

- 2003 the Economic concept was defined.
- 2003/2004 were economic Studies carried out.
- 2004 Analysis and interpretation of data were managed.
- 2005 Five HTA documents were finished and presented to the Federal Committee. At the same time the Steering Committee submitted the final PEK Rapport (Schlussbericht) to the Swiss Government.



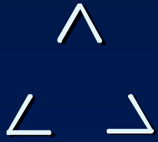
Surplus Value of PEK:

- Internationally the first complete Evaluation of five principal CM Methods.
- Establishment of Evaluation network of General Practitioners Offices.
- Data gathering on General Practitioners Offices.



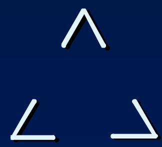
EDI Resolution 2005

- ***EDI's Refusal of continuing the time limited reimbursement.***
- Reason presented at media conference: HTA documentation done under PEK did not follow the principles of Evidence Based Medicine and Critical Appraisal.

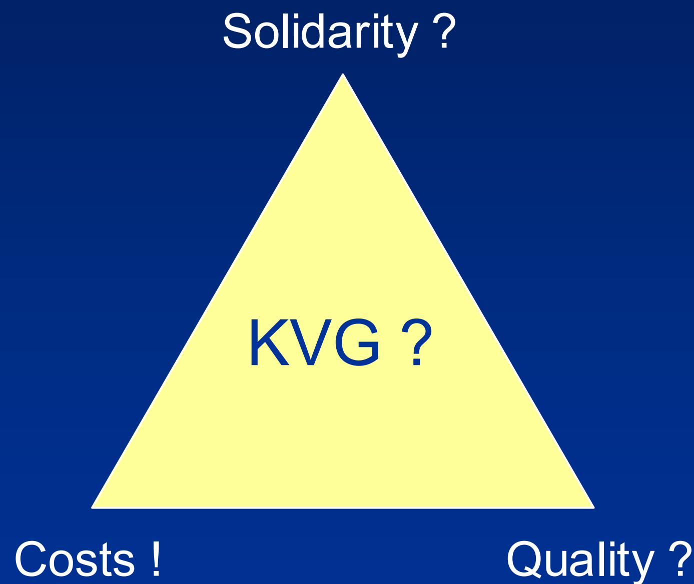


EDI Resolution 2005

- Meaning that at the ***Decisional phase*** (End April/May 2005) Swiss Government did not follow the special principles for CM (Handbook, Version 2000).
- Their motives are for me not scientifically comprehensible. And are damaging for transparency of research processes and for the confidence in Swiss government of experts, physicians, institutes, university department having participated in PEK. As well as for patients! (Citizen’s initiative on CM to be voted)



The challenges that KVG will have to cope: Perceptible Tendencies



- I see that…
  - the health care services of long duration
  - the services not giving prestige to deliverers
  - the services not economically interesting
  - (for deliverers, for industry or sickness funds!)
  - but demanding empathy and considerable human effort
- …are progressively eliminated from HTA based Basic Services Package (Solidarity?)