

Mapping quality assurance approaches in Europe

Reinhard Busse (with Helena Legido-Quigley & Martin McKee)
Professor of Health Care Management,
Technische Universität Berlin
European Observatory on Health Systems and Policies



European
Observatory
on Health Systems and Policies

ASSURING THE QUALITY OF HEALTH CARE IN THE EUROPEAN UNION

A case for action

Helena Legido-Quigley
Martin McKee
Ellen Nolte
Irene A Glinos

Observatory Studies Series N° 12



eunetha
European network for HTA



European
Observatory
on Health Systems and Policies

HEALTH TECHNOLOGY ASSESSMENT AND HEALTH POLICY-MAKING IN EUROPE

Current status, challenges and potential

Marcial Velasco Garrido
Finn Børlum Kristensen
Camilla Palmhøj Nielsen
Reinhard Busse

Observatory Studies Series N° 14

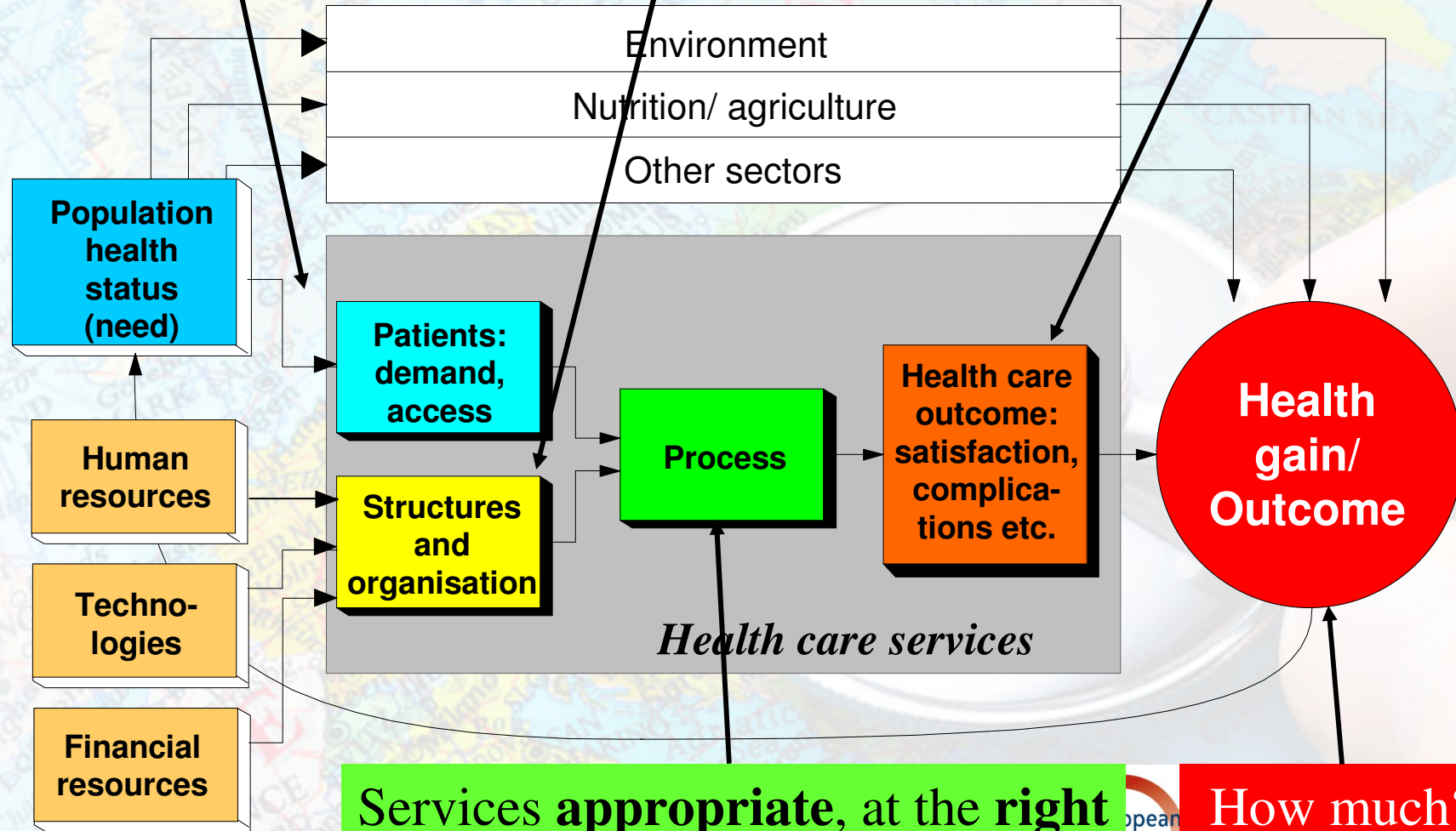
<http://www.euro.who.int/observatory>



Needs-based access?

**Personnel well qualified?
Institutions of high standards?
Technologies effective?**

Services safe and of high quality?



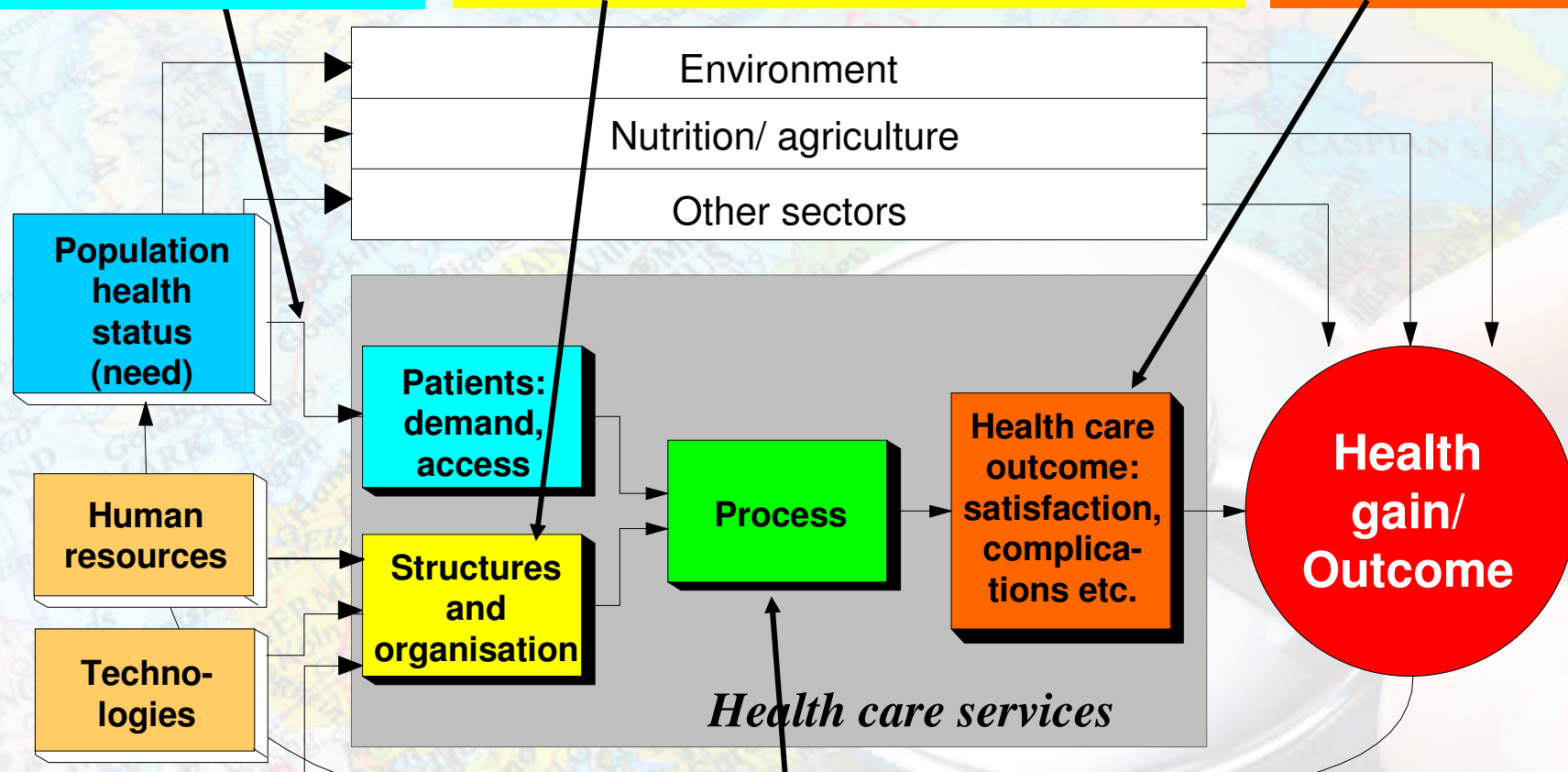
Services appropriate, at the right time and delivered correctly?

**How much?
Is it worth it?**

Universal coverage,
appropriate
entitlements,
limited cost-sharing

Professional (re-)certification
Provider (re-)accreditation
Health Technology Assessment
Concentration of services

Quality
indicators;
registers; pa-
tient surveys

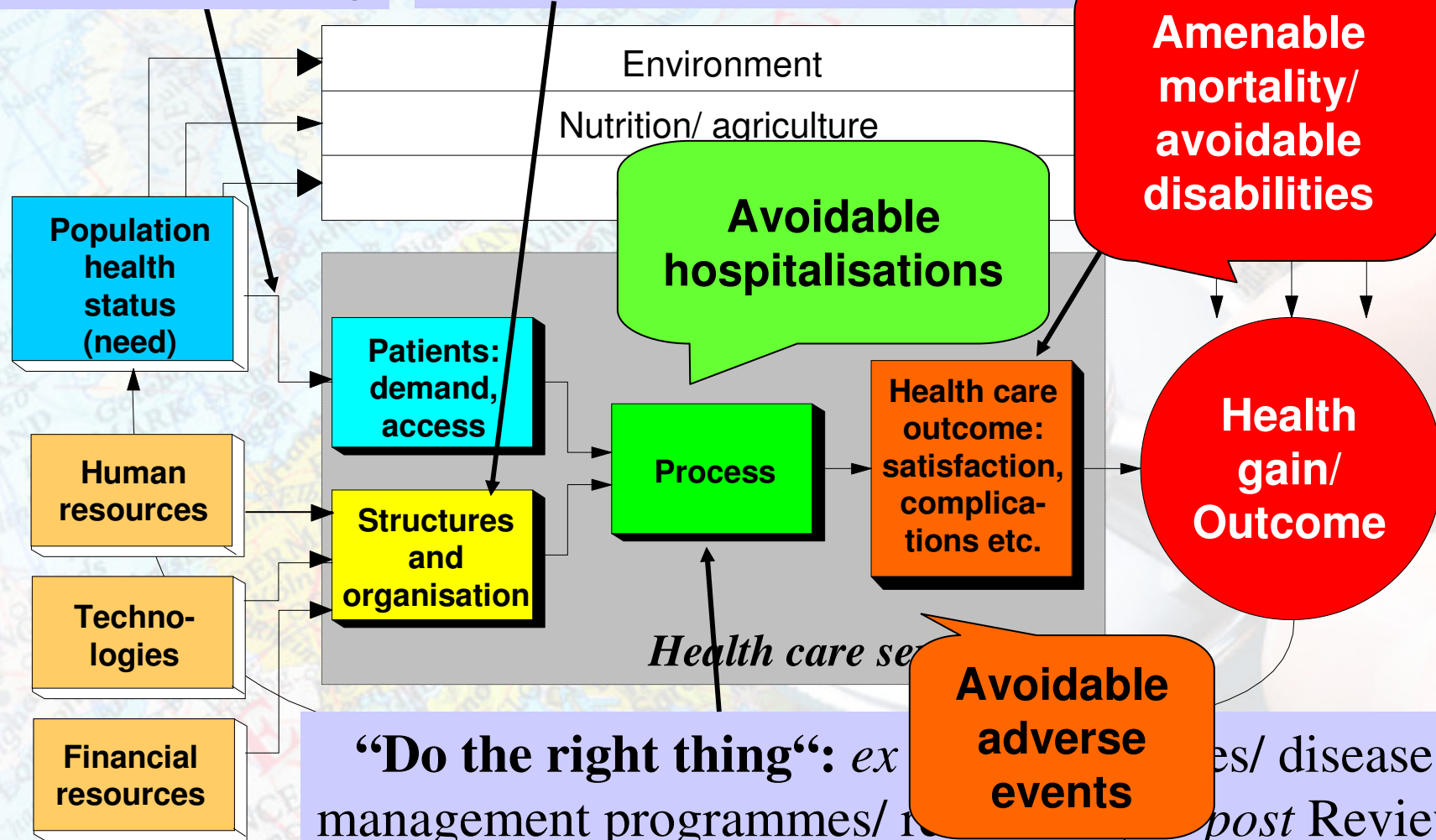


“Do the right thing“: *ex ante* Guidelines/ disease management programmes/ reminders; *ex post* Review
“Do the thing right“: Quality indicators

Universal coverage,
appropriate
entitlements,
limited cost-sharing

Professional (re-)certification
Provider (re-)accreditation
Health Technology Assessment
Concentration of services

Quality
indicators;
registers; pa-
tient surveys

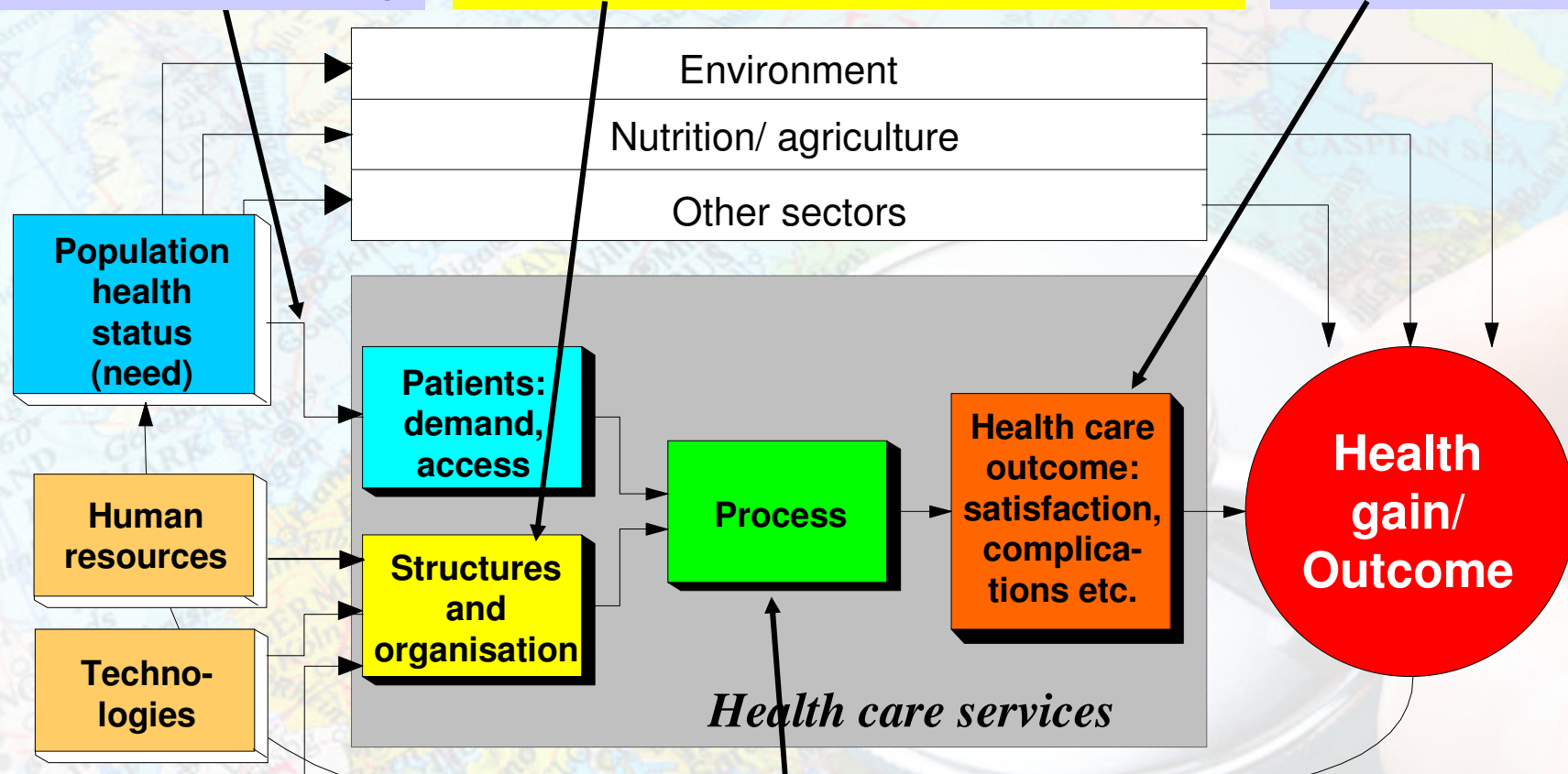


“Do the right thing“: ex... management programmes/ ... post Review
“Do the thing right“: Quality indicators

Universal coverage,
appropriate
entitlements,
limited cost-sharing

Professional (re-)certification
Provider (re-)accreditation
Health Technology Assessment
Concentration of services

Quality
indicators;
registers; pa-
tient surveys



“Do the right thing“: *ex ante* Guidelines/ disease management programmes/ reminders; *ex post* Review
“Do the thing right“: Quality indicators

Market access **Participation/
reimbursement
in public system**

Professionals



Prof. qualif.
2005/36/EC

(Re-)
validation

**Institutions/
facilities**

Varying, partly
certification/
accreditation

Accre-
ditation

**Technologies/
interventions**



Drugs:
EMA ...
Devices:
CE mark

HTA

Health professionals

- Successive EU legislation has established minimum standards for training programmes
 - Based almost entirely on length of training
 - No attention to acquisition of competencies
- No legislation on continuing professional development
- No recognition of concept of revalidation

Professionals - revalidation

- Recognises that knowledge acquired 30 years previously cannot be assumed to remain valid
 - Growth of medical knowledge is exponential
 - New techniques are introduced
 - Established knowledge found to be wrong
- Evidence that some skills (such as manual dexterity) may decline with age

Formal approaches to ensuring maintenance of professional standards

- The Netherlands
 - Dutch physicians must participate in continuing medical education and undergo a peer review every 5 years
 - Comprehensive assessment of practice, adherence to guidelines, and patient input
- Germany
 - Only physicians contracted with Social Health Insurance
 - Requirement to accumulate 250 CME points every 5 years
 - For hospital doctors, 70% must be speciality specific
 - Additional scheme for those reading mammograms
 - Reimbursement can be reduced for non-compliers

United Kingdom

- System will apply to all doctors
 - Many questions still unanswered
- Two elements
 - Relicensure as medical practitioner
 - Revalidation as specialist or GP
- Current tensions
 - Central versus local approach
 - Administrative burden
 - Application to specialities not involving patient contact (pathology, some radiology, public health)
 - Prescribing rights for retired doctors
 - Cost

Ensuring professional standards: Informal systems

- Austria
 - Participation in CME mandatory
- Belgium
 - Voluntary accreditation system for GPs
 - Participation in peer review and CME
 - Accreditation lasts 3 years and allows higher charges
 - Compulsory for hospital doctors
- France
 - Evaluation of professional practice
 - In theory compulsory
 - In practice, not monitored

(Structural) quality of facilities

- All countries have certain basic standards
 - Building regulations
 - Fire regulations
 - Radiation protection regulations
- Also certain EU regulations
 - REACH (Registration, Evaluation, Authorisation and Restriction of Chemicals).
 - Asbestos Directive

(Structural) quality of facilities

Accreditation

- In several MSs some hospitals have been stimulated to seek accreditation in order to procure better contracts with the insurance funds.
- Some MSs have examined forms of accreditation within the framework of wider health care reforms (DK, PL and BE).
- Others have established programmes that are either voluntary or compulsory (CZ, IT, NL, UK, ES, FI, DE). E.g. in FR accreditation (“certification”) is mandatory; in the first round ca. 30% of hospitals showed large deviation from standards.

(Structural) quality of facilities

ISO 9000

- In FR, FI, DE, DK, PL, SE and the UK, some individual hospitals have sought certification by the ISO. The ISO 9000 standard covers areas such as record keeping and initiating action in response to emerging problems, but it is generic rather than specific to clinical quality.

EFQM

- Hospitals in FI, LU, NL and HU, as well as in some regions of Spain and Italy, have adopted the self assessment framework developed by the European Foundation for Quality Management (EFQM), in some cases linked to national award schemes.

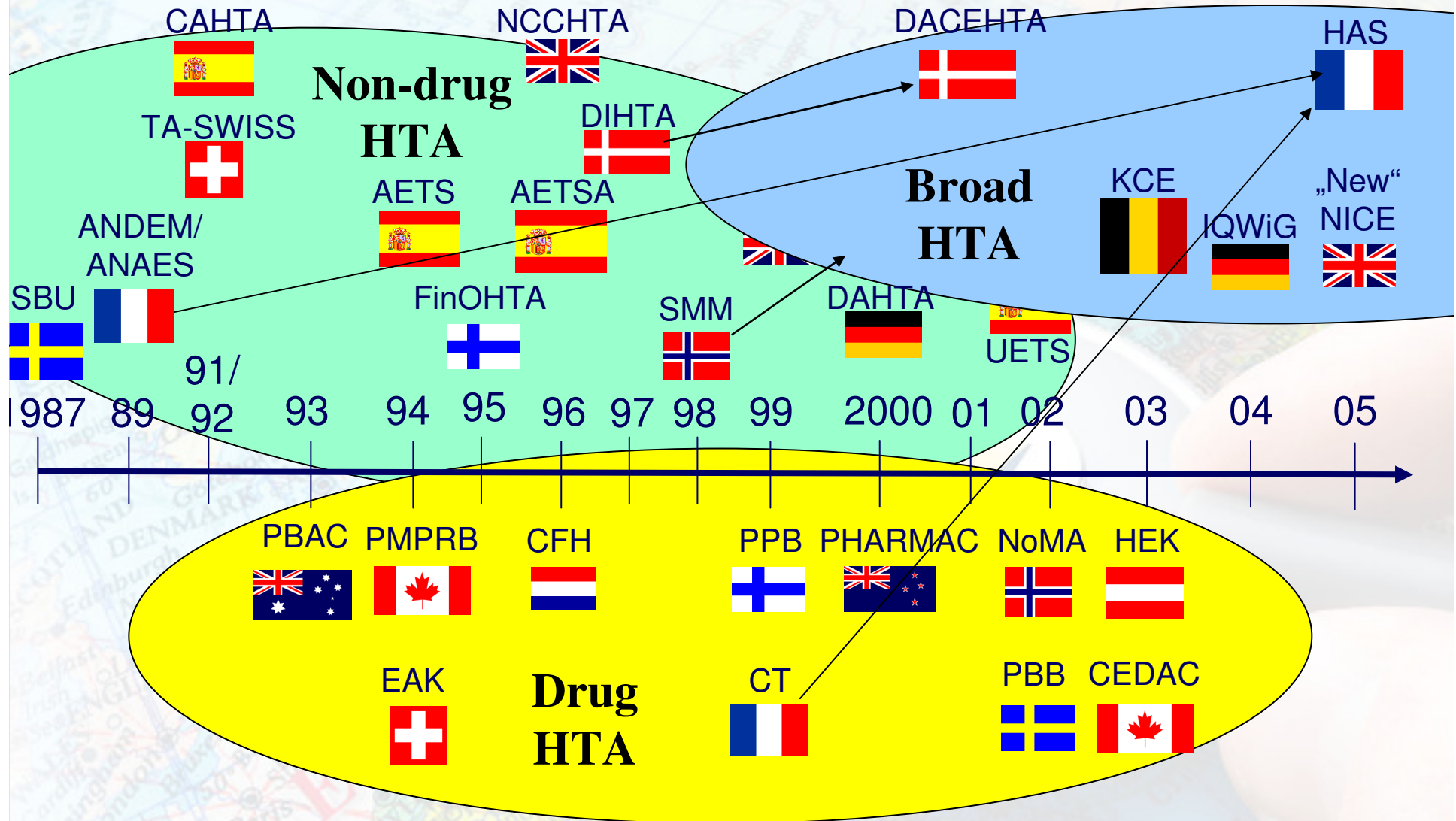
European Practice Assessment

- Offers a means of assessing how well general practices are organised and managed
- Based on five domains
 - Infrastructure
 - Staffing
 - Information
 - Finance
 - Quality and safety
- Designed to facilitate international comparisons
- Used in nine European countries

Health Technology Assessment

- the structured analysis of a health technology, a set of related technologies, or a technology-related issue performed with **the purpose of providing input to a policy decision**
- includes systematic review of research evidence on the **efficacy, safety, effectiveness and efficiency** of the health technology and consideration of the **implications for the delivery of health care and for society** as a whole

Health Technology Assessment



Broad HTA institutions



The roles and responsibilities of NICE since 1 April 2005

NICE produces guidance in three areas:

Public health – the promotion of good health and the prevention of ill health for those working in the NHS, local authorities and the wider public and voluntary sector

Health technologies – the use of new and existing medicines, treatments and procedures within the NHS

Clinical practice – the appropriate treatment and care of people with specific diseases and conditions within the NHS.

- l'analyse des pratiques cliniques et le développement de recommandations de bonne pratique (Good Clinical Practice)
- l'évaluation des technologies médicales (Health Technology Assessment)
- le financement et l'organisation des soins de santé (Health Services Research)
- l'équité et l'étude du comportement des patients (Equity and Patient Behaviour)



BEST PRACTICE IN UNDERTAKING AND REPORTING HEALTH TECHNOLOGY ASSESSMENTS

Working Group 4 Report

Reinhard Busse, Chair
European Observatory on Health Care Systems, Spain & Technische Universität Berlin, Germany

Jacques Orvalin, Co-Chair
National Agency for Accreditation and Evaluation in Health (ANAES), France

Marcial Velasco
Technische Universität Berlin, Germany

Mathias Perleth
ACK-Bundesverband, Germany

Michael Drummond
University of York, Center for Health Economics, United Kingdom

Felix Gürtner
Medical Technology Unit, Federal Social Insurance Office, Switzerland (MTU-FSOS)

Torben Jørgensen
Danish Centre for Evaluation and Health Technology Assessment (DAEHTA), Denmark

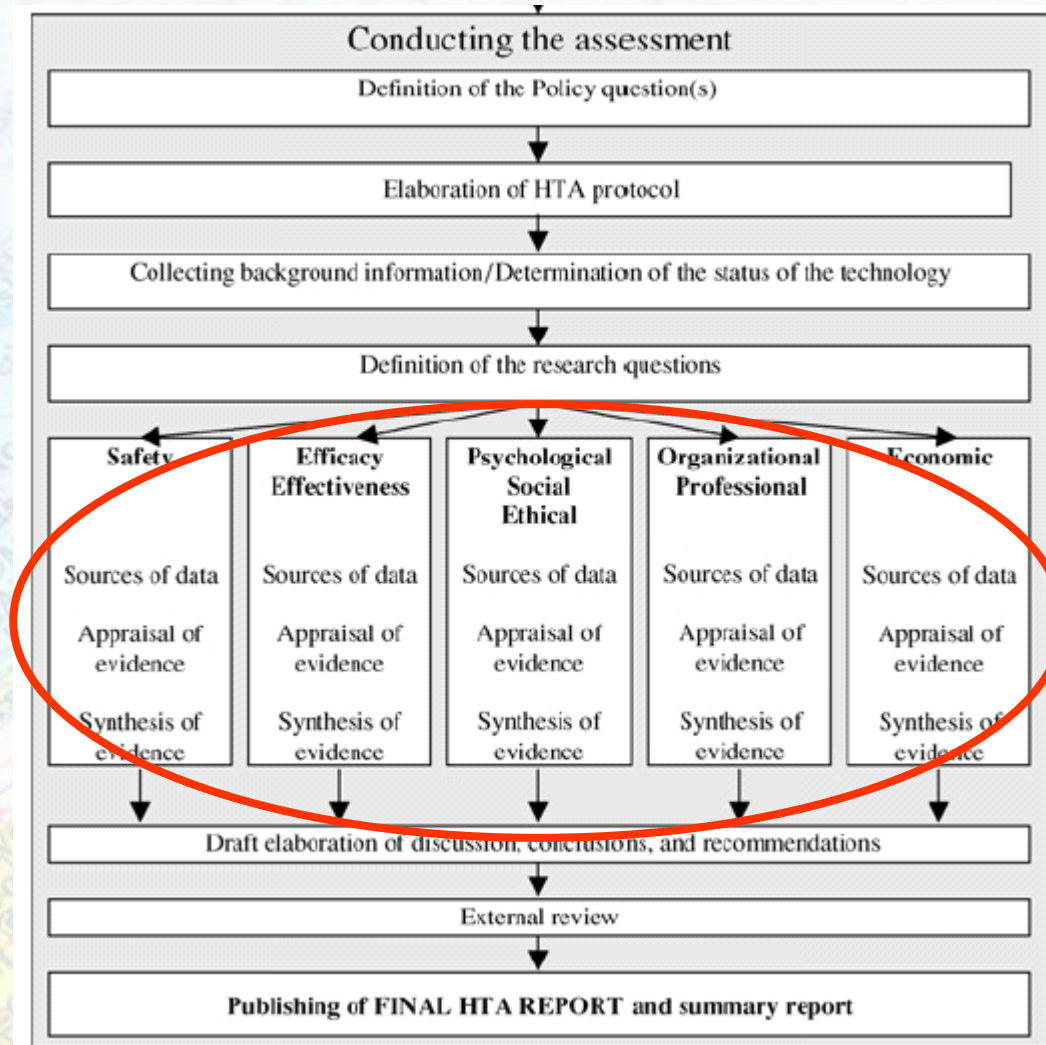
Albert Jovell
Fundació – BBilbao Josep Laporte Casa de Convalescència, Spain

Jim Malone
St. James's Hospital, Ireland

Alric Rütger
German Agency for Health Technology Assessment (DAHTA@DIMDI), Germany

Claudia Wild
HTA-Unit of the Institute of Technology Assessment (ITA), Austrian Academy of Science, Austria

Prepared for and in close collaboration with the working group by Reinhard Busse, Marcial Velasco, Mathias Perleth, and Jacques Orvalin. The authors are indebted to Wendy Wilson (European Observatory on Health Care Systems) for proof-reading English language editing.



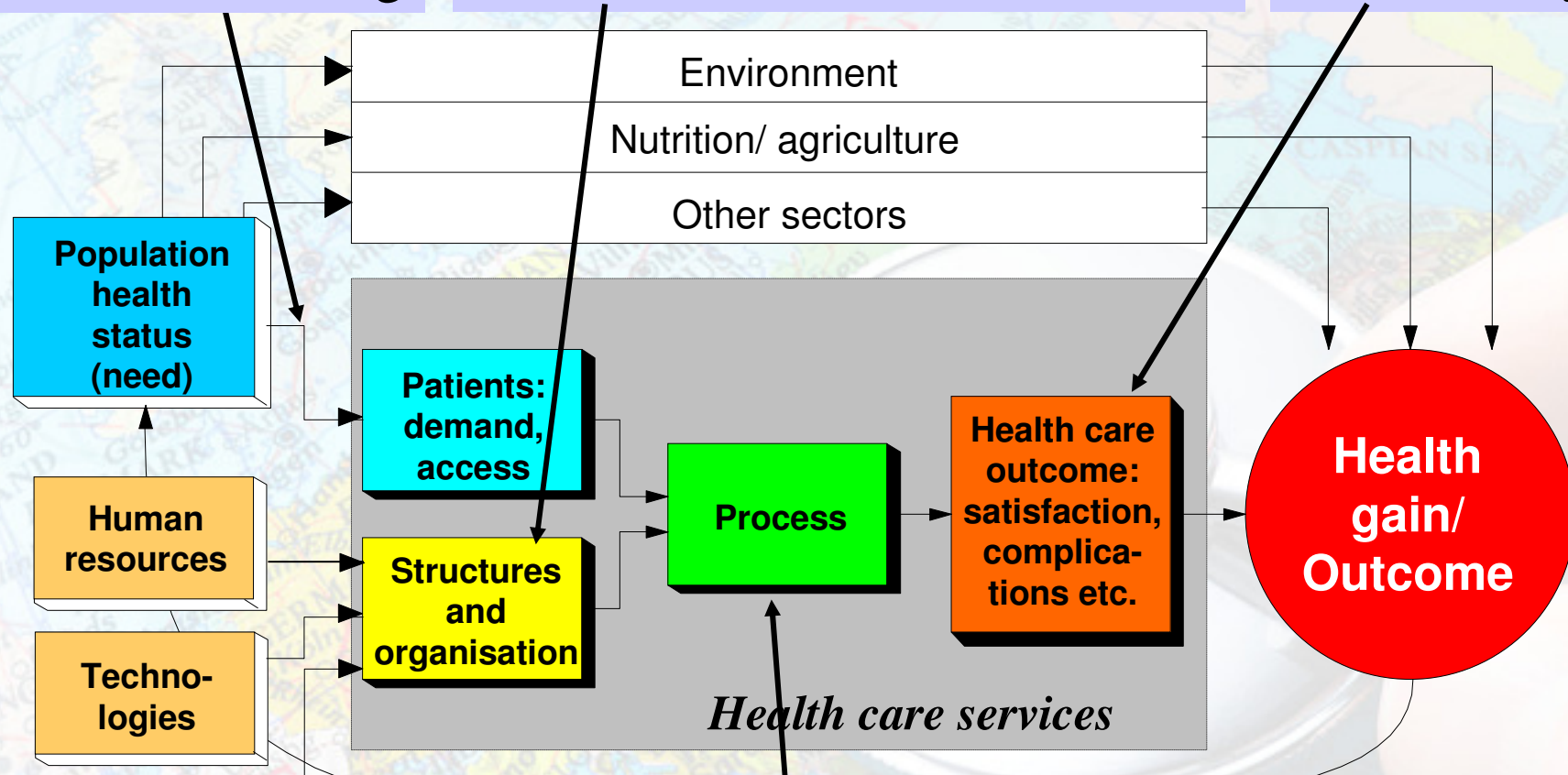
European Network for Health Technology Assessment



Universal coverage,
appropriate
entitlements,
limited cost-sharing

Professional (re-)certification
Provider (re-)accreditation
Health Technology Assessment
Concentration of services

Quality
indicators;
registers; pa-
tient surveys



“Do the right thing“: *ex ante* Guidelines/ disease management programmes/ reminders; *ex post* Review
“Do the thing right“: Quality indicators

Clinical guidelines

- Almost all countries have some systems for developing or adapting clinical guidelines
- Range from initiatives within individual facilities to national programmes that employ teams of analysts conducting systematic reviews
- Council of Europe has recommendations for producing guidelines.
- Several European specialist associations have well established systems of guideline development.
- European research project AGREE and the Guidelines International Network have contributed substantially to creating a consensus at European level

The Dutch Visitatie scheme

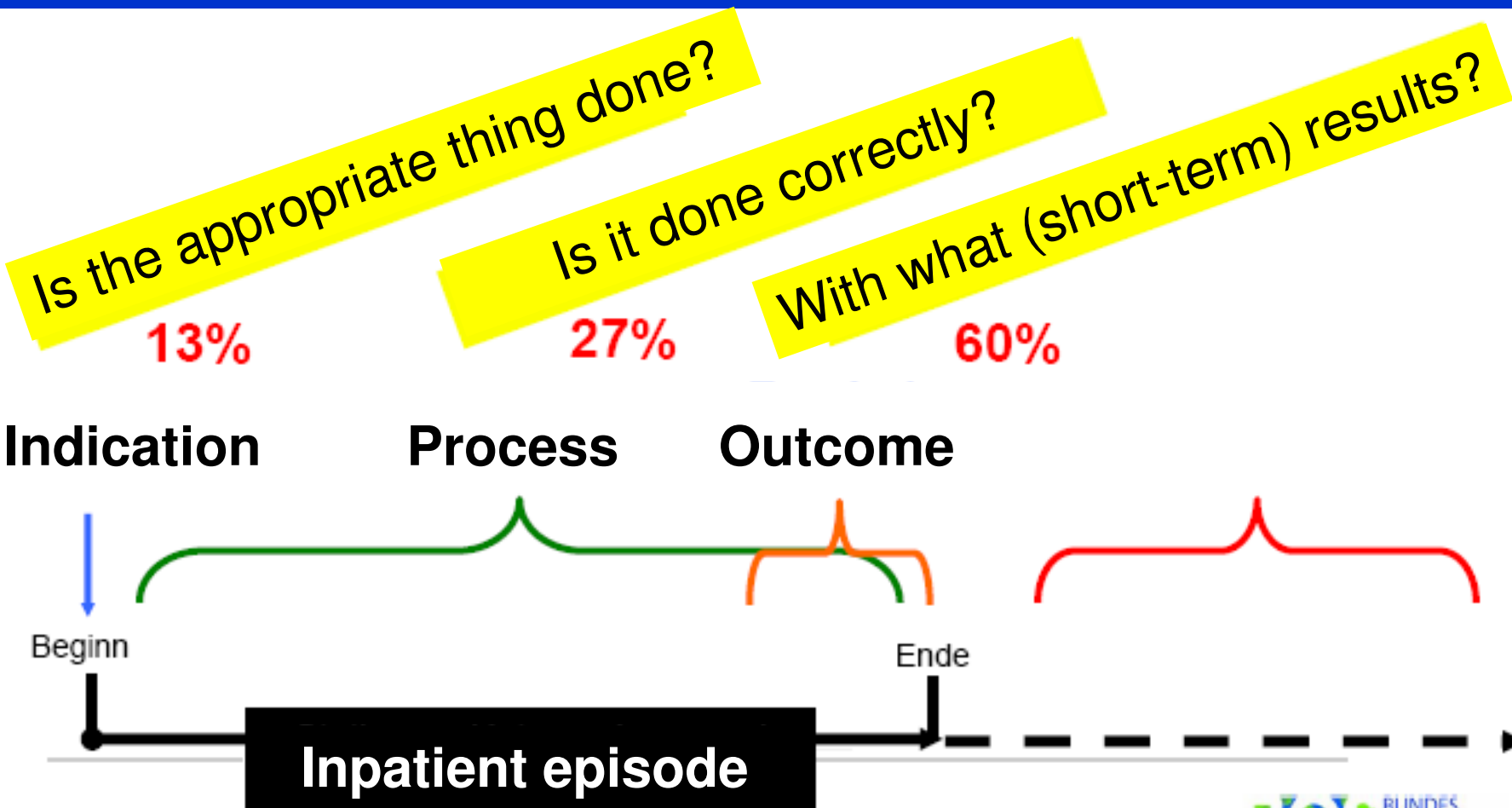
- Originated in the late 1980s as a system of peer review owned and led by doctors, designed to assess the quality of care provided by groups of hospital based medical specialists.
- Organised with specialist groupings and involves visits by a group of peers every 3-5 years.
- Findings documented in confidential reports that contain recommendations for improvement.
- Responsibility for implementing the recommendations lies with the specialists, who are visited, but some specialist societies offer support from management consultants.

Quality indicators (examples)

- Denmark
 - National Indicator Project measures the quality of care provided by hospitals for patients with six common conditions (lung cancer, schizophrenia, heart failure, hip fracture, stroke, and acute surgery for gastrointestinal bleeding).
- United Kingdom
 - Performance of general practitioners is assessed with the quality and outcomes framework.
 - Most measures focus on clinical aspects, although organisational and patient focused elements are also present.
- Germany
 - National benchmarking system was established in 2001, with explicit criteria relating to around 30 diagnoses and procedures.
 - Data cover up to 20% of inpatient cases treated in Germany and are published in annual quality reports.

Federal Office for Quality Assurance (BQS)

since 2001 mandatory for all ca. 1,700 hospitals, 169 indicators, 2.8 million cases (17%), with feedback and “structured dialogue“



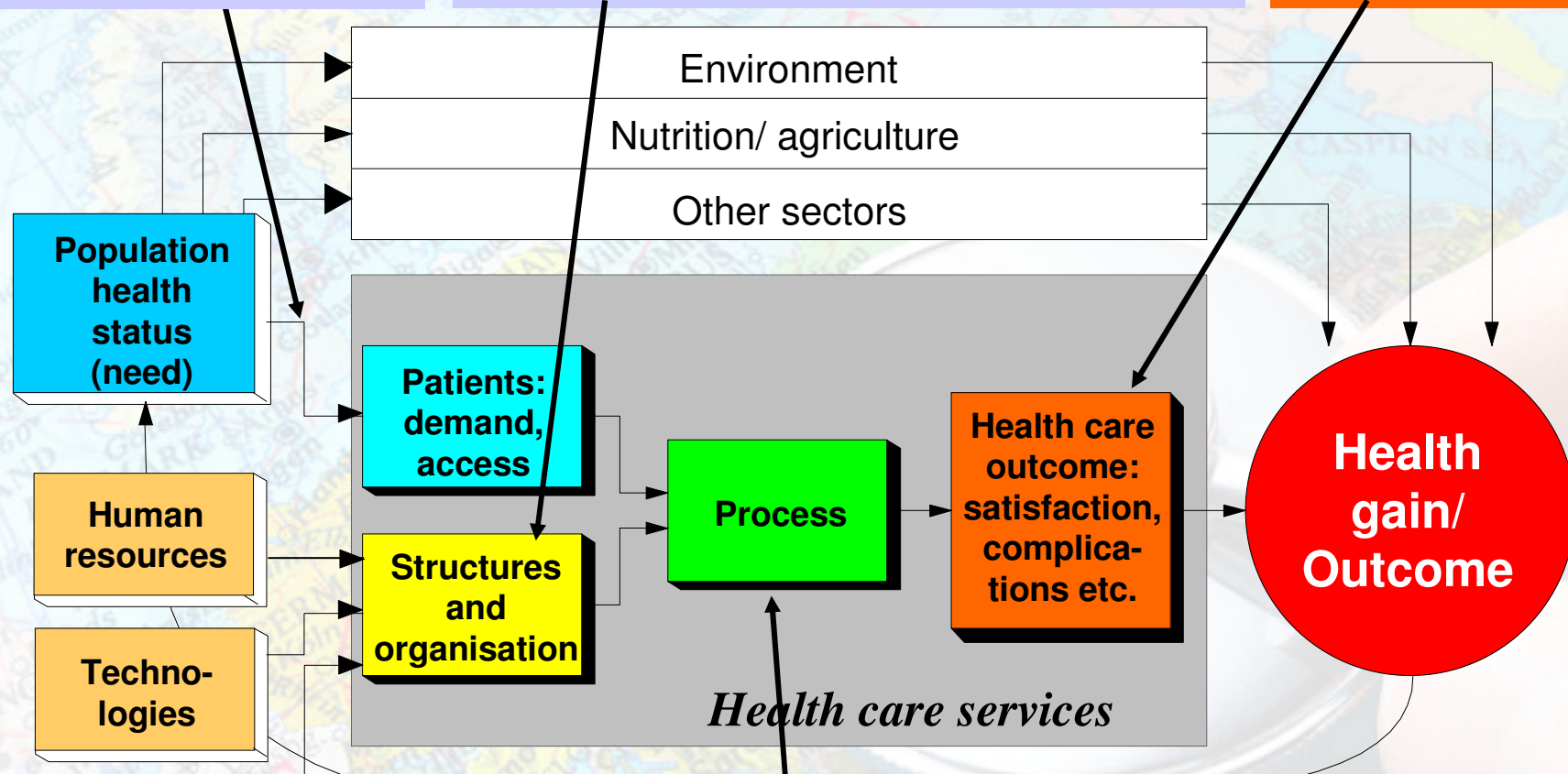
BQS-Bundesauswertung 2005



Universal coverage,
appropriate
entitlements,
limited cost-sharing

Professional (re-)certification
Provider (re-)accreditation
Health Technology Assessment
Concentration of services

Quality
indicators;
registers; pa-
tient surveys



“Do the right thing“: *ex ante* Guidelines/ disease management programmes/ reminders; *ex post* Review
“Do the thing right“: Quality indicators

Patient safety

- Luxembourg and United Kingdom used their rotating presidencies of the EU to make patient safety a priority.
- World Health Organization created a World Alliance for Patient Safety
- Importance of patient safety endorsed by the Council of Europe.
- Recent European study found that in 2005 only Denmark, Germany, Spain, the Netherlands, and the United Kingdom had established specific institutional structures

Patient safety: Denmark

- Confidential, non-punitive, but mandatory system for reporting adverse medical events established in 2004.
- Hospitals required to report medical errors and adverse events to a national database managed by the National Board of Health.
- Focus on learning from experience so as to prevent recurrence of adverse events
- Whistle blowing provision so that healthcare workers who report an adverse event cannot be subjected to investigation or disciplinary action by their employer, the health board, or the courts for doing so.

Patient safety: United Kingdom

- National Patient Safety Agency established in 2001
 - Patient safety division, operating a national reporting and learning system that analyses information on adverse events and takes appropriate action, for example by issuing alerts;
 - National clinical assessment service, providing confidential advice and support where the performance of doctors and dentists is giving cause for concern
 - National research ethics service.
- Confidential inquiries into:
 - suicide and homicide by people with mental illness;
 - maternal and neonatal deaths;
 - perioperative deaths.

Answering the main question

Can a European citizen be confident that they will receive high quality care in every EU Member State?

No, not yet

Do we need EU-wide action on quality?

