‘Best Practice’ in Health Care: State of the Art and Perspectives of the EU in improving the Effectiveness and Efficiency of the European Health Care Systems

Final Report to the
Directorate General V/F/1

March 1999

Authors:

Dr. med. Elke Jakubowski, M.Sc.
Dr. med. Matthias Perleth, MPH
Dr. med. Reinhard Busse, MPH

Department of Epidemiology, Social Medicine and
Health System Research
(Director: Prof. Dr. F. W. Schwartz)
Hannover Medical School
OE 5410
D-30623 Hannover
Germany

Correspondence:
Dr. med. Matthias Perleth, MPH
Tel.: +49-511-532 4451
Fax: +49-511-532 5347
Email: perleth@epi.mh-hannover.de

TABLE OF CONTENTS

LIST OF FIGURES AND TABLES

List of Figures

List of Tables

EXECUTIVE SUMMARY

Aim and Objectives

The basis for the project was the aim to identify areas, in which a Community involvement in informing about best/good practices in the health sector would add value to the effectiveness and cost-effectiveness of the European health systems in terms of (public) health gain.

For this purpose, the project had the following objectives:

1. to develop a framework for the classification of information on "best practice" in the health sector, focusing on activities, disciplines and methods which are available to identify, implement and monitor "best practice";
2. to outline the state of methodologies, state of application and current limitations of "best practice" related undertakings in the EU Member States;
3. to develop research and health policy recommendations for the Community by applying the classification framework for information on "best practice" in the health sector.

Methods

The first stage of the project consisted of a synthesis of the state in undertaking activities, and in applying disciplines and methods related to the search for "best practices" and good practices in the health sector in countries of the European Community. This was undertaken in a sequence of procedures which included: (1) the establishment of a definition for "best practice" in the health sector, (2) the development of a framework to classify information on best/good practices in the health sector, and (3) a synthesis of literature on activities, disciplines and methods which serve as important examples in the search for best/good practices in the health sector. The information was synthesised with respect to the methodological state of art, the current status of application and training in the EU Member States, and a summary over limitations in methodology and application. Data sources included databases of the medical and health related literature, conference reports, grey literature, internet resources, information gathered by visits to institutes and interviews with experts.

The second stage of the project was opened by a workshop, whereby the findings of the draft report were discussed. The workshop then set out the Community's potential for contributing to the Member States' endeavour in improving the effectiveness and cost-effectiveness of the European health systems. This was concluded to areas in which evidence/information about best or good practices should be provided by the Community. The identified areas were then translated into research and health policy recommendations for the European Union.

The draft report underwent extensive peer review by all project partners and other experts in the field, and was revised prior to the final submission to the European Commission.

Results

The framework for best practice consists of the overriding notion that health care should contribute to health. Health care, public health activities and health policy, then, should be advised by the best available evidence.

Information that is needed to improve the effectiveness and cost-effectiveness of health systems through health sector interventions is divided into three information "domains": (1) Input domain for evidence/information on the (potential) ***effects*** of health sector interventions and about actual health care provision; (2) implementation domain for evidence/information on ways to ***implement*** health sector interventions; and (3) monitoring domain for evidence/ information on ways to ***monitor*** the outcome of health sector interventions.

Evaluation is a central function in all three domains for improving the health systems' effectiveness and cost-effectiveness. Evaluation is based on *objectives* (e. g. improving the safety, efficacy, effectiveness, cost-effectiveness, appropriateness, and quality of interventions to tackle or to prevent health problems of individuals, groups of populations or whole populations) and, ultimately, all activities, disciplines, and methods in the three domains aim at the improvement of health (and/or the reduction or maintenance of resources) as an outcome resulting from health sector interventions.

Many activities in the EU Member States are related to the first domain. Three central activities are similar in their relation to the concept of "evidence-based health care" (Health Technology Assessment [HTA], Evidence-Based Medicine [EBM], Guidelines Development). These are activities by which evidence on what works best or good in the health sector is synthesised, evaluated and concluded either as a data base to provide evidence (EBM and most of HTA) or in the format of recommendations (guidelines and some HTA) for different levels of decision making in the health sector. These three activities are not primary research methods. Rather, results from primary research are collected and evaluated in a systematic fashion (by means of "systematic reviews") and thus require input through a number of disciplines (e. g. primary clinical research, clinical epidemiology, health economics, health system and health services research) all of which provide information on specific questions of best practice in the health sector. For HTA and EBM, European and international networks have been established or are in the process of being established while such a network is still missing for guidelines.

However, while primary and secondary research on the (potential) effects of health care interventions are necessary for "best practice", they are not sufficient since the information also has to be disseminated and implemented (i.e. translated into clinical practice, public health interventions and into policies). Furthermore, the outcomes of implementation have to be monitored in order to provide feedback about successful and unsuccessful health sector approaches to improve health. The inventory of the state of activities, disciplines, and methods in the Member States within the framework revealed that both the domain on

evidence/information on good strategies for implementation and the domain on monitoring of best or good practice for clinical decision-making, public health and policy decision making are less developed when compared to the state of evaluation of health care interventions effects.

Conclusions

None of the separate approaches and activities exclusively forms a successful and all-embracing strategy to ascertain good or 'best practices' in the health sector. A collective approach in the management of information is expected to add value to individual efforts. This could be initiated throughout increased co-ordination of best practice activities in the Community which would assert: (1) increase of capacity for the Member States to benefit from each others experience in regard to successful and unsuccessful approaches to best practice in the health sector, (2) reduction of duplication of applied research undertakings in the search for best practices, (3) increase of capacity to provide technical expertise and oversight to solve population health problems at the Community level, and (4) increase of capacity for a profound quality development of information on best practices in the health sector.

Recommendations

A. Research recommendations

1. The Community should devote sustainable resources to increasing the quality and quantity of both primary and secondary research. Decisions on the Community's support of research projects should be advised by the strength of evidence that the project is expected to produce. It is also recommended that quality criteria for conducting and reporting studies are standardised and applied to all Community funded research projects.

2. The following areas of applied research should be given high priority: (1) studies to obtain information on how health system financing and organisational arrangements effect the public's health; (2) studies to obtain information on strategies to disseminate and implement research results in a way likely to change practice; (3) studies to obtain information on strategies to attribute health status information to policies of the health sector and other sectors, and improve methods to monitor policies on their health impact; (4) studies to obtain information on strategies to tackle barriers for changing/improving clinical practice, public health actions and policies; and (5) studies to obtain information on how to increase the transferability of research results between health care settings and systems.

B. Health policy recommendations

1. The Health Monitoring Programme, adopted in 1997, should be emphasised by a legal commitment for health status monitoring by the Member States. The Community should build on Member States' capacities and those of international organisations to improve methodologies for the monitoring of health status, both generic and disease specific.
2. It is recommended that a new Community health policy provides for a programme to build up an evidence base for health sector interventions and policies. A number of databases already exists for health care, which should be supported/extended rather than establishing new databases. For this purpose it is recommended that the Community supports co-ordination and the development of existing networks in the area of evidence-based health care. It is furthermore recommended that the Community acts towards the establishment of a policy advising evidence base for health sector interventions beyond health care (e. g. covering explicit fields of public health, such as for example health promotion and health protection). The Community should also build partnerships to support and benefit from capacities and infrastructures already developed and established by Member States and international organisations. This database could in the long run ideally also provide data on the health effect of interventions which are not primarily directed at health. The development of a model for such a database requires the further development of methods to evaluate the health effect of public health policies and the development of suitable methodologies to evaluate the health effect of social, economic, and other policies (see research recommendations).

Prospect

The framework for categorising information on best practice should be further developed. This could be realised for example in focusing on one specific area of Community public health concern. This should be an area where the health status is already being monitored in order to allow for the development of a method that links health outcome to the development and implementation of health policies. Another focus for further development of the framework model could be sectoral policies beyond health.

1 INTRODUCTION

1.1 Background to the project in regard to a European Union public health policy

The Member States of the European Community are facing common challenges in delivering efficient, adequate and high quality health services at affordable cost in times when national resources have become limited. The demand for quality health care in Europe is growing because of ageing populations and rising public expectations. The combination of demo-graphic changes, bringing about the increase of age-related diseases such as for example cardiovascular disorders, cancer and some mental diseases, and technological developments increases the cost of health care provision. All Member States are facing common problems of socioeconomic deprivation leading to inequalities in health status. On the other hand, there are new opportunities to secure improvements in individual and population health. Increase of know-ledge and clinical advances potentially enable more effective health care delivery and more efficient use of resources. Information on health and health care can be circulated more rapidly.

These common developments in health and health care alongside with the growing economic interdependence and free movement of goods, capital, services and people between the EU countries need to be recognised when reviewing the 1993 Community Framework for Action in the field of Public Health. The framework was put forward in order to make operational Article 129 of the EC Treaty. The existing framework will have to be reconsidered in light of the new public health provisions in the Treaty of Amsterdam and the expected expansion of the Community towards Central and Eastern Europe [Commission of the European Communities 1998]. The Treaty of Amsterdam will change the provision of Article 129 of the Maastricht Treaty (Article 152 in the revised Treaty) which had emphasised the prevention of disease, towards improving public health, preventing human illness and diseases, and obviating sources of danger to human health (summary of health provisions in the Treaties see Appendix 3.1).

A new Community policy on public health will also have to consider that the candidate countries have more substantial health problems to tackle and fewer resources to spend on health in comparison to the existing Member States. Thus, the identification of effective ways to improve the effectiveness and cost-effectiveness of health care systems will be a priority objective of a new European public health policy which would have to be in place by the year of 2001 upon completion of the currently existing public health policy programmes.

In view of the need to develop a new European public health policy, it is necessary to establish guidance on which activities can be taken at Community level to assist Member States in maximising the performance of their health systems. This report summarises the findings of a project which is one of several studies funded by the Commission in order to obtain advice on ‘best practice’ activities in the health sector.

1.2 Policy perspective of the project

The project focus is on health policies and clinical policies, implemented as health sector interventions (Figure 1). In this report, health sector interventions are defined as the operational form of the "health system".

Medical care interventions are illustrated as the constituent implementation form of clinical policies. Clinical policies are one subordinate fraction of health policies.

Figure 1 also reflects the relationship between population health (in this report equivalent to 'public health') and the clinical perspective which is directed at individual health. A European Union perspective for developing, formulating and implementing health policy will primarily aim to improve population health in order to comply with the legal mandate provided in the Treaty of Amsterdam. Policies which are directed at obtaining population health, restoring population health or preventing disease on the population health level, however, are wider than the health sectors' scope alone. The population health perspective takes into account all determinants of health in which context medicine only plays a minor role. It follows that the perspective taken in this project only covers "best practice" for a fraction of possible interventions which could eventually lead to the improvement of the populations' health.

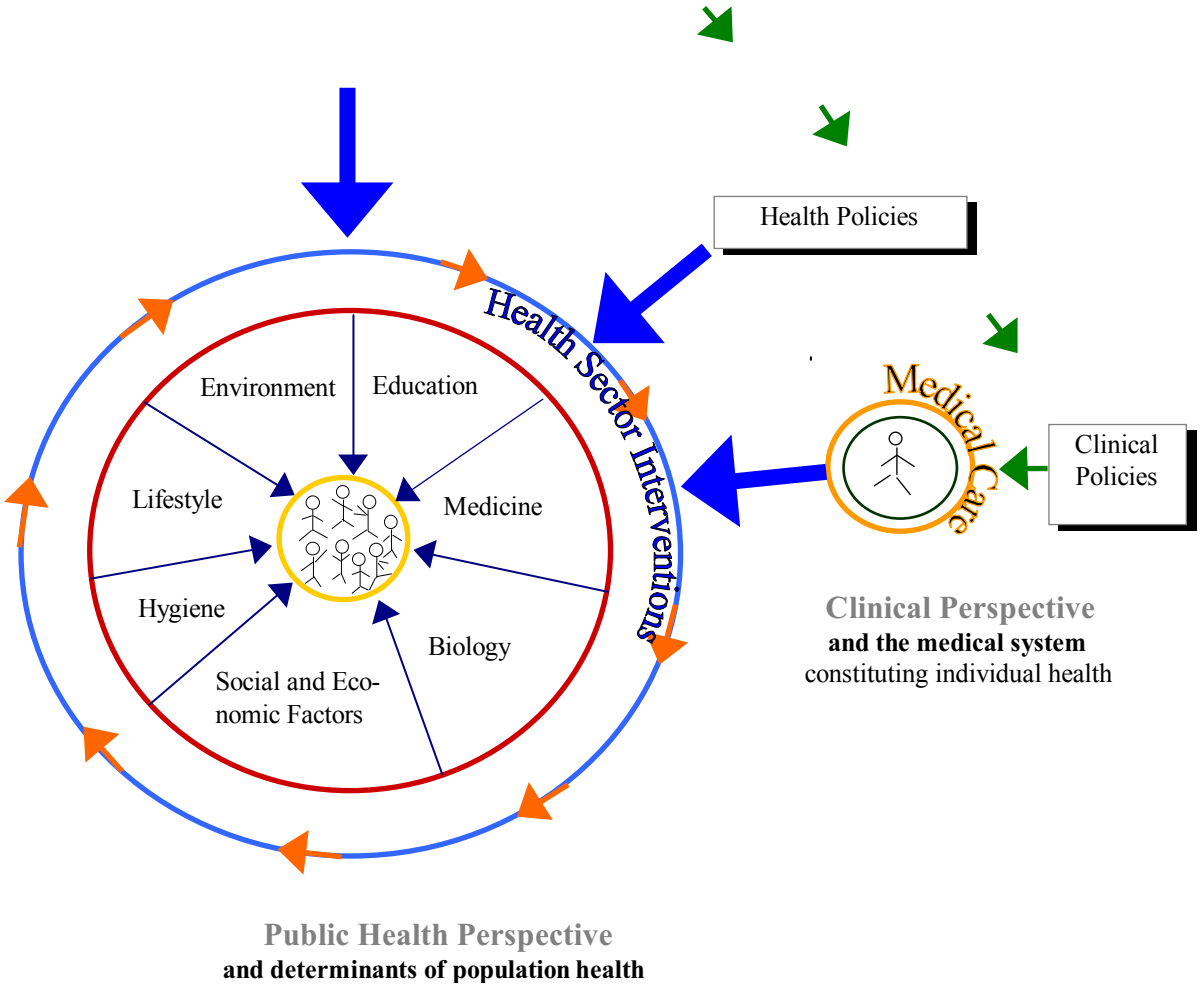

FIG. 1: Relation between the Public Health perspective and the clinical perspective.

1.3 Research perspective of the project

Various activities and health research are available to assist public health policy and clinical decision making with the purpose to organise and provide health services more effectively and efficiently. Few attempts have been made, however, to categorise this information and integrate the many different pieces of knowledge into one theoretical framework. Current activities in this field can be subdivided into two major areas:

1. **Primary Research:** The further development and improvement of primary methods to identify and promote best health care practice. This can be achieved by either increasing the quantity of primary research studies or by increasing their quality (e. g. by standardisation of methodologies for primary clinical or economic studies).

2. **Secondary Research:** The systematic identification, collection, assessment, synthesis, dissemination, implementation and evaluation of the impact of health research results on health sector interventions in terms of individual and population health and the costs associated with health gain.

The first area - promotion of best practice in health care by primary research - is dealt with by the European Commission's BIOMED programme[1]. The present project focuses on the second area in promoting best health care practice. In this respect, the prime focus lies on three major **activities** all of which have gained recognition for health policy and clinical decision-making processes within the past decade: Health Technology Assessment (HTA), Evidence-Based Medicine (EBM) and the development of Clinical Practice Guidelines (CPG). This report is designed to provide an overview over these activities and related disciplines and methods with the purpose to introduce a concept suitable to respond to challenges related to the financing, organisation, management and service delivery of health care systems. Starting from different perspectives, the common aim of these activities is to improve the health care systems' performance measured by criteria related to for example safety, efficacy, effectiveness, costs, cost-effectiveness and appropriateness of health care interventions as well as the quality of health care and the perception of the public.

None of the separate approaches exclusively forms a successful and all-embracing strategy to ascertain good or 'best practices' in health care, but as the individual approaches offer many opportunities for improvement, a collective (integrated) approach seems fully worthwhile.

1.4 Aims and objectives of the project

The joint effort by experts from various disciplines consists of a collective approach in order to define 'best practice' and provides a summary and synthesis of the state of methodology and application of existing activities and their limitations. This inventory of activities is designed to provide a base upon which areas of best practice can be recommended for information collection and dissemination in the Community. In effect, the project aims at proposing the development of a strategy for the EU which could translate into Community wide action by moving the discussion about the potential of recent developments comprised within the concept of 'best practice' to a European level. An essential assumption in the project is that an

[1] The BIOMED programme is implemented by the European Commission, DG XII Science, Research and Development covering scientific biomedicine and health research in the EU Member States. Between 1994 and 1998, health research has been funded within BIOMED 2, covering the following areas: cancer research, research on cardiovascular diseases, research on chronic diseases, ageing and age-related diseases, research on occupational and environmental health, research on rare diseases, public health research and health services research, research on biomedical ethics, ethical, legal and social aspects of research. From 1999, it is replaced by the Fifth Framework Programme.

information strategy in the Community will add value to the Member States' endeavour in improving the effectiveness and cost-effectiveness of their health systems.

For this purpose, the project had the following objectives:

1. The prime objective was to develop a framework which would enable the classification of information on 'best practice' in the health sector, focusing on activities, disciplines and methods which are available to identify, implement and monitor 'best practice'. A model is provided that illustrates the potential to increase knowledge and understanding for a given disorder by means of an integrated view of these activities.
2. The classification should then be the base for an outline of the state of methodologies, state of application and current limitations of 'best practice' related undertakings in the EU Member States. This inventory was directed at the identification of areas of the health sector where the concept of best practice is or can be most clearly defined and those where more information is needed. Another purpose was to identify common methods deployed to set out the potential to limit duplication or overlap of work in individual activities.
3. Finally, the project aimed to identify how to make best common use of information that can be obtained through varied individual approaches in health research and indicate areas where it would be useful to collect and disseminate information on best practice in the Community. These areas should then be translated to concrete research and health policy recommendations for the Community, guided by the classification framework for information on 'best practice' in the health sector.

1.5 Structure of the report

The report provides an outline of the material and methods in chapter 2, an introduction to the meaning of 'best practice based on a systematic search over the origin and definition of the term in the literature (chapter 3) and develops a theoretical framework to enable identification of areas of application for best practice in the health sector (chapter 4). For this purpose, the state of the art of activities, disciplines and methods that can contribute to defining best practice are presented in a summary overview which also includes the state of development of methods to implement best practices, monitor the resulting health and cost effects and the transferability of research results between different settings and systems. In chapter 5, the relevant activities in the Member States are briefly summarised. The final part of the report (chapter 7) is based on expert recommendations on joint activities and a workplan for EU support.

This project has been supported by the European Commission V/F.

The authors have the final responsibility for the report.

2 MATERIAL AND METHODS

The report was drafted in three stages:

A. Initially, definitions of 'best practice' in the health sector were extracted through a systematic literature search. A working definition for 'best practice' was developed thereupon. This was followed by the invention of a framework for the collection of information on best practices. A synthesis of literature on three activities which currently serve as important examples in the process of defining and identifying best practices in the health sector (Health Technology Assessment, Evidence-Based Medicine, and the development of Clinical Practice Guidelines) was undertaken. Contributions from health research disciplines (clinical research, epidemiology, health economics, health system and health services research) were summarised.

Information was obtained through a synthesis of key literature, consultation of experts involved in activities and disciplines related to the concept of 'best practice', information from the medical and health research literature, search of the internet, conference and project reports. Literature search on 'best practice' in the health sector was based on a MEDLINE and HEALTHSTAR search[1]. Information for the different activities, disciplines and methods of best practice was obtained through different sources, mainly by interviews and references provided by the consulted experts and by review of the major medical and health related databases.

Findings of the following project reports were considered for this report:

- EUR-ASSESS (DG XII-BIOMED supported from 1994 - 1997)
- HTA Europe (DG V/F supported from 1996 - 1998)
- Interim Report of the Leonard da Vinci Initiative (World Health Organization, Regional Office for Europe)

Results of the following international conferences were synthesised:

- WHO meeting: "Guidelines in Health Care" (1/97), Velen, Germany;
- 2nd International Conference "Scientific Basis of Health Services" (10/97), Amsterdam, The Netherlands;
- WHO meeting: "Reshaping health systems towards health outcomes" (12/97), Celle, Germany;

[1] Systematic search was only conducted for information on origin, definition and implementation of the term 'best practice'. The basic term used was best practice?. This was combined with the following keywords: 1. Health? 2. Health Care? 3. Health Policy? 4. Medical Care? 5. Medicine? 6. Clinic?al?

- Workshop of the International Society of Technology Assessment in Health Care (ISTAHC) and HTA Europe on "Use of health outcomes information in health policy and health systems" (1/98), Celle, Germany.

Table 1 provides an overview over the main sources of information in the first phase of the project.

TABLE 1: Overview over the information sources and experts involved in the first phase of the project

Issue	'Best Practice'	EBHC / EBM	HTA	Guidelines	Disciplines	Methods / Implementation / Monitoring
Literature search and selection	Based on a systematic search in MEDLINE and HEALTHSTAR	Recommended by experts and based on the authors' valuation	Recommended by experts and based on the authors' valuation	Recommended by experts and based on the authors' valuation	Recommended by experts and based on the authors' valuation	Recommended by experts and based on the authors' valuation
Expert interview consultation	G. Van Wyk; Health Service Outcomes Branch; Commonwealth Department of Health and Family Services, Australia	Dr. N. Hicks Oxfordshire Health Authority, United Kingdom	Prof. D. Banta, TNO Prevention and Health, Division Technology in Health Care, Leiden, The Netherlands	Dr. H. Maisonneuve; ANAES, Directeur de l'Evaluation, Paris, France	(Health Economics): Prof. A. Maynard; Health Economics Consortium, University of York, York, United Kingdom	(Appropriateness Methodology): Prof. J. Kahan, RAND-Europe, Delft
Information selected from Databases		The Cochrane Library	The ISTAHC CD-ROM, 1998 version		NHS Economic Evaluation Database (NEED)	The United Kingdom Clearing House on Health Outcomes; DARE - The NHS Centre for reviews and Dissemination online version, United Kingdom
Findings of projects, conferences and workshops with related subjects			EUR-ASSESS Project Report; HTA Europe Project Report	WHO meeting: "Guidelines in Health Care" (1/97), Velen, Germany; Guideline Database Project, Institute of Health Sciences, Oxford, United Kingdom	1998 Interim Report of the Leonardo da Vinci Initiative (WHO-Europe) in 'Assessing Needs in Training in the Fields of Health Economics and Management in the European Union'	2nd International Conference "Scientific Basis of Health Services" (10/97), The Netherlands; WHO meeting: "Reshaping health systems towards health outcomes" (12/97), Germany; ISTAHC Workshop on the 'Use of health outcomes information in health policy and health systems' (1/98), Germany

All information was structured and integrated into a framework to fit the purpose of the study.

B. A workshop was held during the second phase of the project in order to discuss the content of the draft report and to set out the potential of the Community for added value to national and regional activities in improving the effectiveness and cost-effectiveness of the European health care systems through the discussed areas of best practice. Participants of the workshop mainly consisted of previously interviewed partners in the project (Appendix A2).

C. A substantial review of the draft report was undertaken thereafter, to incorporate the changes proposed by the project partners. Before drafting the final version of the report, the draft was again distributed to all partners of the project, and additionally, the report was sent to several experts which were interested in the findings of the project and kindly provided additional comments on the report (see Appendix A1).

3 DEFINITIONS OF BEST PRACTICE

3.1 Best Practice definitions for health care

Best practice, alongside with 'benchmarking', is an organisational concept deployed in the industrial sector and increasingly related to management and administration. In this context, 'best practice' is referred to as a process-oriented concept to achieve improvements within individual agencies or settings over time. Improvements are characterised by measurement of quality, effectiveness, cost-effectiveness, and productive output. The concept implies targeted activities in regard to resource allocation within the productive sector and is closely related to benchmarking, defined as 'an external focus on internal activities, functions or operations in order to achieve continuous improvement' [McNair and Leibfried 1992]. Benchmarking is a systematic approach described as 'the search for best practices that will lead to superior performance' [Camp 1989]. Benchmarking is practised by comparing practices between groups of similar practice and shared peer group learning of good practice. It is estimated that benchmarking serves as an industrial concept for approximately 15 years and is currently associated with some of the most successful companies in areas such as invoicing, product design and meeting customer need [Lam 1994].

The discussion about applying the industrial concepts of best practice and benchmarking to the delivery of health services and clinical practice has different aspects. In general, there are serious concerns over simply applying industrial economic approaches to the health care sector because the products are very different [Normand 1997]. Nevertheless, there are some signs that in fact those concepts are being increasingly considered and implemented within governmental programmes for health care organisation and management and health service provision. For example have exercises of benchmarking for best practice in clinical practice been sponsored in the United Kingdom by the NHS Management Executive in 1993. The concept was to introduce benchmarking to NHS clinical units, with some 30 units having participated on a voluntary basis by 1994. Benchmarking activities included for example reducing the number of cancelled operations and handling complaints [Lam 1994]. The new approach to quality in the NHS is related to the concept of 'best practice' (see 3.2). In Australia there is a governmental programme in which the concept of best practice and benchmarking is related to some areas in the health care sector (see 3.2). The Programme has related the industrial definition from the Australian Department of Industrial Relation that defines best practice as 'a comprehensive, integrated and co-operative approach to the continuous improvement of all facets of an organisation's operation'. Within the programme, the key principles and processes are attributed to: 'strong leadership', focusing on the 'customer or client', 'identifying a simultaneous improvement needs' and establishing a 'workplace culture' ensuring extensive 'consultations and communications' with unions and employees, 'maximising the potential of human resources', 'removing organisational layers' and 'using

technology for strategic advance' [Carnegie 1994]. In his opening address at the 'Best Practice in the Health Care Sector Conference' in Sydney, Australia on May 30, 1995, S. Duckett from the Department of Human Services and Health of the Commonwealth of Australia, proposed that 'international best practice is a proven basis for the management of change, that it represents a major tool for the future management of the health care system, a fact amply demonstrated by its success in organisations in general industry' [Ducket 1995]. Ducket excluded 'a total commercial approach to health services', but proposed to 'adopt some of the initiatives used by the business community to improve the quality of services to customers while improving productivity' [Ducket 1995]. The Best Practice concept in the New Zealand Hospital and Health Services Knowledge Network was 'to share information on Best Practice and Benchmarking' [http://www.moh.govt.nz/hnetnz/]. Best Practice in this context meant: 'doing things smarter, practices which led to superior performance, achieving consistent quality in what is done, and evidence-based practice'. The outcome from the project was to set up a directory listing based on information received from health care providers from a standardised question framework.

The overview over the health care and medical scientific literature indicates that 'best practice' in the context of medical services provision is mostly referred to in the context of the quality of medical services: as a tool that could complement existing quality management activities in clinical practice such as total quality management, standard setting and clinical auditing [Lam 1994]. For example has 'best practice' been proposed as a structured method in nursing care, for nursing telematic education, and for monitoring nursing services [Baumont 1994; Teixeira 1998; Wilks et al. 1997], planning of a specialist's practice [Conrad et al. 1996], in the context of clinical audits [Staniford 1995], outcomes management [Wojner 1996; Grady 1996; Cole et al. 1996], and quality management in health care in general, primary care, and health promotion [Ducket 1995; Zairi and Matthew 1995; Nutbeam 1996].

Identifying best or good clinical practice is explicitly aimed at in the process of developing clinical practice guidelines [WHO 1997]. Woolf (1998) points to the fact of 'uncertainty when defining 'best practices'' for guidelines. There is a notification for a 'National Clinical Guideline Clearinghouse in Development' which will allow 'Surfing the Best Practice Guidelines', and assisting 'practitioners and consumers' to benefit from the growing volume of clinical practice information [AWHONN Lifelines 1997 Aug;1(4):55]. The 'Best clinical practice' project ('assessment of processes of care and of outcomes in the US Military Health Services System') is an initiative within the National Quality Management Programme of the Military Health Services System of the United States which has undertaken a number of evaluation projects [Krakauer et al. 1998] (see Appendix A.4 for details):

For particular clinical indications, 'best practice' has been regarded for example in the context of the surgical management of breast cancer [Collins 1997], quality management in blood transfusion [Vasconcelos and Segatchian 1997], nursing care in wound assessment [Miller

1996], benchmarking critical care medicine [Angood et al. 1997], a model of care for polydipsia [Visalli 1997], screening for mental disorder [Candelora and Pfeiffer 1994], maternity care and uncomplicated birth [Halligan et al. 1997; Oberer and Auckerman 1996], rectal cancer care [Penniment 1996; Chapuis et al. 1996] and measles control [Hawe 1994].

In conclusion, "best practice" is a term which is used in the context of medical services provision, but seems less common in other areas of the health sector such as for example health care financing and health care organisation. Also, a scientific definition is usually not provided. One of the few explanations of the term "best practice" is given by Glazer (1994) who proposes that "The concept of 'best practices' can be understood in light of the distinction between efficacy of treatment and effectiveness" and points to the term in the way that it "implies the existence of practices that are not the best".

Two recent governmental 'best practice' programmes working for the identification of what constitutes 'best practice' in health care and already mentioned above will be introduced in the following chapter as they provide an operational approach to the term for health care.

3.2 Best Practice definitions in health policy programmes

'Best practice' in the United Kingdom

The December 1997 United Kingdom National Health Service (NHS) White Paper deploys the term in regard to "A new framework for ensuring high performance and quality", placing fair access to effective quality of care at the top of the NHS modernisation agenda [http://www.official-documents.co.uk/document/sdoh/newnhs/forward.htm]. The approach of the reform is to tackle regional variations in health care quality by: 1. sharing best practice, 2. setting national standards for quality care, 3. developing coherent assessments of which treatments work best for which patients and 4. increasing accountability for the quality of care offered and delivered [http://www.open.gov.uk/doh/newnhs/quality.htm]. The search and determination of 'best practice' and quality care is to be evidence-based and will mainly be surfaced by two national institutions: 1. The National Institute of Clinical Excellence (NICE) and 2. The Commission for Health Improvement (CHI).

1. National Institute of Clinical Excellence (NICE)

This will involve a new co-ordination model between the Government and the health professions [http://www.open.gov.uk/doh/newnhs/quality.htm]. A National Service Frame-work will be set in an interdisciplinary approach and will involve standards for service organisation and service delivery for particular conditions between health and social services. NICE will produce national guidance for health professionals (including doctors, nurses and midwives), and undertake assessments of pharmaceuticals, treatments and devices. Health care is required to meet primarily the following objectives: to be appropriate (to peoples' needs), to be effective (drawing on best available clinical evidence), and to be efficient and economic (to maximise health gain for the population) [http://www.open.gov.uk/doh /newnhs/quality.htm]. Standards will be delivered locally throughout a new system of clinical governance, a process by which each part of the NHS is anticipated to assure its clinical decisions. This process is aimed to be supported by the introduction of a system of "lifelong learning" (i.e. to support professional team-working) and "professional self-regulation" [http://www.open.gov.uk/doh/ newnhs/quality.htm].

2. The Commission for Health Improvement (CHI)

The Commission for Health Improvement (CHI) will be authorised to monitor the standards of care in hospitals and will be responsible for the National Framework for Assessing Performance and an annual National Survey of Patient and User Experience of the NHS. The monitor work will be proceeded throughout a rolling programme of review of hospitals. The Survey will be established to evaluate whether services are meeting local needs and expectations of patients.

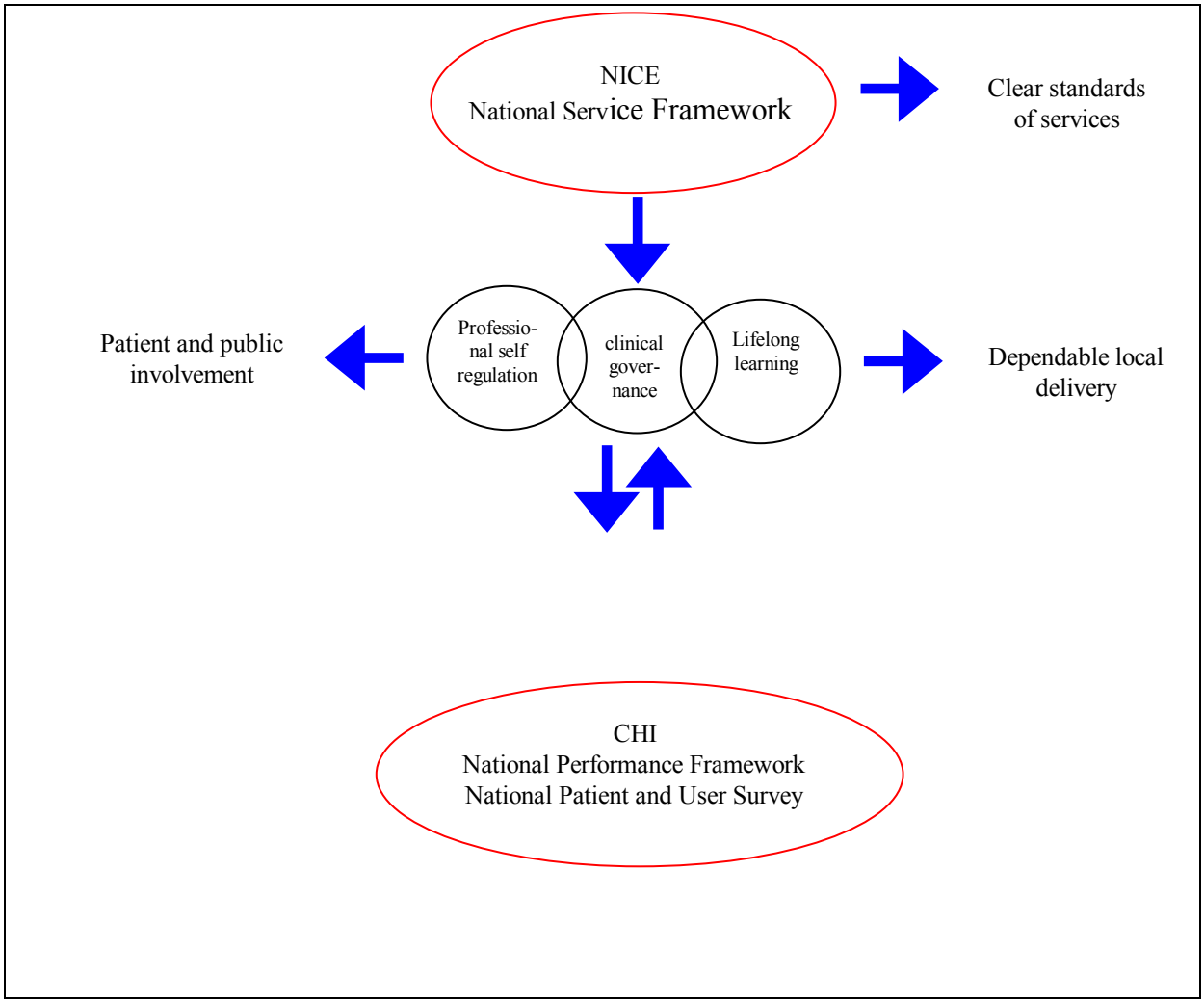

FIG. 2: The new model for setting and monitoring quality standards in the NHS

"Best Practice in the Health Care Sector Program" in Australia

Australia has a national programme entitled "Best Practice in the Health Sector", funded by the Commonwealth Department of Human Services and Health. The programme provides contributory funding to demonstration projects and supports the development and distribution of information about best practice innovations. Allied health professionals (speech pathology, occupational therapy, social work, psychology and others) are the primary target of the Australian best practice project. The funded projects are involved in developing models which should benefit the Australian "health care industry" [Commonwealth of Australia, Department of Health and Family Services 1996]. The focus is on obtaining nationally relevant best practice outcomes that can be readily generalised beyond individual sites and practice settings. This is

ensured by incorporating client-focused methods and a broad multi-disciplinary stakeholder framework.

The following definition is deployed within the Australian "Best Practice in the Health Care Sector Program" [Commonwealth of Australia, Department of Health and Family Services 1996]:

"Best Practice is a comprehensive, integrated and co-operative approach to the continuous improvement of all facets of an organisation's operations. It is the way leading edge organisations manage the delivery of world class standards of performance in all aspects of their operations. The concept of continuous improvement is integral to the achievement of international best practice."

'Quality' is a key concept in the Australian Best Practice in the Health Care Sector Programme, involving "a focus on internal processes and outputs" and including "the reduction of waste and the improvement of productivity."[1] Thus, there is a strong focus on the organisational concept of best practices in the Australian programme: "Total quality is about leadership and the deployment of clear organisational values in on-going pursuit of improved performance," and "conveying an organisation-wide commitment and priority from which no person nor function is excluded."

[1] In communication with Gerry van Wyk, Commonwealth Department of Health and Family Services, Australia, in reference to the Australian Quality Award Assessment Framework, Australian Quality Council.

4 CLASSIFICATION FRAMEWORK TO DEFINE BEST PRACTICE

The concept of 'best practice' in health is an emerging concept in health research and policy programmes, and there is no clearly defined and universally accepted definition that could serve as a baseline working definition for this project. This report will therefore provide a more comprehensive approach to the definition of 'best practice' for health policy in the Community which goes clearly beyond quality issues. This approach was developed because the definition for best practice provided in the literature would not provide a sufficient base to fully comply with the purpose of the project.

'Best practice' in health care will incorporate:

Working Definition of BEST PRACTICE in the health sector

The 'best way' to identify, collect, evaluate, disseminate, and implement information about as well as to monitor the outcomes of health sector interventions for patients/population groups and defined indications or conditions. Information would be required to reflect the best available evidence on: safety, efficacy, effectiveness, cost-effectiveness, appropriateness, social and ethical values and quality of the health sector interventions.

The process of finding a framework for the definition of 'best practice' in the health sector will therefore refer to the duly weighted use of all valid and relevant information for health interventions and monitoring of the outcomes of health sector interventions.

The framework will develop an oversight over the best ways of A. systematically identifying, collecting, and evaluating information (= input domain); B. disseminating and implementing reviewed information (= implementation domain); and C. monitoring the effects of health sector interventions (= outcome domain). The basic approach is to link research findings (input domain) more closely with policy (as part of implementation domain) and to allow for a monitoring process (outcome domain) of these stages (Figure 3).

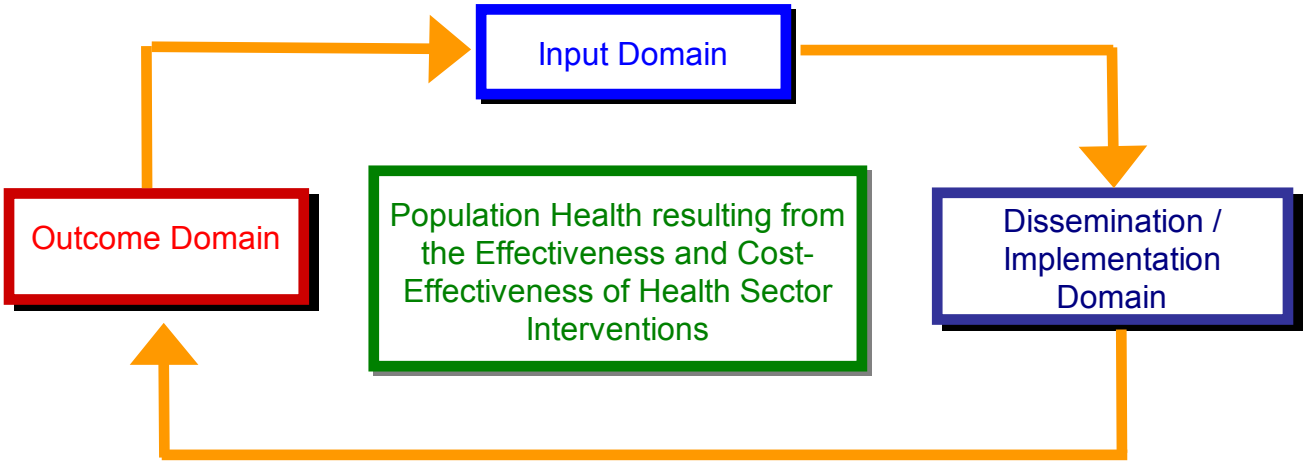

FIG. 3: Framework for defining best practice in the health sector. The input domain provides information on the potential effects of health sector interventions. The implementation domain consists of information on ways to disseminate and implement reviewed health sector interventions. The outcome domain allows for monitoring the implementation of health sector interventions and at the same time delivers information on the real effect of health sector interventions.

The prime objective is the improvement of population health resulting from effective and cost-effective health sector interventions. Thus, evaluation is a central function in all three domains for improving the health systems' performance. Evaluation is based on immediate *objectives* (e. g. improving the safety, efficacy, appropriateness etc. to tackle or to prevent health problems of individuals, groups of populations or whole populations) and, ultimately, all activities, disciplines, and methods in the three domains aim at the improvement of health (and/or the reduction or maintenance of resources) as an outcome resulting from health sector interventions.

A. Identification, collection and evaluation of information on health sector interventions

The identification, collection and evaluation of information on best practices of health sector interventions consists of the overriding notion that the health sector should contribute to health. Health care, public health activities and health policy, then, should be advised by the best available evidence. Evidence-Based Health Care is considered a concept that has already been developed on this basis (described in detail in chapter 4.1). This project is concerned with three related activities, namely Health Technology Assessment (HTA) which is predominately policy-

oriented, Clinical Practice Guidelines (CPGs) for population health and Evidence-Based Medicine (EBM) as an activity that focuses on the individual patient. EBHC is based on systematic information synthesis (systematic reviews) of existing information provided by primary studies (i.e. clinical trials) and studies which are in this project referred to as evaluation methods. Methods, in contrast to activities, provide also new information and are focused on either single or a number of aspects of health sector interventions or health care practice. Related Disciplines provide tools which are essential for the three activities (for example: economic evaluation of health care interventions has been developed within the discipline of Health Economics and constitutes one essential method in Health Technology Assessment). Results from health services research often form the basis for action by providing additional input information. It has to be noted, however, that a clear classification is not possible because many activities, disciplines and methods are overlapping.

For all research results that are obtained in one specific health care system or setting (e. g. National Health Service Setting versus Social Security Setting, private insurer versus public insurer, ambulatory care setting versus hospital care setting etc.), the framework will have to consider transferability of results (see chapter 4.5). The input domain of best practice in health care is illustrated in Figure 4.

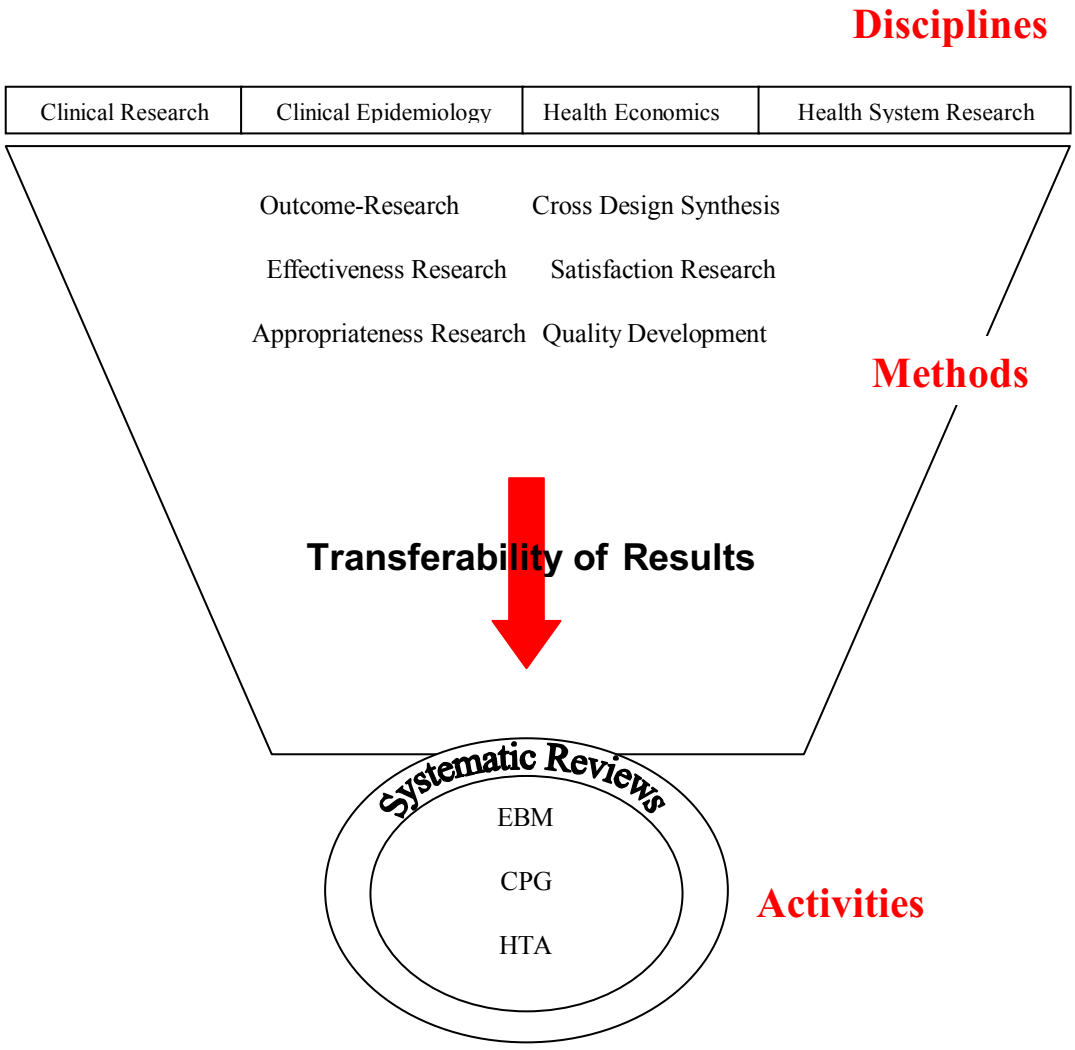

FIG. 4: Input domain for Best Practice, based on the concept of Evidence-Based Health care. Information that constitutes evidence is delivered through disciplines and methods. Within activities, evidence derived from different (and ideally all relevant) disciplines and methods, is systematically reviewed and concluded to recommendations on different levels of decision-making in health care (i.e. policy, clinical).

B. Dissemination and implementation of (evaluated) health sector interventions

The framework for defining what constitutes best practice in health care will also take into account that produced evidence has to be adopted by decision-makers. The framework will thus consider different methods to effectively translate evidence into practice, that is dissemination and implementation of evidence for practical use. This domain of the framework will also consider barriers to implement evidence. (Implementation tools to translate evidence into

practice will be summarised in chapter 4.7.2.) Figure 5 illustrates how this domain will constitute to the framework for defining best practice in health care.

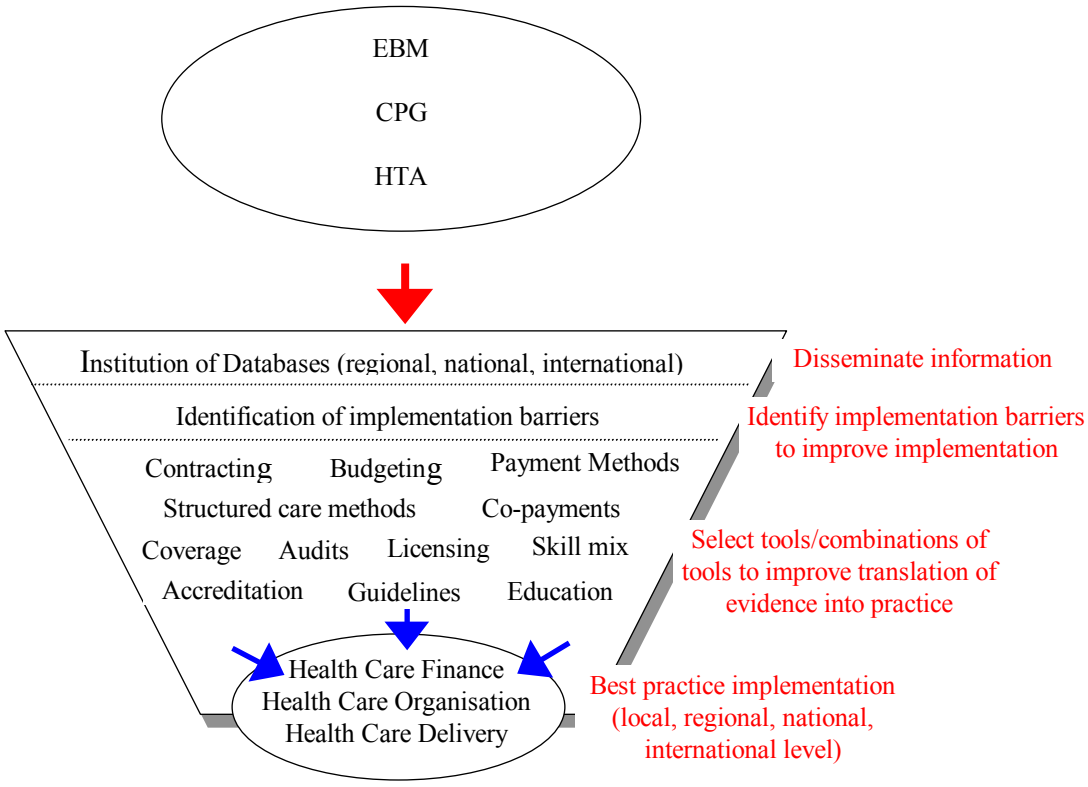

FIG. 5: Implementation do main for Best Practice. This domain p rovides information on the dissemination of evidence, for the identification of implementation barriers and for the implementation of evaluated health sector interventions.

C. Outcome domain of best practice

The outcome domain will consider methods to monitor health o utcomes of health sector interventions. This implies that indicators of performance at different levels of health care have to be identified which could serve as measures of success of the implementation of components considered to be 'best practice' (Figure 6). It follows from Figure 3 that t he outcome domain will also produce information for the input domain.

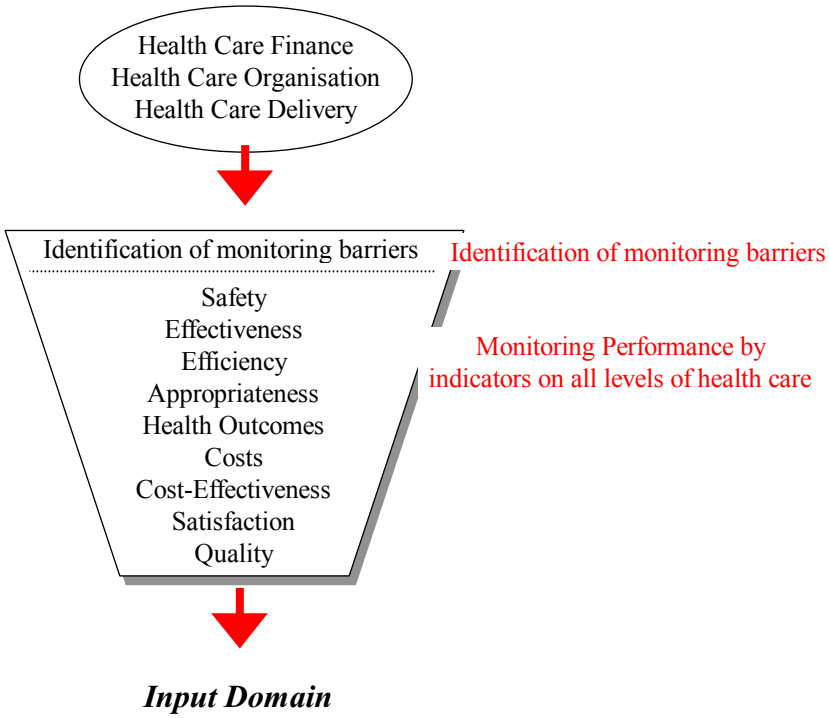

FIG. 6: Outcome domain for the best practice framework

In the following chapters we will:

1. Shortly summarise the different available ac tivities, disciplines and methods which are available to form a framework for best practice (excluding clinical research) and provide an overview and identify methods to transfer health information between different health care systems and between different health care settings.
2. Identify implementation barriers and tools available to implement best practices.
3. Identify barriers and describe methods to monitor best practices.

4.1 Best Practice framework: the case for Evidence-based Health Care (EBHC)

The best practice framework makes use of a number of different methods and disciplines with each of them being at best part of different strands of research (e. g. health economics). A concept that currently offers the most sophisticated approach of integrating these pieces of evidence in decision-making is Evidence-based Health Care (EBHC). The concept of EBHC is important because it systematically utilises 'best practice' information for the management of health problems that affect the pubic's health. EBHC is therefore described in more detail.

Definition, purpose and process: Evidence-Based Health Care is a comprehensive concept that is applicable to all levels of decision-making in health care, using the best available evidence in combination with other factors (i. e. values derived from historical, cultural and ideological influences, financial and organisational structures of the health care system including available resources etc.) in order to conclude to a decision about health services for whole populations or groups of patients [Gray 1997]. It is the most comprehensive concept for the identification of best practice currently available:

"Evidence-based health care takes place when (any) decisions that affect the care of patients and populations are taken with due weight accorded to all valid, relevant information" [Hicks 1998].

There are five key implications for the application of EBHC following from this definition:

1. 'Decisions that affect the care of patients' are taken by managers and health policy makers as well as by clinicians. EBHC is therefore just as relevant to managers and policy makers as it is to clinicians.
2. 'Due weight' implicitly acknowledges that there are many factors that contribute to decisions about the care of patients. There are many factors other than the results of randomised controlled trials that may weigh heavily in both clinical and policy decisions (for instance, patient preferences and resources). This definition requires that valid, relevant evidence should be considered alongside other relevant factors in the decision making process. It does not assume that any one sort of evidence should necessarily be the determining factor in a decision.
3. 'All' is aspirational - but it implies that there should be an active search for valid, relevant information.
4. 'Valid, relevant' implies that before information is used in a decision, an assessment should be made of the accuracy of the information and the applicability of the evidence to the decision in question; that is information should be appraised.
5. 'Information' is deliberately left unspecified; there are many types of information that may be valid and relevant in particular circumstances. There is no reason to exclude any particular

type of information as long as an appraisal is made of its validity and relevance and the information is given 'due weight' – neither more nor less.

While this definition predominantly focuses on patients, it can also be applied to the population level in areas such as for example health education and health information, screening, immunisation and other ways of disease prevention, as well as environmental and other ways of health protection. The above named principles remain in place for all decisions that affect the public's health. Figure 7 provides an overview over the scope of Evidence-Based Health Care and the prerequisite of production, availability and implementation of evidence.

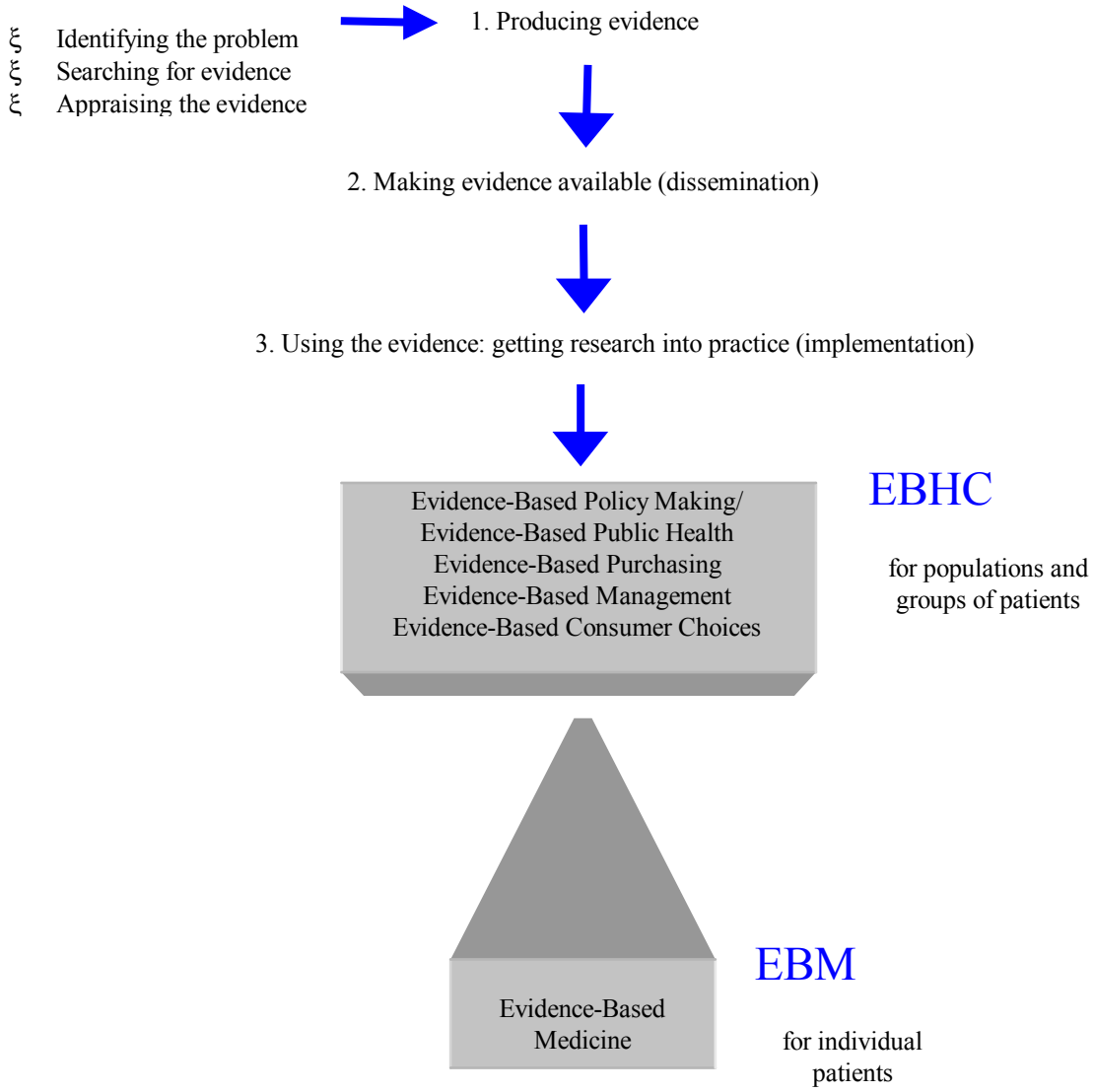

FIG. 7: The concept of Evidence-Based Health Care

EBHC involves health care relevant to populations, EBM defines decision-making for individual patients

Application: The concept is applicable to various policy areas where decisions can in theory be based on evidence such as for example insurance coverage, regulation, taxation, contracting,

payment systems, education, finance, resource allocation, provision of health services, and practice guidelines. Evidence-based policies have been proposed and supported in many areas, e. g. in prevention [Bradley & Sheldon 1997; Florin 1996].

A non-clinical area where the concept of EBHC has been proposed is Evidence-Based Purchasing, where purchasers, e. g. public and private insurers or other purchasing authorities such as fundholders, might enter a contract with a provider for service delivery on the basis of evidence on outcomes, costs and appropriateness of interventions [Maynard 1997]. As barriers to implement the concept it is argued, that the evidence produced is irrelevant to purchasers or that evidence is presented in a way tending to bias the purchasing decision [Gray 1997, Fahey et al. 1995]. Priority might rather lie on cost-effectiveness than effectiveness and there is possibly a lack of advocates for patients in both evidence-based policy-making and purchasing [Gray 1997]. Thus, the concept inevitably needs to take into account the preferences, expectations, and informed choices of clients (patients, insured, consumers) of health care. This corresponds to so-called 'Evidence-Based Consumer Choices'. The concept implies, that information about health and the alternative ways in which health can be protected, disease can be prevented, and health can be restored, is accessible to consumers in a way suitable to inform persons without a professional health background (see also chapter 4.7.3). A randomised controlled trial of the effect on information on prostate screening showed that interest in being screening decreased substantially with information about prostate cancer screening (i.e. the chance of getting prostate cancer and dying from prostrate cancer, prostate-specific antigen (PSA) screening detecting the cancer, how a positive test would be evaluated and the main options for management of prostate cancer) [Wolf 1997].

Details of implementation of the concept and barriers to implementation are specified in chapter 4.7.

Users: It follows, that the concept can assist decision-making for all persons concerned with health and health care on a collective, non-individual level (as opposed to EBM which more likely refers to an individual decision of patient and health professional): mainly health policy makers, managers, health professionals, consumer groups, and insurers.

Current issues in improving EBHC: A number of unsolved general problems has been addressed with the concept of EBHC, and the most frequent issues are summarised in the following:

1. It has repeatedly been criticised that the concept reduces the complexity of clinical problems and the complexity of policy decision making for health care [Carr-Hill 1998]. For health services delivery, Gray has consequently indicated that the practice of EBHC has to be supplemented with quality management measures to obtain the maximum health benefit at the lowest possible risk and cost from the resources available [Gray 1997]. The same could be proposed for other policy-decisions which inevitably are influenced e. g. by political,

cultural, ethical values. Thus, the concept has limitations and high-quality evidence alone will not necessarily lead to change of policy and clinical practice. The concept is not a guarantee that any potential benefits identified within a research setting will be achieved. This is not only because of particular motives for decision-making (such as ideology and ethics) but also because the real setting might differ from the research setting (see also chapter 4.5). It furthermore has to be respected, that evidence-based conclusions will strongly depend on the targeted audiences [Clancy & Kamerow 1996]. Evidence-Based Health Care is thus considered a model concept in this project which can only guide (rather than dictate) decisions on all levels of health care. EBHC does not resolve the difficult value judgements that are at the core of most policy decisions [Hicks 1997].

2. There is lack of evidence on the effect of health care organisational and financial settings on health outcomes (e. g. the health outcome of different provider payment systems, co-payments, financial budgeting, skill-mix and the volume of human and capital health care resources). This is in contrast to evidence on many clinical interventions. Within the concept, research methods would preferably focus on controlled trials, when possible. Primary studies would have to be synthesised (that is according to the concept: searching, assessing and synthesising the evidence). The logical consequence would be the establishment of an evidence-based policy database in the long run. This could be within a new setting or already existing databases. In addition, information on cost-effectiveness and cost-utility of all different interventions (including clinical) should increasingly be collected, preferably in the settings of prospective randomised controlled trials [Leidl 1997, OTA 1994].
3. Capacity to practice EBHC is required - whether at administrative, managerial or clinical policy level - to access, interpret and adapt the relevant evidence, this in essence requires practical skills to conduct a systematic literature review [Britton & McKee 1997]. For this purpose there is limited indication that postgraduate training in areas such as health economics and health management in the countries of the European Union are provided in a sufficient quantity, but it is also uniquely reported, that educational options have substantially increased over the past 10 years [Leonardo da Vinci Initiative, interim report 1998].

4.2 Best Practice activities

4.2.1 Health Technology Assessment (HTA)

Definition, purpose and process: Health Technology Assessment defines a multidisciplinary activity that systematically examines technical performance, safety, clinical efficacy and effectiveness, cost, cost-effectiveness, organisational impact, social consequences, legal and ethical aspects of the application of a health technology [EUR-ASSESS 1997]. The term roots in the political and social debates about environmental and social consequences of technologies in the 1960s and 1970s [OTA 1994]. Health technologies according to the former U.S. Office of Technology Assessment 'are the drugs, devices, procedures, and the organisational support systems within which health care is delivered' [U.S. Congress 1980]. Given this broad context, HTA is not defined by a set of methods, but by its intention [EUR-ASSESS 1997]. HTA is as a structured analysis activity that relies on primary studies, such as for example prospective randomised trials, systematic reviews, economic analysis, small area variation studies (into utilisation / practice) and technology diffusion studies. The purpose is to provide input into a policy decision, while taking different perspectives ideally in combination (e. g. clinical, social, economic etc.) [OTA 1994]. For this purpose, HTA can be technology-orientated (e. g. HTA on mammography screening), health problem-oriented (e. g. HTA strategies on breast cancer), or project-oriented (e. g. HTA of Europe against cancer).

The standard (ideal) HTA process comprises a set of processes [EUR-ASSESS 1997][1]:

1 The *identification* of technology, health or health care problems and possible assessments to address these;

2 The *priority setting* of possible assessments;

3 *Assessment*;

4 *Dissemination* of the findings and conclusions to assessments;

5 The *implementation* of findings and conclusions in policy and practice; and

6 *Impact assessment* of resulting change.

Primary studies are assessed and synthesised which is the core activity in HTA, precisely the method of systematic reviews [EUR-ASSESS 1997].

Application: Application/implementation of HTA falls into the following categories: Research & Development (R&D), regulation of pharmaceuticals and equipment (technology regulation), regulation of numbers and location of services (volume regulation), human resources planning,

[1] For a detailed explanation of all processes compare the results of the EUR-ASSESS Reports, published in the International Journal of Technology Assessment in Health Care 1997;13(2):133-340.

coverage of services, quality management, education and training of providers, information of consumers and the general public [EUR-ASSESS 1997; HTA Europe Report 1998].

TABLE 2: Application areas and users of HTA

	R & D	Regulation and licensing	Payment systems and resource allocation	Insurance coverage	Education & Training	Information
Policy-maker	x	x	x	x	x	
Administrators and Managers		x	x	x*	x	
Health Professionals			x**		x	x
Consumers			x***			x

* i.e. Managed Care
** e. g. self employed
*** e. g. the privately insured

Funding of HTA is a crucial issue. There has been a remarkable increase of private sector HTA activities and funding with the rise of Managed Care in the United States [OTA 1994, Power et al. 1994, Rettig 1997]. In most European countries, HTA often (still) follows public policy purposes and is mainly financed out of public funds. Public funding can be at the international level such as for example in the case of the above named EUR-ASSESS and HTA-Europe projects, at national level such as for example in most national health systems (e. g. the United Kingdom) or at regional level (e. g. Catalonia) or at local level.

Infrastructure and Training: HTA in Europe is organised and implemented somewhat differently in every country so that HTA might primarily be linked e. g. with coverage (e. g. the Netherlands and in German ambulatory care) or regulation (e. g. France) [HTA Europe Report 1998]. EU countries with a national health service deploy a national agency for HTA with the exception of Ireland. Countries which rely on social health insurance tend to implement HTA for licensing of pharmaceuticals and reimbursement purposes of the sickness funds and insurance companies (with the exception of France which employs a national agency for HTA). Major HTA activity is reported for Catalonia, Denmark, France, The Netherlands, Sweden and the United Kingdom. Developing activities can be observed in Belgium, Finland, Germany, Greece, Ireland, Luxembourg, Norway and Portugal [Banta and Perry 1997]. For a more detailed description of HTA activities in the European Union see chapter 5.2. International co-operation is promoted by the International Society of Technology Assessment in Health Care (ISTAHC), founded in 1985, and the International Network of Agencies for Health Technology Assessment (INAHTA), founded in the early 1990s. The DG X II project EUR-ASSESS (finished in 1997) and the DG V project HTA Europe (finished in 1998) have substantially

increased the basis for co-ordination and information transfer of HTA activities throughout the European Union and Switzerland (see EUR-ASSESS Reports 1995-1998 and HTA Europe Report 1998). A system for exchange of information is also developed under the auspices of INAHTA, with the secretariat currently located in Sweden.

Postgraduate programmes (leading to a Master diploma with a minimum of duration of 1 year, and excluding short-termed diploma or certified courses) are not explicitly focused on HTA, but rather directed at health economics, health services management, analytic methods, or public health [Leonardo da Vinci Initiative, Interim report 1998].

Current issues in improving HTA:

1. There is growing activity into HTA in the countries of the European Union, often, but not always, using common methods. Interest has increased in more co-ordination of activities on the international level. This has for example been preceded through formulation of consented quality criteria for the different HTA processes (and especially considering methodological standards for assessments, guiding best practice in the production of systematic reviews, guidelines on primary studies such as economic analysis and consenting basic principles to conduct, evaluate or use HTA studies (for more details see EUR-ASSESS 1997). The value in co-ordination of HTA in different countries is that methods and results can be compared to learn from each other, to avoid waste and duplication while gaining from the strength of diversity [EUR-ASSESS 1997]. In practice this has been realised through conferences and meetings to discuss subjects such as methods of assessment, priority setting, dissemination, and coverage decisions within the EUR-ASSESS project [EUR-ASSESS 1997]. For the future it was recommended to explore more efficient ways to share information (e. g. by exploring the potential of mass media including the internet), and a general conclusion is to increase activities at the national level and study the relationship between HTA and the health systems in the Member States. The HTA-Europe project has been a step forward towards this direction, covering HTA activities on illustrative examples in all countries of the European Union and Switzerland in the system context as well as discussing HTA methods and results in the international European context. This resulted in concrete activities at the European level that could be encouraged (i.e. “collecting, collating and disseminating information on priorities in health technology assessment, ensuring that the findings of HTA from across the world are readily available across the European Union, providing opportunities for developing, defining and sharing best practice in undertaking and reporting assessments, designing and organising a system for co-ordination and co-operation of HTA in Europe”). The most important conclusions of the HTA-Europe report were to utilise and strengthen the existing network under the principle of subsidiarity, with four independent needs to ensure effectiveness:

   - A board or steering body presenting all Member States, in addition to a smaller executive committee or board for continual oversight.

- An administrative centre to support all activities of the network.
- A mechanism to assure the optimal use of the relevant experience, expertise and commitment of different health programmes and individuals in Europe. In summary this would mean a system in which important and substantive functions are decentralised to different sites in Europe.
- Funding to cover the added activities inherent in European programme of work.

2. There is interest in utilisation of HTA results for the purpose of consumer information in general and the public's active role in HTA is increasingly being addressed [Heitman 1996, EUR-ASSESS 1997]. In this context, EUR-ASSESS has supported an exploration of the potential of mass media to promote information for consumers and patients. This is in tune with proposals elsewhere, for example in clinical medicine.
3. There is a number of studies published in different countries indicating that the actual impact of HTA in health policy decisions on a political level has been as yet limited [for example: see Davis & Howden–Chapman 1996, Van Den Heuvel et al. 1997]. In this context, it has been proposed to involve managers and policy makers in the development and focus of research and to increase responsibility for researchers for seeing their research translated into policy [Davis & Howden–Chapman 1996, Jacob and McGregor 1997]. It has also been proposed to increase activities into studies addressing the actual impact of HTA results into health policy making [Van Den Heuvel et al. 1997]. The HTA Europe project has concluded that 'health care policy and health technology assessment must interact with each other more than in the past' [HTA Europe Report 1998]. HTA results should, for example, be used to implement technologies more effectively [Van Den Heuvel et al. 1997].
4. There are still methodological issues that have to be addressed in the long run. For example, systematic reviews might be based on incomplete search of databases (e. g. only search within the MEDLINE database with predominately Anglo-Saxon literature), and unpublished evidence might often not be taken into account. Systematic reviews rely on the availability of information uptake. Language can be a barrier to utilisation of good quality studies. Heterogeneity of information might not be adjusted for, and criteria for exclusion or inclusion of studies are often not documented [Gray 1997].
5. It is recognised that interests in beneficial or detrimental application of technologies – whether in terms of health outcome, consumer satisfaction, or costs – depend on the indication for use. If technologies should be considered for individual indications, HTA will result in a high complexity in the health care decision-making process. Thus, implications of HTA for clinical decision making is as yet limited.

4.2.2 Clinical Practice Guidelines (CPGs)

Definition, purpose and process: Clinical guidelines aim at supporting clinical decisions of health care professionals (including providers) and patients/consumers on interventions for specific clinical conditions, discouraging inappropriate practices and improving co-ordination between different providers. Guidelines are "systematically developed statements to assist practitioner and patient decisions about appropriate health care for specific clinical circumstances" [Field and Lohr 1992]. Guidelines are usually based on 1. scientific evidence and 2. expert professional consensus for good medical care. The methods of developing CPGs rely increasingly on the tools endorsed by the EBM movement. For a thorough review of the commonalities of CGPs and EBM see Lohr et al. 1998.

Clinical practice guidelines are more likely to be evidence-based the more rigorous the review methods used are, and the higher the quality of primary research that is synthesised [Cook et al. 1997a]. Guidelines can serve as instruments to improve effectiveness in clinical medicine and as instruments for quality assurance, by being primarily designed to improve processes and outcomes of health interventions. Costs are less frequently considered to date, but there are more powers to develop guidelines which would also consider economic aspects of health care interventions and also powers to cost outcomes attributable to the guidelines implementation in practice alongside with health outcomes [Lohr 1994, Leidl 1997, Caspari 1998]. Most clinical practice guidelines recommend the use of certain technologies / procedures for certain indications, starting from a defined clinical condition or clinical symptoms (e. g. back pain). Guidelines developed in the countries of the European Union are usually not legally binding or sanctioned.

Two examples of guideline programmes are the Scottish Intercollegiate Guidelines Network (SIGN) [http://pc47.cee.hw.ac.uk/sign/home.htm] and the French Medical Reference Program (Références Médicales) at the Agence Nationale d'Accréditation et d'Evaluation en Santé (ANAES) (the French National Agency for accreditation and evaluation of health services).

The SIGN was formed in 1993 as a interdisciplinary network of clinicians and healthcare professionals. Its objective is to improve the effectiveness and cost-effectiveness of clinical care for patients in Scotland by developing, publishing and disseminating guidelines which identify and promote good clinical practice. Patients' views are represented on SIGN through the Scottish Association of Health Councils. SIGN selects guideline topics on the basis of the burden of disease, evidence of variation in practice and the potential to improve outcome. Over 40 guidelines have been published to date or are in development. SIGNs' criteria for the development and assessment of the methodological quality of guidelines are recognised as exemplary in the field.

Within the French medical reference programme, criteria are explicitly formulated to identify *inappropriate* indications for health services, in particular, diagnostic and therapeutic

interventions [Maisonneuve a nd Matillon 1997]. Medical references, however, define *inappropriate* care, and are therefore distinct from clinical guidelines for interventions [Maisonneuve et al. 1996].

Application: Guidelines are a pplied as clinical policies in the form of practical working documents on prevention, diagnosis, treatment and rehabilitation and through incorporation into continuous medical education programmes. Adaptation of national guidelines in local audits is a promising way of implementing the recommendations of guidelines currently practices in different countries [Gerlach et al. 1998].

Users: Guidelines are mainly used b y Clinicians/practitioners and – less frequently – b y patients. Due to the clinical focus utilisation by policy-makers or purchasers is still rare.

Infrastructure and Training: Models for guidelines development have been developed by several organisations e. g. the Scottish Intercollegiate Guidelines Network (SIGN), the Royal College of Physicians, United Kingdom, the Agency for Health Care Policy and Research and the Institute of Medicine, United States, the Canadian Medical Association, the National Guidelines Programme for General Practice of the Dutch College of General Practitioners and several others. Guidelines are produced by several types of institutions:

1 by scientific societies, common in most of the Member States;

2 by non-governmental organisations, such as Managed Care or private organisations;

3 by the pharmaceutical industry;

4 by national institutions (for example in France) and

5 by professional groups, such as quality circles (e. g. in Germany) or auditing bodies.

Irrespective from the site of the producing institution, guidelines can be developed on the national, regional or local/institutional l evel. In most of the EU Member States clinical guidelines have been produced b y the beginning of 1998, and most of them are provided on Internet for clinical practice use.

There are a number of established international guidelines databases[1]:

- Guidelines Database Project, United Kingdom: A database of critically appraised guidelines [http://www.ihs.ox.ac.uk/guidelines/]. The database is organised by the Public Health Resource Unit of the Institute of Health Sciences at Oxford in the United Kingdom.
- US Agency for Health Care Policy and Research (AHCPR): The AHCPR has launched a guidelines clearinghouse recently [http://www.guideline.gov/].

[1] This list is not intended to be complete, it just illustrates some recent developments.

- Agency for Quality in Medicine (AZQ), Germany provides a comprehensive list of international guidelines databases. [https://www.dgn.de/kammern_kven/AEZQ/].
- Guidelines Database of the Alberta Medical Association, Canada [http://www.amda.ab.ca/general/clinical-practice-guidelines/catalouge/index.html]
- Guidelines Catalogue of the Scottish Intercollegiate Guidelines Network (SIGN) [http://pc47.cee.hw.ac.uk/sign/home.htm].
- The New Zealand Guidelines Group [http://www.nzgg.org.nz/library.htm].
- US Centers for Disease Control (CDC) Prevention Guidelines Database [http://aepo-xdv-www. epo.cdc. gov/wonder/prevguid/prevguid.htm].
- ANAES [http://www.anaes.fr].

There are no university programmes exclusively offering training in guidelines development throughout the European Union. In the United Kingdom, there are two programmes leading to a Master in Quality Management in Health Care (M.Sc.) at the Nuffield Institute, University of Leeds, and the University of Nottingham. In Barcelona, Spain, the Catalan Agency for Health Technology Assessment, together with the Autonomous University of Barcelona, offers courses in guidelines development in two postgraduate master programmes (Health Care Services Research, Evaluation and Management; Health Policy and Evaluation). It is likely, that more training is provided within other Master of Science programmes in Public Health, Health Economics, Health Policy and Health Services Management.

Current issues in improving clinical practice guidelines:

1. Many practice guidelines are not evidence-based in which case guidelines are open to bias or cannot readily be assessed because of poor documentation quality [Grimshaw and Russel 1993, Helou et al. 1998]. Several steps for the developmental process of guidelines have been identified by different organisations [cf. U.S. Congress 1994]. These include:

   - Criteria for identification of guideline topics / priority setting: public health impact, cost of procedure, availability of evidence, variation in clinical practice, controversy, new versus established technologies.
   - Selection of guideline panels: number and qualification of panel members (homogeneous or heterogeneous panels).
   - Scope and perspectives of guidelines: safety, efficacy, effectiveness, cost-effectiveness, patient preferences, aspects of healthcare organisation; target audience.
   - Process used to extract the evidence from the scientific literature: extension of literature review, rating of the quality of the evidence, utilisation of "causal pathways", method of synthesising the evidence, coping with the limitations of available evidence (e. g. lack of RCTs, conflicting evidence, lack of data on cost and utilisation, incomplete or contradictory data on indications and appropriateness of procedures, no evidence at all).
   - Group processes used to consider evidence and produce agreement on recommendations: degree of formalisation of group processes (e. g. nominal group technique, Delphi procedure), impact of panel composition on decision-making and interpretation of study results, decision support systems.
   - Transparency and quality of documentation of the developmental process (report quality).
   - Linking of guideline recommendations to scientific evidence: degree of reliance on 'pure' scientific evidence on the one hand and expert opinion on the other hand; providing informational statements rather than prescriptive recommendations.

   While the developmental process reveal considerable differences between organisations and countries, criteria for the methodological quality (attributes of "good" guidelines) are widely accepted [Field and Lohr 1992]:

   - Validity / soundness: guidelines should lead to the outcomes they are projected for. This implies that guidelines must be based on best available evidence.
   - Reliability: given the same evidence and methods for guidelines development, another set of experts should produce the same results.

- Clinical applicability and specificity: guidelines should be as inclusive and as explicit of appropriately defined patient populations as evidence and expert judgement permit including appropriateness of indications.
- Clinical flexibility: guidelines should explicitly identify exceptions and how patient preferences should be dealt with.
- Comprehensiveness: guidelines should include all likely clinical alternatives or indications for the use of an intervention.
- Ease of use: guidelines should be concise, unambiguous and in an easy to use format.
- Scheduled review: a statement about when a guideline should be reviewed for revision should be given.
- Documentation: a meticulous description of methods and processes of the developmental process should be included.

In addition, guidelines should specify what has been proved and what remains uncertain [Woolf 1998]. This would enable to identify priority areas for further research. Guidelines have to be regularly updated.

2. The attempt to standardise care potentially ignores the heterogeneity of patients and the complexity of medical decisions. Guidelines might even be 'inappropriate for specific individuals' [Woolf 1998]. Guidelines are only one approach for quality improvement in health care that apply to the majority but not necessary to all patients seen in everyday practice. Guidelines should therefore be regarded as suitable to direct health care decisions to ensure population (or group of population) rather than individual health. Guidelines do allow for different individual decision. Guidelines can supplement but do not supplant individual decisions that have to take into account specific clinical circumstances and patient preferences. It thus needs to be stressed on all levels of implementation of guidelines, that guidelines are primarily invented to form recommendations.
3. Expert recommendations might be biased due to outdated assumptions, personal bias from clinical experience, training, self interest and 'fatigue from the guidelines development process' [Woolf 1998].
4. Clinical Practice Guidelines usually do not consider cost-effectiveness aspects. It has therefore been proposed to extend clinical practice guidelines for economic data, such as for example the German guideline on the treatment of gastric Helicobacter pylori infections [Leidl 1997]. It is noted repeatedly, that guidelines might drive costs upwards because they recommend effective treatment for symptoms or conditions that previously have been remained untreated [OTA 1994; Ham et al. 1995]. This may be especially true for elderly and disabled persons.

5. Guidelines might lead to medicolegal conflicts by setting an arbitrary standard of care that might be cited in court [Hyams et al. 1996].
6. The guideline developmental process, in spite of being widely accepted for the potential to improve the quality of care and diminish unexplained practice variations, is in different developmental stage in the countries of the European Union. There is evidence that local providers who will be responsible in implementing the guidelines should be involved in the guidelines development process in order to improve compliance by means of enhancing ownership of the guidelines [Liles et al. 1995]. Guidelines are designed to consider regional circumstances of health care finance, organisation and delivery.
7. To be effective in changing clinical practice towards optimal medical care, guidelines have to be coupled with effective implementation strategies that also consider barriers to implementation.
8. There are few approaches to systematically evaluate/monitor the effect of guidelines on the effectiveness of health services in clinical settings. There is a need to develop effective strategies in order to monitor the effect of clinical guidelines on professional and consumer behaviour, patient outcomes and costs.
9. It follows that in the process of defining a framework for best practice in health care, practice guidelines will have to be supplemented by activities that consider cost-effectiveness criteria (e. g. technology assessment activities). This in effect eventually might lead to establishing guidelines that incorporate cost aspects.

4.2.3 Evidence-Based Medicine (EBM)

Definition, purpose and process: The most widely quoted definition of EBM is: 'Evidence-based medicine is the conscientious, explicit and judicious use of current best evidence in making decisions about the care of individual patients' [Sackett et al. 1996]. EBM is an activity that promotes the utilisation of scientific evidence on the efficacy and effectiveness of interventions *in combination* with the clinical experience/expertise ('judgement') of health professions. The definition of EBM, however, also leaves space for the adjustment of care to the patients' choice because 'judgement' is not refined to the decision of the health profession. The authors of this definition provide five essential operational steps alongside the definition for EBM [Hicks 1997]:

1. The re-formulation of clinical problems as answerable questions.
2. The efficient search for the best evidence that addresses those questions.
3. The critical appraisal of that evidence.
4. The application of the results of that appraisal in clinical practice.

5. The evaluation of the ensuing clinical practice.

The activity is focused on synthesising and reviewing information on efficacy (effects of interventions under trial conditions) based on studies with a specified hierarchy of evidence. The level of evidence scale deployed by the U.S. Preventive Services Task Force is widely accepted (see Appendix A.4).

Other authors have classified the level of evidence slightly different (level I: Randomised Controlled Trials (RCTs) with low false-positive (Δ) and low false-negative (E) errors, level II: RCT with high Δ and high E errors, level III: non randomised concurrent cohort studies, level IV: non-randomised historical cohort studies, level V: case series) [Cook et al. 1992]. Level I is at the top of hierarchy according to the concept of strength of evidence because it attempts to minimise by design factors that could bias the results. Thus, the study design for RCTs is considered the optimum study design within the notion of EBM. The study design of the RCT involves randomisation into comparison groups, with one group forming the experimental group and one group being the control group. This, alongside with the meta-analyses of RCTs, is seen as the 'gold standard' (or best evidence) for the measurement of efficacy within the notion of EBM. RCTs produce a high standard of internal validity owing to the fact that inclusion and exclusion criteria are explicitly defined and the effects of one experimental intervention are compared with the effects of another intervention for randomly assigned subjects resulting in equal distribution of baseline and prognostic criteria. However, the RCT is confined by lower external validity in comparison to not randomised study designs because many subjects to which the intervention would subsequently be applied are excluded either by the study protocol or *de facto*. This limits the use of RCTs for policy-making: "The value of an RCT for public policy and planning purposes is directly related to the generalisability of results" [Shapiro 1998]. An effective way to challenge generalisability is by replication or the organisation of multiple trials. Non-randomised studies tend to be more open to selection and other forms of bias [Britton et al. 1997]. Evidence-based Medicine relies on primary studies and the synthesis of all available information on primary studies by means of systematic reviews of the literature (see chapter 4.4.1). These include meta-analyses and qualitative methods to systematically identify, select, evaluate, and present a relevant literature overview in order to answer a specific question.

Application: EBM is primarily applied in clinical decision-making for individual patients. Increasingly, EBM is viewed as an important information tool for decisions on all levels of health care (policy makers, purchasers, clinicians, consumers) [Lohr et al. 1998].

Users: The concept of EBM is to serve health professionals and their patients.

Training: One university programme leading to a Master in Evidence-Based Medicine (M.Sc.) is offered by the Health Economics Research Centre at the University of Oxford, United

Kingdom. Short courses in EBM are offered in a number of countries in the European Union [Leonardo da Vinci Initiative, Interim Report 1998].

Current issues in improving EBM:

1. Utilisation and feasibility of EBM as an instrument for clinical everyday decisions seem to be restricted to date when considering limited access to suitable databases apart from academic settings, lack of motivation or skills to interpret the evidence for a rational decision, and organisational problems in making use of the available evidence. Apart from those organisational issues, limitations within the concept have to be respected. For example, time constraints in an emergency case might always be an argument for decision-making under the circumstances of scientific uncertainty. There are also some so-called grey-zones of medical procedures for which evidence is conflicting (e. g. carotid endarterectomy on patients with asymptomatic high grade carotid artery stenosis [Jakubowski et al. 1998]) or not existing (e. g. radical prostatectomy for any prostate condition), in which case decisions will have to rely on health professional experience, judgement and the choice of the patients [Naylor 1995]. EBM can not and does not promise to solve every clinical problem occurring in clinical practice, but helps to identify obsolete and unnecessary medical practice [Raspe 1996]. However, many questions are still awaiting to be resolved (e. g. How can research results effectively been implemented in practice? How can the implementation of high quality standard research be monitored for the effect on health outcomes and cost outcomes? Who synthesises evidence to what cost?) [Raspe 1996].
2. Much emphasis is placed on the definition of a problem, identification, assessment and application of relevant literature within this activity. There is, however, a substantial lack of a target setting process. This can be seen as reflective of practices in clinical medicine: patient charts (as well as some public health programmes such as for example screening programmes) usually lack to specify a target prior to the documentation of a treatment plan. Ideally, a patient chart should incorporate the following stages:

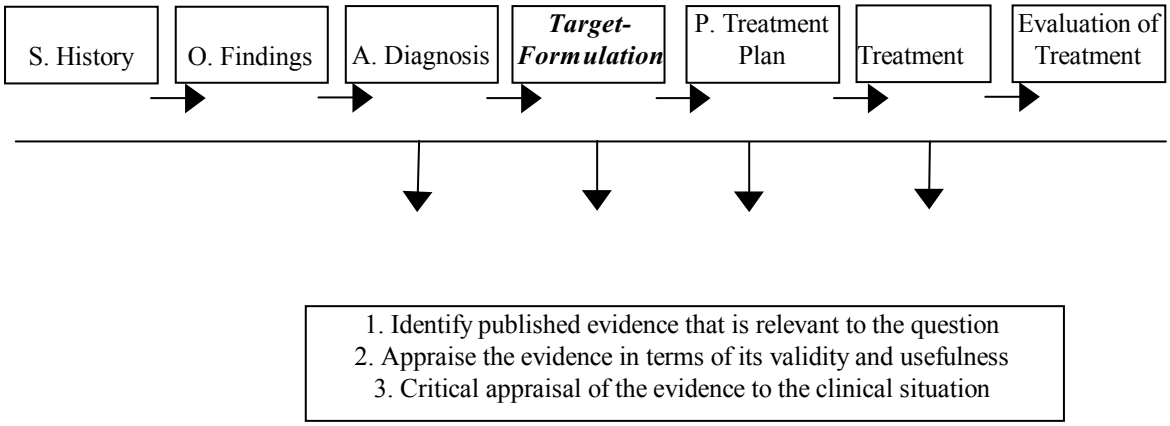

Fig. 8: Consecutive components of the patient chart. Components included in the SOAP-model (=S[ubjective], O[bjective], A[ssessment], P[lan]) are marked. A target is usually not documented in clinical routine.

As an integral part of EBM, a target setting process would in essence orientate the activity towards clinical outcomes and could assist to evaluate decisions based on evidence by the degree of target achievement. In tune with the call for evidence-based patient choices, the process would have to involve both patients and health professionals [Hope 1996].

3. The emphasis of EBM on RCTs – and thus efficacy of procedures – has been regarded as its major weakness [Davis & Howden-Chapman 1996]. EBM does not primarily address the difference between efficacy (effects of interventions under trial conditions) and effectiveness (effects of interventions under average conditions). Since studies on effectiveness often (necessarily) employ an uncontrolled design, they usually are assigned to a lower level of evidence in the EBM hierarchy. Quantitative epidemiological studies (non-randomised controlled trials, cohort studies and case-control studies) offer research methods, where RCTs are limited in principle or by procedure [Black 1996]. Limitations of RCTs might involve settings where experimentation is unnecessary, inappropriate (e. g. study group would be too small, outcomes of interest are far in future, randomisation would reduce the effectiveness of intervention) or impossible (e. g. due to ethical objections) [Black 1996]. On the other hand, EBM does not (yet) recognise methods to systematically adjust for differences between efficacy and effectiveness. A way for adjustment, for example, would be to utilise observational data (e. g. from administrative databases) [Roos et al. 1987; Hornberger & Wrone 1997] (for details see chapter 4.5).

EBM starts from a micro-perspective, that considers health care problems (e. g. variations of practice, standard quality deficiencies in health care) and health system problems (e. g. rising health care costs) as products resulting from many thousands of individual clinical decisions [Hicks 1997]. From this perspective, health care problems are regarded as symptoms of

imperfect clinical decisions rather than symptoms of imperfect health system design [Sackett et al. 1997]. EBM, by focusing on the individual decision irrespective of the regard to available resources, will cause a conflict between the individual and the population ethic [Maynard 1997]. There are a number of reasons why this approach to tackle health system problems would be incomplete. Decision-making is not only up to the most effective clinical choices but also dependent on resources, and "currently the allocation criterion is need, which is generally interpreted as equity weighted health gain per unit resource" [Maynard 1997]. This applies to the individual clinical decision as well as to population-based decisions in health care, such as for example for insurance coverage decisions. The latter furthermore rely on many factors other than health care. It has been shown for example that the remarkable mortality decrease in the present and past century has been mainly due to changes in living standards, nutrition and hygienic factors [McKeown 1979]. The variety, intensity, and availability of health services are often considered relatively unimportant in explaining differences in mortality between developed countries [Cochrane 1978, Culyer 1995] but these observations are usually based on cross-sectional studies while longitudinal studies produce larger effect estimates [Busse 1998].

Table 3: Summary overview of activities

	HTA	Clinical Practice Guidelines	EBM
Target Audience	Policy Maker	Clinician	Clinician
Target population	Population Health	(Group) Population Health	Individual Health
Data Sources	Clinical Trials, Population Health Information Systems, Vital Statistics, Disease Surveillance, Surveys	Clinical Trials (primarily)	Clinical Trials (primarily)
Methods	Systematic Reviews, Meta-analysis on Efficacy, Safety, community effectiveness, Costs, Ethics, Social Effects	Systematic Reviews and Consensus Methods	Systematic Reviews, Meta-analysis, Primary Studies on Efficacy
Tools	e. g. Cost-Effectiveness Studies	Consensus panels	e. g. Decision Analysis, Algorithm
Baseline Measure	Health Care Technology	Medical Condition	Medical Condition
(Prime) Implementation	Coverage, Regulation, Investment	Clinical Decision-Making	Clinical Decision-Making, Guidelines Development
Objective:			
Efficacy	+	+	+
Effectiveness	+	(not yet)	(not yet)
Appropriateness	(+)	+	+
Costs	+	(not yet)	-
Quality	(+)	-	-
Major contributing disciplines and methods	all EBM information plus Health Economics	All EBM information plus Appropriateness Research	Clinical Epidemiology, Effectiveness/outcomes Research, Decision Analysis
Complementary	Observations from administrative databases, appropriateness research, cross design synthesis	Cross design synthesis Health economics	cross design synthesis
Evaluation tools	?	Clinical Audits	Clinical Audits
Particular weaknesses	Limited assessment of social and ethical aspects of health technologies	Often lack of evidence base	Lack of target setting process, Lack of priority setting
Priority for strengthening support	Promotion of primary economic studies, HTA databases (EBHC databases with a focus on health system issues), promotion of international co-ordination as concluded by HTA-Europe report, promotion of HTA education	Institution of a European clearinghouse on evidence-based guidelines (not limited to english language)	EBM databases with a focus on information derived from European health care systems, EBM education for health professionals, Strengthen EBM expertise centres

4.3 Related disciplines[1]

4.3.1 Clinical Epidemiology (CE)

Definition and purpose: Clinical Epidemiology is "a basic science for clinical medicine" [Sackett et al. 1991]. It provides epidemiological and biostatistical tools for interpreting clinical signs and symptoms. It is a research field that enables the prediction of health events of individual patients by linking patient data and population data. Predictions are obtained from results of scientific studies (i. e. randomised and non-randomised trials, cohort studies, case-control studies), on population groups with similar attributes. The aim is to develop and apply scientific and biometric methods in clinical research and clinical practice in order to avoid systematic errors and findings by chance and therefore allow reliable conclusions. CE focuses on the appraisal of diagnostic tests, therapeutic interventions, preventive measures, and the identification of risk factors and relevant prognostic parameters.

Application: Clinical Epidemiology forms one scientific basis for clinical decision-making. In addition to clinical research, other research areas such as health services research rely in part on clinical epidemiology methods.

Users: Clinicians and Researchers.

Infrastructure and training: Clinical Epidemiology is instituted within clinical, usually academic, settings in countries of the European Union. A number of courses in clinical epidemiology are offered in the EU (e. g. in France, the Netherlands, in the United Kingdom.

Contribution to best practice activities: Clinical Epidemiology builds the methodological foundation of Evidence-Based Medicine and is a baseline information source for Evidence-Based Health Care.

4.3.2 Health Economics (HE)

Definition and purposes: Health Economics is a sub-discipline within the science of economics and most relevant in the context of HTA. It also serves as a fundamental research field in health sciences, dealing with the production of health and dynamics of health care markets [Getzen 1997]. Economic aspects of health and health care are evaluated throughout methods derived from general macro- and predominately microeconomic theory. The rationale behind health economics is how to make the best use of scarce resources. Health economics derives from basic economic ideas as well as from developments of its own [Leidl 1994].

[1] For the purpose of this report, disciplines are only provided as short summary overviews in regard to their contribution to best practice in health care.

It is a heterogeneous and applied discipline primarily designed to assist health policy decision-making (specific questions relevant to health policy might be, for example: Do certain methods or levels of payment for services will deter their use? Which preventive and curative services will be likely to have the largest health impact for a given monetary input?).

Health economics is interdisciplinary in the respect that it requires knowledge from many disciplines such as the clinical sciences and clinical epidemiology. There are two predominant domains of the discipline as a research field that cover economic aspects of health and health care systems:

a. Economics of health:

This area of health economics covers the production of health on the individual as well as the population level irrespective of the underlying health care system. It aims to explain the relation between monetary and non-monetary resources and the (resulting) health outcomes, it incorporates the measurement of health and changes in health (status) attributable to different types of interventions, for example clinical or political interventions.

b. Economics of health care systems:

This area covers structural, organisational and financial aspects of health care systems in a normative approach. Of interest are for example analyses of steering mechanisms of health systems, and in particular analyses of health system outcomes with respect to allocative and technical efficiency and with respect to distributional justice. This area also conceives the contribution of the health care sector to overall economic growth and stability.

Health economics is applied through basic economic methods (A, B, C), however, a number of individual methods have been developed by health economists (D), mostly in the context of socio-economic evaluation:

A. Microeconomics: Covers the analysis of the production of health and demand for health and health care, and economic behaviour of stakeholders in the health care system (consumers, insured, patients, insurers, providers, policy makers).

B. Public Finance: Analysis of revenues and expenditures, structure and regulation of health service provision, public goods and externalities, collective decision-making, economic analysis of non-market goods.

C. Business Administration: Planning, financing, marketing and controlling in health care institutions.

D. Explicit methods in health economics: Valuation of human life, index instruments to measure quality of life, utility scores (QALYs, DALYs, HYEs, see below for explanation) for the valuation across interventions.

The most important tool for health economists is economic evaluation. *"Economic evaluation is the comparative analysis of alternative courses of action in terms of both their costs and their consequences"* [Drummond et al. 1987]. The emphasis in this definition is on two elements: the need of a comparison between at least two alternatives and the need to consider both costs and outcomes of such alternatives. The most common types of economic evaluation are [Drummond et al. 1997, CCOHTA 1997]:

1. **C**ost-**M**inimisation-**A**nalysis (CMA): assumes equal outcomes or effectiveness from alternative interventions and compares the direct costs attached to each intervention.
2. **C**ost-**E**ffectiveness **A**nalysis (CEA): includes a comparison of costs and outcomes. The outcomes of alternatives are measured e. g. in units of life years saved, cases successfully treated or cases averted. The outcomes are then related to the direct and indirect costs of the procedure by calculating cost-effectiveness ratios, or cost per unit of effectiveness, such as cost per life year gained. Cost-effectiveness analysis is a useful source of information for choices between alternatives within therapeutic categories but not for choices across categories.
3. **C**ost-**U**tility **A**nalysis (CUA): is similar to CEA in many respects but the difference is in the measure of outcomes. Cost-utility combines mortality and morbidity data into a single measure. The QALY (**Q**uality **A**djusted **L**ife **Y**ear), the most commonly used measure in countries of the European Union, is a (subjective) measure of the quantity of life gained by treatment, weighted, or adjusted, by increases in the quality of life.
4. **C**ost-**B**enefit **A**nalysis (CBA): determines the absolute benefit of a programme. All benefits must be valued in the same units as the costs of interventions, usually in monetary terms. The monetary valuation in health care, in particular of a life, is problematic and sometimes a full monetary valuation of the intangible benefits of a treatment is not included.

Application and use: Prime users so far are decision-makers in health policy, on the different executive levels (international, national, state, local). Economic evaluation has become most relevant in the context of HTA and increasingly in regard to the use for clinical practice guidelines [OTA 1994, Johannesson 1995, Russell et al. 1996; WHO 1996]. In this context, economic evaluation is rather concerned with population than individual health, suggesting limited scope for the clinical decision-maker on the individual level [Leidl 1997].

Infrastructure and training: The UK economic evaluation database (NEED) compiled by the CRD or the economic evaluation database of the University of Lyon in France are recent examples of important databases in this field.

University training has somewhat increased substantially during the past 5 years in all countries of the European Union [Leonardo da Vinci Initiative, Interim Report 1998], both as formal university postgraduate training programmes leading to a Master of Science or Doctorate (PhD)

programme in Health Economics (HE) and, even more pronounced, Master programmes in business and administration for health services (or health services management).

Contribution to best practice activities: Health economics is an integral component of the concept of Evidence-Based Health Care. Economic analysis provides substantial information for HTA and potentially for clinical practice guidelines, but methods have to be further developed [WHO 1996] (see below).

Current issues in improving methods and impact of health economics:

1. Health care system financing and organisational factors are determinants of the health care production function. An effect on health is empirically proven [John 1997]. However, research on the ways in which organisational and financial factors effect health is as yet underdeveloped (when compared to the quantity of research devoted to clinical interventions) [Maynard 1997]. For example, a systematic review on the evidence base for hospital volume in combination with health care outcomes, costs and patient access has shown that there is no evidence that cost savings are produced by increasing the scale of acute care hospitals beyond 200 beds and that there is no *general* relationship between volume and quality. Moreover, there is evidence that patient utilisation of hospital services is effected when services are geographically concentrated [NHS Centre for Review and Dissemination 1996; Maynard 1997].
2. Economic evaluation is expanding towards an integrated methodology in health sciences but is still not routinely used in many areas of health care decision making. Sloan noted, "even though that there is some agreement about fundamentals of cost-effectiveness/cost-benefit analysis, there is much disagreement about specific details" [Sloan 1995]. Improvement has been suggested by standardisation of the evaluation procedure (see below), a priority setting process for economic evaluation, improvement of the quality and quantity of economic evidence by prospective and retrospective controlled study designs, consecutive adjustment of results obtained under trial conditions to daily routine practice, and inclusion of economic evidence into policy and clinical databases [Rittenhouse 1996; Rovira 1996; Johannson 1995; Drummond and Stoddard 1995; Drummond and Davies 1991].
3. There still no consensus on the state-of-art type of economic analysis. Cost-utility analysis, for example, facilitates comparisons across health care and systems by incorporating comparable utility scores from interventions on one hand. This technique on the other hand has been questioned. QALYs are said not to be methodologically sound and may give an impression that they are based on consumer preferences [Mehrez & Gafni 1989]. Health year equivalents (HYEs) might not suffer from this defect, but have other limitations [Culyer & Wagstaff 1992]. For a number of interventions, cost-effectiveness analysis might be considered the appropriate technique. Because the additional effort at the margin is relatively small, it has been suggested to form a hierarchy of consecutive techniques, with Cost-Effectiveness Analysis (CEA) and Cost-Utility Analysis (CUA) at the top to obtain

objective information on the cost-effectiveness of intervention and secondly to make this intervention comparable to each other [CCOHTA 1997].

4. Economic evaluation studies are inconsistent in regard to the health effects and costs included and in the way these are valued and combined [Udvarhelyi et al. 1992]. This can lead to the same interventions producing different cost-effectiveness ratios [Russell et al. 1996]. Outside Europe, standardisation of methods of economic evaluation has been of interest in Canada and Australia [Rovira 1996]. In Canada, standards for economic evaluation of pharmaceuticals recently underwent update in 1997 [Canadian Coordinating Office for Health Technology Assessment 1997]. In Europe the issue of standardisation of economic studies has been addressed by a number of initiatives to formulate standards for economic evaluation including a European Community project on the Methodology of Economic Appraisal of Health Technology, a concerted action within the COMAC-HSR from 1985 to 1991, and a WHO consulting meeting on Standardisation of Economic Evaluation Methodologies held in 1990 in Barcelona [Rovira 1994]. A set of standard guidelines is imposed on the market approval process of pharmaceuticals in the United Kingdom [UK Department of Health 1994]. The standardisation in economic evaluation is being promoted within the BIOMED programme in the " European Network on Methodology and Application of Economic Evaluation Techniques" (EUROMET). The experts from the different countries aim to reach a consensus on the standard for economic evaluation. Most dominant advantages in standardising the methodology in economic evaluation would be comparability of results, a potential decrease of bias, improved transparency of information for the reader, increased quality of the studies and increased scope for an integration into the policy-making process [Russell et al. 1996, Coyle & Davies 1993]. However, there are also a number of critical issues being raised, including doubts that a guideline for economic evaluations would have any impact as long as "they are not related to systematic regulatory procedures [for Health technologies] either at the national or at the EU level" [Rovira 1996]. Economic submissions to be published in the BMJ have to comply to the set of normative standards issued in 1996 to meet a certain quality standard for publication [Drummond & Jefferson 1996].

5. The concept of so-called cost-effectiveness (or cost-utility) league tables was introduced in 1985 [Williams 1985]. League tables are rankings between interventions according to their relative cost-effectiveness (expressed either as cost per life-year or cost per quality-adjusted life year gained) [Drummond et al. 1993]. In the meantime, cost-effectiveness tables have been cautiously considered for the allocation of public resources in the State of Oregon, and in the United Kingdom [Hadorn 1991; Eddy 1991; Drummond et al. 1993]. However, a number of problems have been raised in the context of the league tables. These include methodological issues such as heterogeneity of source studies or disagreement with utility measures, concerns over the applicability of the tables to particular local circumstances and

ethical concerns [Drummond et al. 1993, Gerard & Mooney 1992; Drummond 1989; Birch & Gafni 1992]. It has therefore been suggested that in order to increase the potential of cost-effectiveness league tables for the assistance of policy makers, decision makers should be able to assess the relevance and reliability of the evidence in their own setting [Drummond et al. 1993].

6. There is a lack of primary prospective economic studies and interest in closer integration of economic with clinical research, which also raises a number of methodological issues [Drummond & Davies 1991]. The feasibility of a prospective economic evaluation within a randomised multi-centre setting has been proven for example alongside a clinical phase II trial with severe congestive heart failure [Schulman et al. 1996]. Yet, because cost results derived from an efficacy trial may not be applicable outside the trial, all cost-efficacy data have to be transferred to cost-effectiveness data for example by a consecutive economic study in the community. Another problem is that the focus of those studies will be more on clinical outcome rather than on economic outcomes.

7. In general, the quantity and quality of economic evaluations of health care interventions performed is seen as being inadequate [Maynard & Godfrey 1994]. Economic evaluation can potentially identify the most cost-effective interventions and inform policy choices. Information on the costs and consequences of alternative interventions are also required for rationing and allocation of resources [Maynard & Bloor 1995].

4.4 Related methods

4.4.1 Systematic Reviews

Definition and purpose: "Systematic reviews are scientific investigations in themselves, with pre-planned methods and an assembly of original studies as their 'subjects'." [Cook et al. 1997]. Systematic reviews qualitatively or quantitatively synthesise the results of multiple primary investigations by using strategies that limit bias and random error. These strategies include a comprehensive search of all potentially relevant articles and the use of explicit, reproducible criteria in the selection of articles for review. They differ from so-called narrative reviews in that they start with a clearly formulated question or a set of focused questions and are conducted and reported in a way that the results may be replicated by other investigators. When the results of primary studies are summarised but not statistically combined, the review may be called a qualitative systematic review. A quantitative systematic review, or meta-analysis, is a systematic review that uses statistical methods to combine the results of two or more studies.

Table 4: Differences between narrative and systematic reviews [adapted from Cook et al. 1997]

Feature	Narrative Review	Systematic Review
Question	Often broad in scope	Focused clinical question
Sources and literature search	Not usually specified, potential publication bias	Comprehensive sources and explicit search strategy
Selection of studies	Not usually specified, potentially biased	Criterion-based selection, uniformly applied
Appraisal of studies	Variable	Rigorous criterion-based critical appraisal
Synthesis	Often a qualitative summary	Often quantitative summary
Inferences	Sometimes evidence-based	Usually evidence-based according to level of evidence
Updating	No	Yes

A common method of conducting systematic reviews is a stepwise approach: identifying the need for a review; background research and specification of research questions; determining inclusion and exclusion criteria for studies and the method of data synthesis (qualitative or quantitative); literature search (electronic databases, scanning reference lists, handsearching of grey literature, conference proceedings and health technology assessment reports, consultation with leading experts); assessment of retrieved studies (relevance, validity); extraction and synthesis of the study data; writing and peer review of the report; revision of the report and dissemination of the results [Cook et al. 1997].

User: Clinicians, policy decision-makers, medical managers, consumers

Contribution to best practice activities: Systematic reviews currently represent the "gold standard" of synthesising scientific evidence in the absence of decisive mega-trials (large randomised controlled trials, RCTs) or in case of conflicting evidence from different studies. Ideally, they summarise the results of RCTs. Thus, when conducted properly, systematic reviews may be trustworthy concerning known evidence of health interventions and could thus serve decision-making at all levels of health care.

Current issues in improving systematic reviews: Systematic reviews, even if they employ meta-analysis are subject to bias which can result in misleading results and recommendations. The main source of bias in meta-analysis is selective use of publications. This may be due to selective publication of research results, with positive results are more likely to be published than negative results (publication bias). Many other sources of bias have been described [cf. Egger and Smith 1995, Egger et al. 1997, Jadad 1998] The Cochrane Collaboration has set standards for conducting systematic reviews including meta-analysis that have reduced sources of bias in systematic reviews (presumably these standards are not yet been applied very often outside the Cochrane Collaboration).

4.4.2 Appropriateness and Necessity Research based on consensus methods

Definition and purpose: Consensus methods are based on (usually expert) panel scientific conventions designed to establish recommendations on health care practice within a professional community. Consensus methods utilise the process of group interaction to derive at a collective opinion. A number of consensus methods has been developed from social science from the late 1940s onwards (Delphi Method, Nominal Group Technique, NIH Consensus Method, Glaser's state-of-the-art Approach) [see Fink et. al. 1984 and, more recently, Murphy et al. 1998]. Appropriateness research is in most cases based on a modified Delphi Method (also called the RAND Appropriateness Method) and has been developed for the purpose of health services research, aiming at the improvement of quality care by measuring overuse and underuse of procedures [e. g. Bernstein et al. 1993; Kahan et al. 1996; Kravitz et al. 1995] and developing clinical practice guidelines [Herrin et al. 1997].

Appropriateness in the context of this research is defined as the 'consistency and reliability in delivery of cost-effective care whose benefits outweigh its risks, which is faithful to the values of the society where the care takes place and as responsive as possible to the individual needs and values of the care recipients' [Kahan 1997]. In regard to the rating procedure[1], appropriateness is usually specified such as: 'Expected health benefit (quality of life and/or longevity) exceeding the expected negative consequences' by 'a large enough margin to justify

[1] The RAND appropriate rating procedure is standardised in regard to the *succession* of procedural steps, but realisation might differ (e.g. in regard to the panel composition).

performing the procedure rather than other alternatives' [Kahan et al. 1996; Herrin et al. 1997]. The actual rating procedure on appropriateness differs between researchers, but they follow a common approach [Phelps 1993]. The procedure usually is in four stages:

1. A medical intervention is chosen and a set of clinical indications is identified in a systematic literature synthesis. The information is summed up as a type of systematic review to serve the panelists as information.
2. A panel of experts (9-12) is convened to rank each of the indications on a score of appropriateness between 1 (certainly inappropriate), and 9 (certainly appropriate), with a score of 4-6 being equivocal. The original rating is performed by each panelist of her own. Panelists are selected according to degree of recognised expertise, community influence (e. g. affiliation to professional organisations) and geographic location. By some researchers ratings are discussed in a group which is followed by a re-rating procedure to allow for an appraisal of the original rating decision and possibly modification [Mc Donnell et al. 1996].
3. A group of investigators (usually nurses) abstracts records of patients (on average 1,000 to 1,300 cases per procedure) which have received the diagnostic or treatment intervention. Stratification of hospitals is by geographic location and / or volume of performed procedures.
4. The researcher matches the records to the closest possible indication and assigns the appropriateness score associated with that indication.

Ratings have been performed for example on gastrointestinal endoscopy, abdominal aortic surgery, cholecystectomy, coronary artery bypass graft surgery, coronary angiography, PTCA, cholecystectomy, cataract surgery, spinal manipulation, diagnostic radiological imaging, and carotid endarterectomy [Herrin et al. 1997; Kahan et al. 1996; Kahn et al. 1992; Coulter et al. 1995; Leape et al. 1992]. The appropriateness rating procedure has been extended for rating medical necessity of interventions (in this context equal to the "crucial importance" of those procedures) [Kahan et al. 1994]. The rating on necessity depends on the definition of a procedure as "the only possible means of providing substantial benefit for the patient" [Kahan 1997]. Necessity is rated only on indications which have been rated appropriate and are consecutively rated according to three specific criteria which all have to be met [Kahan 1994]:

1. It would be improper care not to recommend this service.
2. There is a reasonable chance that the procedure will benefit the patient.
3. The benefit to the patient is not small.

The consensus process for necessity ratings has to be further promoted and the method in general has to be further validated, but it is suggested that necessity ratings together with

appropriateness ratings can address not only overuse but also underuse of services [Kahan 1994].

Appropriateness research is designed to fill the gap between results obtained by empirical data under the optimal conditions of randomised controlled studies and the daily conditions under which decisions are made in community practice.

Users: The method has been originally designed to assist policy-makers in decision-making.

Application: The research method has mainly been proposed in the context of quality management of health services (for example increasing public information on the quality of care, issues of accreditation and licensing, of informing patient choices, developing clinical practice guidelines) and in the context of health professional education [Brook & Kamberg 1993; Kahan et al. 1994]. The approach is not applicable to the individual patient level but rather on a population (or group population) level.

Contribution to best practice activities: The approach has underlined the belief that some portions of medical care can be eliminated when actually improving the quality and effectiveness of care provided [OTA 1994].

In this context, the approach is aiming to assist quality improvement, by adjusting theoretical (ideal) constellations to real settings. In this context, for example, co-morbidity factors and factors such as age and ethnic background have underlined the importance to adjust for these factors for decisions in real settings [Kahn 1988]. The approach is increasing information on the difference between decision-making across specialities [Herrin et al. 1997]. Appropriateness research results thus should be incorporated into HTA and EBM databases. Policy impact in the respect that the approach would deliver actual operational tools for the definition of best practice at this developmental stage are limited, but interest of the private sector has been noticed in the United States in regard to a potential use of the method for the development of clinical guidelines. On the European level, the approach should be considered for promoting research into preventive measures and measures of health protection.

Current issues in improving appropriateness research: Most of the issues have been raised in regard to the methodology. From RAND researchers it is stated that the „appropriateness method is far from perfect“, in particular, it has been issued that „appropriateness criteria may be useful in comparing levels of appropriate procedures among populations but should not by themselves be used to direct care for individual patients“ [Shekelle et al. 1998]. Some concern is issued on validity and reliability of consensus ratings because this method is vulnerable to the subjective opinion of forceful members in the panel [Phelps 1993]. The influence of the composition of the expert panels on the reproducibility of results have been called to attention recently [Shekelle et al. 1998; Ayanian et al. 1998]. Another problem is limited assessment (evaluation) of this approach due to only a small group of researchers that apply the method, and it is hardly transparent to differ between recommendations based on evidence and those

based on consensus [Phelps 1993]. OTA has warned that the proportion of procedures rated inappropriate or equivocal up to one forth of procedures and up to half of prescribed medications might be overstated due to biased selection of technologies because inappropriate use was suspected [OTA 1994]. The process (activity) rather than outcome-related focus implies that the method will have to be combined with ways to examine health care outcomes [Casparie 1996]. Other limitations are that only factors systematically included in the clinical investigation are considered, often leaving unusual conditions and patient preferences aside.

4.4.3 Outcomes Research

Definition and purpose: Outcomes research is a field without a homogeneous definition, a field that has expanded dramatically in the past years through interdisciplinary efforts involving health service researchers, epidemiologists, health economists, sociologists, statisticians and ethicists [Epstein & Sherwood 1996]. However, the term outcomes research has been described as "problematic" leading to confusing by the Office of Technology Assessment of the US Congress [OTA 1994]. OTA argued within a difficult demarcation to effectiveness research (which is described as its successor term) and more important to "outcomes based management", which is not to be taken as a research field [OTA 1994]. This confusion is preserved by a call to integrate "outcomes research" with "disease management" [Epstein & Sherwood 1996]. As an earlier respond to the – apparently ongoing - terminology confusion, OTA has chosen not to use the term in their last comprehensive methodological and application guide for "Identifying Health Technologies that work" [OTA 1994].

Among other researchers there are different lines of possible definitions for outcomes research. Goodman (1997), for example, defines outcomes research as a research that encompasses the assessment of the effects of medical care structures and processes on patient outcomes under average conditions. In this respect, outcome measures can be 1. population-based, 2. group-population-based, and 3. based on an individual patient and can be divided into: 1. health outcomes (for example morbidity, mortality, life expectancy, functional measures, health related quality of life etc.), 2. consumer/patient and professional satisfaction and 3. costs [Goodman 1998]. Considering Donabedian's classical triad of structure, process and outcomes, outcomes research is also closely related to the concept of quality in health care [Donabedian 1966]. Quality in the Donabedian understanding again is more of an operational rather than of a research approach to health services sciences. Outcome research may entail in any range of primary data collection methods and synthesis methods that combine data from primary studies, in particular controlled trials that use patient-centred measures, database studies, decision analyses, cost-effectiveness analyses, and meta-analyses [Goodman 1998].

When health outcomes are defined as "a change of health status attributable to some antecedent", outcome research will focus on the quantity and quality of the health status

response to a change in the antecedent of interest that can be a health care intervention, health care system structure or an antecedent beyond the health care sector [Bond and McColl 1997].

A third line of definition is the focus of outcomes research on methods for establishing reliable and valid methods to measure outcomes which are then deployed in other research, i.e. effectiveness research. In any case, outcomes research is - depending on the definition - closely related and clearly overlapping with both the concepts of quality and effectiveness in health care.

Infrastructure: The European Clearing Houses on Health Outcomes (ECHHO) have been established as a concerted action funded by the European Union between 1994 and 1997. The Clearing House maintains a database that is accessible via the ECHHO world wide web (http://www.leeds.ac.uk/nuffield/infoservices/UKCH/home.html) and provides a network for information on the application of outcome measures and measurement in clinical practice.

Application: Results of outcome research can inform management and policy makers for the sake of promoting change towards a better outcome. Application can be in the form of clinical practice guidelines, HTA, EBM, critical pathways, payment policies, outcomes/disease management, physician profiling, and is most often referred to in the context of quality management and quality improvement. In most of those policies, outcome-orientation will imply to specify a target (an hypothetic example: outcome-oriented reimbursement for an influenza immunisation policy would need a specified number of people to be vaccinated).

Contribution to best practice activities: The methodological aspect of outcomes research is a central component of any best practice activity, both for synthesis of information and for evaluation.

Current issues in improving outcomes research: Outcomes are not necessarily related to the process of care and there is limited evidence that health care interventions affect those outcomes that are actually measured. In other words, a conclusion from a result obtained from outcomes research can only be drawn when other factors than health care with (potential) impact on the outcome are considered [Hammermeister et al. 1995; McGlynn 1997; Armenian & Shapiro 1998]. It appears that under controlled trial conditions this could be more easily done in comparison to the uncontrolled conditions in everyday practice. Related to the problem of "attributability" is the observation that outcome measures such as quality of life or morbidity are not exclusively confined to health care but also relate to other social policy sectors and thus do not necessarily result in implications for a change in health service provision [Mant and Hick 1996]. As it has been suggested that for the close association with effectiveness research alongside with its facilitation in many disparate activities, definitions of the phrase are inhomogeneous to the extent that the authors of this report support the recommendation that the term should be entirely integrated into the field of effectiveness research [OTA 1994].

4.4.4 Effectiveness Research

Definition and purpose: Effectiveness research has two approaches with one representing a macrolevel perspective considering population health and one a microlevel clinical perspective considering individual health (see figure 8 for perspectives of individual health and population health) [Aday et al. 1998]. Within both perspectives, effectiveness research is confined to the development and refinement of methods to support the identification of effective care [OTA 1994]. Effectiveness research has been strongly promoted by the United States Agency for Health Care Policy and Research (AHCPR).

Effectiveness research is based on different methods. One way of exploring the effectiveness of interventions are the so-called Patient Outcome Research Teams (PORTs), funded by AHCPR in their Medical Treatment and Effectiveness Programme (MEDTEP). PORTs are interdisciplinary research teams who seek to identify and analyse the outcomes and costs of alternative interventions for a given clinical condition, in order to determine the most effective and cost-effective means to prevent, diagnose, treat, or manage it and develop and test methods for reducing inappropriate or unnecessary variations. Methods that have been used are divided into basic tools, primary studies and secondary techniques [OTA 1994]:

1. Basic Tools

   Measuring health outcomes: e. g. death, utility indices by Karnofsky and various Activities of Daily Living scales, functional measures, generic self reported measures: Health related Quality of Life measuring the combination of functional ability, perceived health, psychological well-being, role functioning. Limitations: Growing recognition that these measure can be valid and reliable, but sensitivity is still low. Another problem is that measuring increases administration and costs of research.

2. Primary Studies:

   A. Observational studies (case-control and cohort studies)

   B. Experimental studies (RCTs)

   C. Database studies:

      Descriptive use of administrative databases

      Comparative use of administrative databases

3. Secondary techniques to synthesise trials

   A. Meta-analysis and other systematic reviews

   B. Decision-Analysis

There are many situations in which randomised clinical trials (RCTs) are not feasible and large-scale observational studies are necessary to generate information about what happens in the real

world (as opposed to the 'controlled' conditions in a clinical study). This information deepens the understanding of effectiveness as opposed to theoretical efficacy since trials do not always measure all the outcomes of interest to patients and physicians. One way to solve the problem of inaccurate data of observational studies is by establishing a specific registry to measure in an efficient way key patient characteristics, process of care elements and relevant outcomes.

Between 1989 and 1995, 14 PORTs have been completed. Currently, a second generation of eight PORTs is running, focusing also on economic issues and try to take into account the patient perspective in terms of patient satisfaction and patient-centred outcomes. In addition, some Inter-PORTs work on methodological issues.

PORTs base their work on systematic literature reviews, analysis of variations in medical practice and associated patient outcomes (using claims and other sources of data), dissemination of findings about effective care, and evaluation of the effects of dissemination. Medical conditions studied include among others back pain, acute myocardial infarction, cataract management, benign prostate hypertrophy, management of diabetes, osteoarthritis, pneumonia, childbirth, stroke prevention, local breast cancer, cardiac arrhythmia, and dialysis care [OTA 1994].

Contribution to best practice activities: In spite of the problems in the US Federal Government's approach to effectiveness research, there are many lessons to learn when defining a framework for what activities, disciplines, methods, and tools should constitute the definition of best practice for different executive levels of public health and the health care sector. A limiting factor in regard to the scope of this project is that effectiveness research is confined to health care interventions whereas other units of the health care system (e. g. health system structure factors) might not all be feasible for a randomised study design.

In general, the experience with PORTs limited success on individual methods supports the argument for the development of a compound best practice model, which is proposed in this project. Such a model should include information from all research methods, not only experimental and observational epidemiologic research designs, but also information input from administrative databases (see chapter I.6).

Current issues in improving effectiveness research: It appears that medical effectiveness research is not yet successfully linked with comparative clinical trials [OTA 1994]. For example, the design of the RCT has been proposed for a wider and refined application, in that large *simple* trials could be performed in community settings and units of randomisation could be innovated e. g. randomising not individual patients but different practices or geographic areas [OTA 1994]. Given, that RCTs will continue to be regarded as one central study design for evaluating the effectiveness of health care and health policy interventions for clinical and topics of public health, these approaches to improving effectiveness research should be reconsidered in the European context of effectiveness of policies for public health.

4.4.5 Decision Analysis (DA)

Definition and purpose: Decision analysis is a quantitative technique first proposed by Lusted in 1971 [Lusted 1971]. Decision analysis aims at guiding rational decision-making u nder the conditions of uncertainty. Decision analysis enables to quantify the effect of different alternative options involved in any decision. It is a method to model a rationale for a decision among different alternative strategies. The a nalysis consists of the definition o f each strategy, the description o f subsequent events for each strategy and the a ttribution o f probabilities to each such event [Thornton et al. 1992]. A frequent way to undertake a DA is by using decision trees, which are usually constructed by computer software. When a decision tree has been constructed it will start from alternative measures (e. g. immunisation vs. non-immunisation), consequences of different decisions are then displayed together with the probability occurring, and values are incorporated into the e ndpoints of the decisions. The value is expressed as average utility or disutility for each individual strategy. Multiplied with the probabilities, projected outcomes can then be compared to each others [Thornton et al. 1992]. To adjust for differences of estimated effects used in the decision analysis and real effects, a sensitivity analysis s hould always be performed. Steps in a decision analysis are:

A. Develop a model by structuring the a lternative c ourses of action, e. g. by developing a decision tree

B. Assign (estimates of) probabilities based on available literature to events or outcomes

C. Assess the utility of outcomes (e. g. QALYs)

D. Calculate the expected value of the outcomes

E. Perform a sensitivity analysis

Contribution to best practice activities: Decision analysis can be used to predict the likelihood of potential outcomes of alternative c linical strategies (and p ossibly associated costs) for patients with specific c onditions. DA may also be useful i n supporting the development of clinical practice guidelines or to assess the a ppropriateness of interventions. In a recent paper for example, results of two appropriateness panels were c ompared with the results of a decision analytic model of cardiac interventions in patients with coronary artery disease [Bernstein et al. 1997].

In regard to research into best practice, DA can be used to provide an estimate over the impact that an intervention might have on population h ealth [Gray 1997]. Facing the c hallenge of heterogeneous s ources of evidence (e. g. evidence c oming from well controlled randomised trials, administrative databases, observational studies etc.), models of integrating these different pieces using DA have been proposed [Mulrow et al. 1997]. This approach is particularly

important with respect to the integrative nature of the concept of best practice. As outlined in the case study on carotid endarterectomy (see III), different types of studies are necessary to obtain a complete picture of an intervention.

4.4.6 Satisfaction Research

Definition and purpose: Consumer/patient satisfaction research systematically evaluates satisfaction of patients in regard to their experiences, perceptions, valuations and judgements of health care interventions usually based on a collective sample. The method was originally developed from compliance research but has moved towards an outcome-oriented field in health science [Satzinger 1997]. The method is now closely associated with outcomes research and quality management. Being based on patient surveys, the method aims at an enhancement of patient orientation in health care delivery and the role of the patient as a health care decision-maker. Tools in satisfaction research are normally standardised instruments that allow for statistical grounding of relations. Satisfaction relates to structure, processes or outcomes from health care and is at the same time seen as a potential outcome indicator for health care. It is classified as overall satisfaction, satisfaction with costs, access, overall quality, humanness, competence, information supplied by the provider, bureaucratic arrangements, physical facilities, provider's attention, continuity of care and outcome from care [Hall and Dornan 1988]. Of importance is the context of the setting in which satisfaction studies are performed. For example, in managed care environment, satisfaction research might serve competitive motives. Other motives might be quality improvement and others cost containment. Not only the overall level of satisfaction, but also the relative level between different aspects of medical care is measured and of interest are also differences between consumers. It has been shown that aspects of satisfaction with different areas of medical care are measured with uneven frequencies in satisfaction instruments [Hall & Dornan 1988].

Contribution to best practice activities: Satisfaction research can potentially increase the scope for a more consumer/client and patient focused to best practice, given that results are systematically taken into account in policy-making. Limitations of the methodology do clearly indicate that in the context of best practice it is only a supplementary method to best practice activities.

Current issues in improving satisfaction research: Patient satisfaction is still disputed as a valid measure of quality of care because the impact of consumer factors such as demographic factors (e. g. age, gender, education, race, marital status etc.), measures of health related variables (e. g. health status, previous experiences in health care utilisation) is still uncertain and because the standardised survey might be tentative in previous selection of patients views [Williams 1997]. However, more and more studies address these factors and sources of bias. There is limited experience in the formal integration of patient satisfaction as a subjective measure into objective quality measurements (professional evaluation) partly because there is no clear evidence on the nature of the relationship between satisfaction and health, and patient satisfaction is seen as an 'element in health status itself' [Donabedian 1988, Satzinger 1997]. In addition, satisfaction information in the context of health care is rather used for management purposes than public accountability for services [Schwartz 1998].

Methodological improvements could be achieved by repeated surveying of the patients at different times, by differentiation between satisfaction derived from different compartments of the health care delivery process, by relating patient satisfaction with professional valuation of particular indications and by using report-type approaches alongside evaluative approaches [Satzinger 1997, Cleary 1998].

4.5 Transferability of results

For results of every kind of medical research to be transferable across different groups of patients, settings, countries etc. they have to be generalisable. In terms of generalising research results obtained under controlled (standardised) conditions ('efficacy'), they have to be translated into everyday conditions ('effectiveness'). Many procedures indicate a better effect in efficacy settings, i.e. if assessed under the conditions of clinical trials. The complexity of factors influencing the effectiveness of interventions, that is the actual effect in community settings, has not yet been not fully addressed. On the other hand, there has been some research undertaken into assessing the factors explaining different effects of interventions performed in clinical trials and real conditions in the community. The range of factors which might confound effectiveness of interventions under community conditions include hospital admission practices, case-mix, practice patterns, co-morbidity and case severity. The differences can be categorised to [adopted from Serra-Prat and Jovell 1998, Busse 1996]:

Table 5 : Factors explaining differences in 'Efficacy' and 'Effectiveness' of interventions under the conditions of RCTs and under daily conditions in community practice

Factor	RCTs	Community Conditions
Patient selection[1]	Yes	No
Patient compliance[2]	Potentially higher (?)	Potentially lower (?)
Site of intervention	Usually centres of expertise: university / teaching hospitals; health professionals act according to standard protocols Education and training in university settings lead to more rigorous use of methodological skills	Various: all types of hospitals, including community hospitals, outpatient and ambulatory care; less standardised action of health professionals, thus potentially more variation in provision of care
Incentives	Potentially high monetary and non-monetary incentives, e. g. in pharmaceutical trials	Incentives according to the baseline payment methods (i.e. lower for capitated and higher for fee-for-service payment)
Workload of the Professional	Potentially lower, e. g. in case of a professional selected exclusively for the trial, or higher if considering academic work-load alongside routine clinical responsibilities	Potentially higher or lower
Process[3] **of intervention**	Standardised	Usually not standardised
Hospitalisation	Potentially longer for the monitoring process	Potentially shorter
Decision maker	Usually unidisciplinary or oligodisciplinary	Often multidisciplinary
Outcomes	Prospectively, usually short and medium term outcomes; comparison with placebo may not correspond to everyday practice	Usually retrospectively, usually long term outcomes

Thus, in theory effectiveness biases could be addressed if all relevant variables are identified and adjusted for. In practice, data may be incomplete and inaccurate and it is impossible to adjust for measures which have not been considered or are not measurable. In addition, quality of databases does not always allow for conclusive evaluation of all factors determining the effectiveness of a health care intervention [Mant & Hicks, 1996]. A number of interrelated methods has been concerned with the problem of transferability of controlled study results, including appropriateness research, cross design synthesis, and community effectiveness research, mostly to obtain community level evidence. Research into transferability of effectiveness results between settings and systems, however, has not been associated with a single defined methodology.

[1] Trial patients are often not representative of general patients. This applies e. g. to gender (fewer women), age usually beyond 75, health status, co-morbidity factors. Accordingly, inclusion and exclusion criteria are usually rigorous.

[2] For example to comply with the treatment protocol.

[3] For example indication for the intervention, timing, performance

1. Appropriateness research (for description see 4.4.2): Appropriateness research is also considered to provide input into clinical practice guidelines (CPGs). This idea has its justification in the fact that for many groups of patients (e. g. elderly patients, children, patients with severe forms of diseases) no information is available about the benefit of an intervention from clinical studies. Appropriateness studies could serve as 'surrogates' for this lack of evidence and hence for recommendations in CPGs.

2. Cross design synthesis: Cross design synthesis is a research approach that was proposed by an expert research panel for the United States General Accounting Office (GAO) as a 'new strategy for Medical Effectiveness Research' [GAO 1992]. The method has been developed on the basis of a critical evaluation of existing study designs for medical effectiveness that led to the identification of a strategy to avoid limitations within existing designs. Cross design synthesis is a method that is focused on the extension of results from controlled studies to the conditions of medical practice. Specifically, the method complements RCT designs with data base analyses with the purpose to increase generalisability of RCT results by data bases on the one hand and correct results from data base analysis with balanced comparison groups of the RCT design on the other hand. The tool of cross design synthesis is an extension of the logic of meta-analysis, in combining results with complementary, other than common design. The method was specifically designed to develop clinical practice guidelines in the US health care setting.

By other researchers, administrative database studies are recommended as a supplementation of primary data collection for the special case of longitudinal research because follow-up has been found more simple and it has been argued that data base facilitates certain research which would be impossible using other methodologies [Roos et al. 1987].

And others have pointed to the low costs and relative ease in comparison to randomised controlled trials [Hornberger & Wrone 1997]. However, the same authors have also illustrated examples were results of RCTs differed substantially from epidemiological studies and observational approaches (e. g. the case of digoxin were RCTs showed that digoxin was beneficial in the selected patients which was conflicting to the concerns expressed through observational studies; and the case of E-carotene where more than 20 epidemiologic studies indicated a risk reduction for cancer, but two of the three RCTs conducted on the topic showed increased risk for lung cancer and death in the study group that received non-dietary carotene in comparison to the control group) [Hornberger & Wrone 1997].

3. Community effectiveness research: It has been suggested that for the purpose of a transfer of efficacy data to effectiveness, the effect of an intervention in the community can be expressed as a function of the following variables [adapted from Tugwell et al. 1984]:

Community effectiveness = efficacy$_{\text{outcomes in RCTs}}$ x diagnostic accuracy$_{\text{accuracy of diagnosis for indications}}$ x Health Professional Compliance x Patient Compliance x Coverage

Efficacy and diagnostic accuracy can be formally determined within primary clinical studies. More complicated is the approximate for professional and patients compliance. Professional compliance (defined as compliance with e. g. guidelines) depends on the degree of training and specialisation, the frequency of the procedure performed, incentive structures and other factors. Because professional compliance is multidimensional, this factor can at best be empirically measured (e. g. surgical interventions) and extrapolated for similar interventions. This is also valid for patient compliance where in the treatment of hypertension for example, illustrative evidence exists as to the substantial influence of patient compliance on health outcomes. Coverage is the extend to which patients are eligible to receive an efficacious technology. Coverage can be assessed by surveys that sample the appropriate population for asymptomatic diseases, for example in undertaking a community survey.

The model has some limitations. Firstly, it is not complete, since it does not take into account access to health care on the patient side and the quality of service provision on the physician side. Secondly, the model assumes that all patients benefit from a technology equally, i. e. the efficacy is the same in all patients. Results from appropriateness research show, however, that the efficacy depends on individual patient factors.

Predictions on the magnitude of community effectiveness of an intervention can be derived from randomised trials where technologies are compared with the existing technology in current use in a practical setting. Where trials of benefit in practical settings have not been performed, community effectiveness has to be estimated indirectly by using data from explanatory trials and then taking into account individual estimates of each of the five components of community effectiveness. For components for which data are inadequate, appropriateness studies can be carried out. The estimate of community effectiveness is a prerequisite for analysis of cost-effectiveness of interventions in the community.

While outcomes from interventions tend to be better in efficacy settings, intervention costs might be overestimated due to the more intensive monitoring process.

In this regard, a number of factors mentioned in table 5 can be associated with causes for different cost structures. To estimate costs of an intervention in a community setting, it is crucial to consider the following questions:

1. How does the skill mix differ in the community setting (morbidity, socio-economic status, level of education)?
2. What is the average provider's complication rate (morbidity and mortality)?
3. What is the average case-severity and burden of disease in the community?

4. What is the average length of institutional stay in the community?
5. What is the average (combined) treatment rate in the community?
6. What is the particular fee-structure of the intervention performed in the community institution?
7. What is the average capacity of the operating technology for performing the intervention (e.g. working at 60% versus 80% capacity)?
8. What is the degree of consumerism in relation to the various types of procedures?

If it is not possible to obtain empirical data that will influence costs of interventions on the local level, attempts should be made to approximate average productivity and resource use. An approximate tool is sensitivity analysis. Yet, at the same time there should be continuous research undertaken into comparative community effectiveness and cost-effectiveness analyses to more precisely evaluate the different factors with possible impact.

4. Transferability between countries and health care settings: Corresponding to the interest in transferring results from trials to the conditions in the community, there is substantial interest in improving the transferability of best practice evidence and experience from one country to another and between different settings of health care delivery (e.g. transfer of evidence from ambulatory care settings to the hospital and vice versa). Therefore factors that have been identified in influencing health outcomes from interventions in terms of effectiveness, costs, and appropriateness in a specific country or a specific setting have to be adjusted for prior to implementing evidence into practice within a different specific country or setting.

These factors include [Busse 1996]:

1. epidemiology (incidence, prevalence, predictive values),
2. structure and organisation of the health care system (human resources, skill-mix),
3. financing and remuneration,
4. indication for treatment,
5. preferences, expectations and compliance of patients,
6. service utilisation, and
7. costs.

The interest in international comparisons and comparisons between settings, for example difference in practice patterns in regard to the quality and quantity of interventions (=large area variation) is growing. However, in order to increase the feasibility for international and cross setting study designs to evaluate the change of health outcomes or effectiveness of interventions and relate them to the differences of health care system factors and settings, there is a need to

provide more standardised definitions for the baseline measures (e. g. health outcomes). This is a prerequisite for the development of effectiveness and economic data that can be compared between systems and settings and can subsequently be tested on how useful they are in *predicting* outcomes in the community between countries and settings. The Community offers a large potential for such comparative research because of a variety of system organisational and financial structures represented in the Member States.

4.6 Dissemination of information on Best Practices

4.6.1 Meaning of Dissemination

Dissemination is the process of spreading, making available and marketing evidence or information to inform the general public, the research community and decision-makers in the health sector about best practices. Dissemination is closely related to implementation because dissemination usually aims to increase the accessibility of research results. Dissemination and implementation of best practice information can be overlapping processes while for many instances the terminology is not sharply defined and delimited. This is for example true for educational strategies to disseminate information about best practices, which in this report is associated with the tools for implementation. Information about best practices can also be disseminated without inevitable consequences for health sector interventions. This is to say that research findings are only one of several input factors (e. g. values, emotions, expectations, available resources) for a health sector decision. Decisions, however, should be advised by the best available evidence and in this context, dissemination of evidence is a prerequisite to successful implementation of information about best practices.

4.6.2 Practice of dissemination

Dissemination of information about best or good practices can be actively promoted by research institutions, policy institutions (e. g. HTA agencies), governmental agencies, interest groups, international organisations and others. Examples for traditional dissemination strategies are the publication of printed reports, short reviews, evidence summaries, guides for patients / the general public / health professionals / decision-makers, journal articles, practice guidelines; newsletters; group meetings; academic detailing; online information; presentations and conferences; telephone help lines for patients / the general public / health professionals / decision-makers; briefings to key decision makers and ambassador strategies (i.e. research representatives are delegated to the regional or local settings in order to convey the health message to the communities).

A comprehensive model for communication of research results is provided by "social marketing". Social marketing is defined as "the design, implementation and control of programmes seeking to increase the acceptability of a social idea or practice in a target group" [Kotler 1984]. Targeting is therefore a crucial focus in social marketing strategies. Effective marketing requires tailoring the message and choice of the communication medium. For this purpose, information about the characteristics of the target audience (e. g. target group by age, socio-economic status, family and marital status, cultural and ethnical status, religious status, level of risk, accessibility of media to the target group, timing) and about the target group's knowledge, preferences, and attitudes has to be gathered. Obstacles to benefit from the information may be related to[1]:

- distinction between accurate and inaccurate information;
- deciding how to use information from the media;
- setting of priorities with regard to the importance of health information and its relevance to the individual;
- having knowledge about the sources and motives of informants;
- having appropriate technical skills to use newer forms of the media.

Social marketing implies to choose the suitable communication medium. There is no doubt that for the general public, information will have to be provided in a more ubiquitous way in comparison to professional groups (e. g. through television, newspapers etc.). Media options are for example newspapers, magazines, television, radio, video, floppy disks, CD-ROM, online and telematic services, direct mail and media events.

4.6.3 Current issues in improving dissemination

The EUR-ASSESS project has made specific proposals to increase the impact of HTA findings through dissemination [Granados et al. 1997]:

1. Dissemination is an integral part of the HTA process, organisations should therefore devote resources and attention to the dissemination of their results.
2. HTA organisations should consider dissemination in an early stage of planning of the HTA process.
3. Organisations should target their dissemination to special groups and tailor their messages to meet specific needs.
4. Organisations should evaluate the cost-effectiveness of their dissemination strategies.

[1] In reference to findings of the „Salzburg Seminar: Education for Health and Wellness", May 30, 1998

These proposals are well transferable to other activities. In addition, special attention should be devoted to the differentiation in improving strategies for the different users of information. A high proportion of efforts to improve dissemination will have to focus on the consumer, taken into consideration that the ultimate beneficiary for all health sector interventions is the patient and the potential patient (i.e. the general public).

Dissemination of evidence-based and quality accredited information on best or good practices is a suitable area for Community action because dissemination of evidence-based information by the Community can potentially increase the scope and accessibility of information and therefore capacities to benefit from information.

4.7 Implementation of information on Best Practices

4.7.1 Meaning of implementation and implementation barriers

Implementation is the process of getting evidence or information on best or good practices translated into clinical practice, public health interventions and policy-making in general. This has been one of the weaker links in the schema for best practice activities, in spite of increasing interest in basing clinical and policy decisions on research findings [Sheldon et al. 1998; Haines & Donald 1998].

The prerequisite for a targeted strategy for a change (or support) of clinical or policy practice is to tackle social, organisational and institutional barriers for implementation and change [Haines & Donald 1998]. These barriers need to be differentiated between the perspective of patients, the general public, health professionals and policy decision makers [Granados et al. 1997]. Most of the research undertaken in this field has focused on the health professional target group, little research has focused on changing the behaviour of policy decision maker and the public [Granados et al. 1997].

Barriers can be subdivided into environmental including organisational barriers, personal characteristic or behavioural barriers, social barriers, and barriers through prevailing opinions [Granados et al. 1997; Haines & Donald 1998].

For the purpose of overview in this report, only the most important examples of barriers to implementation will be summarised.[1]

1. A fundamental barrier to evidence-based change is lack of scientific evidence. This barrier not only applies to clinical, but also to health policy practice. For example, health promotion clinics were established prior to the availability of scientific evidence that would favour the

[1] Comprehensive details on this issue can be obtained through the EUR-ASSESS project subgroup report on dissemination and impact and the series of articles in the British Medical Journal analysing the gap between research and practice [Granados et al. 1997].

institution of such clinics in the United Kingdom [Florin 1996]. Lack of appropriate timing between the availability of evidence and the claim of a policy decision can be the cause for obstacles to implement research findings.

2. Conflicting evidence might be a substantial barrier. Even after publication of evidence, e. g. for health promotion actions, interpretations can differ widely differ and eventually result in a lack of consensus [Florin 1996]. Lack of consistent interpretations and consensus on research results might present a substantial barrier to the implementation of research findings into clinical practice as well as health policy development. Some research has been frustrated by the matter of conflicting evidence referred to earlier on in this report. More research has to follow in order to tackle the issue of conflicting evidence.
3. Availability of and limited access to scientific evidence prior to the decision-making process can be a significant barrier for implementation of best practice information into policy and clinical practice.
4. A lack of a suitable organisational infrastructure to translate evidence into practice for health policy development and for clinical practice might be a significant problem related to the limited access to evidence. Limiting organisational factors might include availability of personnel and financial resources, competition for limited resources, and political factors [Granados et al. 1997]. Smaller clinical sites might not yet have access to electronic databases for synthesised evidence. This might also apply to sites for health policy development, for example in governmental departments, with sickness fund administration and management as well as professional and consumer organisations.
5. Policy decisions might be influenced by political interests, by lobby and interests groups and the public which might occur as a barrier to translate best practice evidence into health policy. This factor tends to be especially relevant when health policy decisions are made by elected politicians [Gray 1997, Florin 1996]. On the clinical level, limitation of the transfer of evidence from research to practice might be hindered by low patient adherence to health care [Haynes & Haines 1998]. Unsolved problems also occur for cases were patients' choices are opposed to guidance suggested through best evidence.

4.7.2 Implementation tools

Several concepts exist in order to improve the translation of best practice information into practice. These can be divided into approaches from bottom-up (e. g. professional initiatives such as quality circles and professional peer review, structured care methodologies) and top-down approaches (e. g. health sector policies such as financial measures, coverage and regulation). The majority of the tools listed below are bottom-up implementation policies directed at clinical practice change.

1. **Professional Educational Approach**: Strengthening of formal education in priority setting for population health and evaluation of health interventions on all levels of health care decisions is for example a baseline concept underlying the Leonardo da Vinci Initiative of the European Commission and the World Health Organization. This initiative aims at scanning for future needs of postgraduate training in the field of health economics and health management in the European Union. Shorter term educational professional concepts underlie initiatives of small group interactive learning, problem-based and self structured learning and 'academic detailing' (one-on-one educational outreach most commonly used for pharmaceutical prescribing patterns). Continuing education courses aim to ensure that professionals stay up to date with information (evidence on the reasons of practitioners choices of continuing education courses however suggests to combine financial with educational incentives [Murray & Campbell 1997]).
2. **Building intermediate expert structures** would help to bridge the gap between best practice knowledge and best practice in policy and clinical settings. For policy development this could be accomplished within the institution of policy analysis consultant centres or units within policy institutions. For the clinical setting this would require to institute additional experts for clinical evaluation at the clinical setting, at least as long as capacity building in hospitals, practices and health centres is concluded.
3. **Quality Management / Outcomes Management**. Best practice evidence should be integrated into the management of quality and outcomes in health care. Outcomes management assumes that optimal treatment strategies can be determined by systematically reviewing the outcomes attributable to the intervention that preceded the outcome [Epstein & Sherwood 1996]. Outcomes management seeks to produce desirable outcomes in clinical settings and is considered as the translation of outcome research results to practice.

   Quality management is considered integral in modern medicine. Quality management originally started from Donabedian's functional triad of structure, process and outcome as the fundamental components to measurement, assurance and improvement of quality in medical care [Donabedian 1966]. Quality management today subsumes many different operational concepts. Among them are for example "Total Quality Management" and "Continuous Quality Improvement". Quality is measured through indicators which can be generic or disease specific. Current questions of concern in many European countries are questions of who should measure quality (e. g. external independent institutions versus internal professional stakeholders), how quality measures should be used (e. g. as benchmarks, for stakeholders' information, for the information of the general public), what should be incorporated into the framework for quality measurement (e. g. hospital accreditation), and remaining questions on how to evaluate the effect of quality management measures on health and health care resources.

4. **Deployment of structured care methodologies**: Structured care methodologies are instruments to manage health care delivery. They do not provide new information, and thus are considered instruments to implement best practice, rather than providing research on best practice. Some methods however are at the interface between research and implementation for example clinical guidelines and decision support tools. There are two predominant concepts in implementing best practice evidence by structured care methodologies:

   A. *Disease management* is a tool to optimise the provision of health care with a main focus on quality and cost-effectiveness of care. Disease management aims at co-ordinating health care in regard to the available resources for individual conditions. The concept systematically determines (manages) health care throughout 1. each conditional (or disease/health) stage and 2. throughout each institutional level of the health care delivery process. Disease management requires an information basis on costs and guidelines on health care. An institutional co-ordination has to be established within a health care providing unit (for example hospitals) and among different health care providing units (for example primary care units, hospital units, rehabilitation units). Characteristically, the disease management concept provides for a more integrative approach to health care delivery and aims to weaken the strict separation between different levels of care (primary, secondary, tertiary care) and between specialities. 3. Institution of mechanism to continuously evaluate the standards of managed care.

   B. *Clinical Pathways* (synonyms: Critical Care Paths, Care Maps, Anticipated Recovery Paths) are an approach to structure care for the typical uncomplicated patients according to the time and capital resources spent. Clinical pathways organise, sequence, and time the care given to a patient [Cook et al. 1997]. A pathway is divided into time intervals during which specific goals and expected progress are defined. In effect, this makes it a multidisciplinary integrated approach to health care, that is said to be a powerful audit tool because outcome within the intervals can be more constantly monitored in comparison to other health care delivery models [Kitchiner et al. 1996]. In addition, local circumstances for health care delivery can be adjusted to the path model of each individual institution.

5. **Contracting** is thought to be an effective instrument of health care planning and management [Wiley 1997]. It is suggested that for the improvement of the system's performance, more focus should be on: A. the decentralisation of management through clear specification of commitments between contracts, B. information prior to choices (equivalent to improvement of 'informed choices') about providers, and C. the extension of the financial accountability of providers for an agreed level of service volume and quality at specified prices.

6. **Provider payment methods:** Comparative studies on payment systems in ambulatory care conclude that fee-for-service payment systems tend to relate to more frequent physician consultations in comparison to capitated payment systems. This selective example illustrates the potential role of payment systems as steering instruments for best practice health care. Hospital payment methods are frequently moving towards payment methods according to diagnostic related groups. How far cost-effectiveness advantages of this particular payment system are outweighed by adverse effects on health outcomes (e. g. through decreased length of hospital stay in absence of sufficient home care facilities) should be subject to the evidence production process in line with implementation.
7. **Regulation:** regulation can comprise coverage decisions, human resources planning, skill mix change, payment systems, licensing, accreditation and legal pursuits.
8. **Behavioural concepts:** Examples of implementation tools in line with behavioural strategies are audits and feedback, reminder systems, incentives and sanctions.
9. **Organisational approaches:** Organisational approaches for example cover structured care methodologies, team building, the establishment of corporate identity, changing tasks or structures, and leadership development.
10. **Decision support tools:** in assisting information on best practice evidence, decision support tools can be applied for different stakeholders of the system, it is a powerful tool that has mainly focused on decision support for health professionals, but is increasingly applied within concepts of shared decision-making (chapter 4.6).
11. **Reminder Systems:** Reminder systems aim at promoting effective clinical practice. They are most common as patient specific computerised-reminders and have been proved capable for changing clinical practice by a number of authors [Nuffield Institute of Health 1994; Johnsston et al. 1994; Nurack & Gimotti 1997].

4.7.3 Consumer information methods

There is no clearly defined area to organise or summarise methods available for increasing consumer information on health and care. Consumers in this report are referred to as lay people who are members of the general community. There has been a trend towards an increase of a client-centred orientation in some areas of public administration during the 1970s in many parts of Europe, however, this trend effectively has long not yet been related to the health care sector [Schwartz 1998]. The majority of the research, activities, disciplines and methods so far has rather focused on either the provider or the health policy maker perspective. Only lately, there is growing acceptance of the legitimacy of consumer involvement in health care and health policy throughout the world [Sisk 1998]. An indication is for example an extra issue devoted to the

consumer and health technology by the International Journal of Technology Assessment in Health Care in 1998 (Volume 14, Number 1, 1998).

There are several ways in which consumer information as part of best practice activities can potentially contribute to health as well as improving the effectiveness and cost-effectiveness of health care systems. Contribution can follow scientific approaches (consumers being part of research), market approaches (consumers are informed users of goods and services), legal approaches (consumers as citizens with rights) and democratic participation (consumers as equal partners and citizens with rights) [Bastian 1998].

The increased involvement of consumers into public health decision-making (and also involvement of patients involvement in defining treatment options and outcome measures) is one priority area:

1. At once consumer advocacy has a high potential to implement best practice concepts, because consumers have the political power to change.
2. A number of strategies to implement best practices rely on the consumers active contribution (e. g. some anti-tobacco and sexually transmitted diseases campaigns).
3. An incorporation of the consumers preferences into evidence-based decisions for example on preventive decisions will increase their compliance with especially preventive health sector interventions.
4. A consumer information system on matters of public health might decrease some of the problems mentioned above, when instituted in the way that information to Europeans is widely available, voluntarily accessible, suitable for lay understanding, and organised towards different (healthy) target groups (e. g. for age groups, genders, adolescents, high-risk groups etc.).

Selective methods summarised in this chapter are divided into evidence-based patient and consumer choices, "shared decision-making", "decision-aid" for patients, public information systems on quality in health care and public health information systems for consumers.

1. **Evidence-based patient and consumer choices:** The promotion of the concept of evidence-based patient and consumer choices follows the understanding that the patient or consumer should make rational and informed health care decisions based on the best available evidence on for the protection of health and the prevention of disease. The concept is being promoted by several initiatives, for example in the context of the Patient Carter in the UK [Entwistle et al. 1998]. A Consumer Network is being established by the Cochrane Collaboration. Another possibility is to sum up HTA recommendations or guidelines in a format suitable for lay understanding.

   Current issues in promoting the concept: A large number of unsolved questions need further attention in order to exploit the concept's full potential for improving the public's health [Entwistle et al 1998]. Among these questions are for example:

- How much autonomy is beneficial to the patient/consumer on one hand and to the social community on the other hand?
- How much and exactly what information is likely to have a beneficial impact on rational decision-making?
- How does more information actually effect health and health outcomes from interventions and policies?
- How is evidence to be combined with preferences and which part should have more of decision-making power when each conclusion would exactly take the opposite direction?

It also has been consistently found in studies of patient's role preferences, that not all patients inevitably wish to participate in decision-making, either due to professional and lay role traditions, the wish for a transfer of responsibility and avoidance of possible failure of the decision, conflicting demands of time, and an adverse acceptance of uncertainty [Entwistle et al 1998]. The concept also assumes suitable knowledge and skills of patients and professionals, a positive attitude towards involving patients / consumers into decision-making, a suitable organisational infrastructure and sufficient certainty over the quality of information.

2. **Shared-Decision Making:** Shared decision-making is a concept that aims to let patients decide which choice between alternative medical interventions is best for them [Woolf 1997]. Shared Decision-making Programmes (SDPs) were developed by the Foundation for Informed Medical Decision Making (FIMDM) in Hanover, New Hampshire, to assist in the treatment decision-making process. The programme is assisted by interactive videodisks. The programmes provide patients with clear, unbiased information about available treatment options including the probabilities and implications of negative and beneficial consequences of each alternative option. With this information, patients can become more active participants in making treatment decisions. The programme follows the notion that so far patients' need for information is not sufficiently met [Crawford 1997]. The concept is thus only being applied at the clinical setting, where patients decide between alternative interventions. Frequently the concept has been applied to cancer care, most frequently published for prostate cancer care [e. g. Woolf 1997, Crawford et al. 1997; Gramlich et al. 1998, Onel et al. 1998]. It has been suggested for other areas such as for example end-of-life care [Alpert & Emanuel 1998]. The model also has been tested on preventive measures [e. g. Chen et al. 1997, La Croix et al. 1997]. A community concept for shared decision-making to health problems such as for example alcohol, tobacco and drug abuse has been suggested by Butterfoss et al. in 1996. A special form of shared decision-making is "Decision Aid", a computerised decision model in which patients/ consumers can identify their individual disease risks, their choices of interventions and their individual probabilities to benefit (or not benefit) from alternative measures an can take a decision according to their individual preferences. While Decision Aid was originally designed for health professional diagnostic and treatment decisions, it now being suggested as a shared decision tool

between patients and their practitioners, and can in principle be applied to areas of public health [O'Connor et al. 1998]. The model is said to be preferred by patients [Silberfeld 1996]. However, Evidence on the effectiveness on shared decision-making models is still incomplete.

3. **Public information systems on quality in health care:** There is some experience with public reporting systems on health care quality in the United States, but very limited experience outside the US. There are two direction of such quality information systems. The first public quality publication was initiated by the Health Care Financing Administration on Medicare hospital mortality [Epstein 1998]. The publication of risk adjusted mortality rates in cardiac surgery in New York and Pennsylvania has raised a very controversial, emotional and unsolved discussion on the methods and details of quality reporting [Hannan et al. 1995; Schneider & Epstein 1996; Hannan et al. 1997; Epstein 1998; Bentley & Nash in press][1]. By 1997, about half of the states have required hospitals to adopt uniform risk-adjusted data on hospital-level activities. The Commission on Accreditation of Healthcare Organizations (JCAHO) has also created a national hospital database derived from its new clinical indicators [http:www.jcaho.org]. The purpose is to accredit that structural and process standards are met which increase the probability of a high quality outcome. Hospital accreditation systems are implemented in the United States, Australia and Canada, and are either just being implemented or in the developmental stage in France , the Netherlands, the United Kingdom, Finland, Sweden and Germany.

   Another line of public quality reporting is the Health Plan Employer Data and Information Set (HEDIS), a database on comparative quality of health plans developed by the National Committee for Quality Assurance [Epstein 1998]. The Database was originally developed as an information service to health plan purchasers and employers. The "Quality Compass" is now also aiming to assist consumers in their decision for a health plan, but so far the quality information is thought of little impact on consumer decision-making [Epstein 1998]. Data are analysed by administrative as well as clinical data: with 71 measures related to clinical performance, procedure utilisation, patients' experience and satisfaction with health care [Thompson et al. 1998].

4. **Public health information systems for consumers:**[2] An information system for public health education for consumers is in principle perceivable, for example by utilisation of mass media (in particular the Internet). Public health information will need to be tailored to the specific needs of different segments of the population (e. g. preventive and health maintenance measures for the healthy population, particular information for individuals who have a physical or mental problem or are interested in a particular health problem, special

[1] Arguments hold against publication of mortality rates have been: adverse patient selection with resulting access problems, polarisation of physicians, cost increase throughout administrative control of data, confidence issues of data, political sensibility and uncertainty over validity and reliability of data.

[2] Adopted from findings of the "Salzburg Seminar: Education for Health and Wellness", May 30, 1998.

sub-groups such as the elderly, children, the adolescent, women, men). The National Patient Library (NPL) follows an approach to offer evidence-based information to consumers, an initiative by the US National Institute of Health [Lerner 1998]. Library staff is supposed to help tailor general information to patient's need. The library also includes an electronic network.

Particular areas in which elaboration of public health information for consumers could prioritise are:

- Preventive health guidelines: e. g. immunisations, protection against infectious diseases, dental health, pap smear screening, exercise, teen pregnancy and prevention, traveller's prevention
- Family planning, mother-baby care, sterilisation options, contraception options
- Prevention/handling of eating disorders, prevention/handling of drug, alcohol and tobacco abuse, prevention/handling of depressive disorders
- Internet use, computer use, use of decision support techniques
- Information on preventive alternatives, information on complementary medicines
- Information in how to choose a provider, how to assess the provider's competence, and how to report incompetence of the provider.

4.7.4 Current issues in improving implementation

1. Limited capacity of health care systems to absorb new research results and to overcome obstacles for the implementation of research results make it necessary to prioritise health sector interventions for implementation; the decision on implementation might depend on the quality of research results, the degree of uncertainty of findings, the relevance of the findings to the clinical or policy setting, and the trade off between benefits and risks or costs of interventions [Sheldon et al. 1989].
2. It has been proposed to involve managers and policy makers in the development and focus of research on one hand and to increase responsibility for researchers to ensure that their research results are reflected in policy decisions on the other hand [Davis & Howden–Chapman 1996, Jacob and McGregor 1997]. Ideally should the development of strategies to change involve all people or representatives of people who will have to implement the change or who can influence change hand [Haines & Donald 1998]. EUR-ASSESS has made a similar proposal in that co-ordination between those that synthesise evidence and those responsible for implementation should be increased [Granados 1997]. Communication between best practice experts and policy makers would have to take into account the decision-makers' specific constraints in the appraisal of the evidence.

3. An important factor in improving scientific literacy i.e. skills, competence, capacities and knowledge to use research evidence for rational decisions will be to improve the assessments of trade-offs between benefits and risks, and understanding the basics of probabilities [Granados et al. 1997].
4. It has been proposed to establish independent health policy analysis units / institutions in order to establish a suitable organisational infrastructure with sufficient capacities to provide access services to research findings targeted at specific policy concerns. The potentiality of establishing an international service should be further exploited.
5. It has been proposed to increase activities into studies addressing the actual impact of HTA results into health policy making [Van Den Heuvel et al. 1997]. The HTA Europe project has concluded that 'health care policy and health technology assessment must interact with each other more than in the past' [HTA Europe Report 1998]. HTA results should be used to implement technologies more effectively [Van Den Heuvel et al. 1997]. In this context, focus should also be directed to traditional, cultural, economic or prestigious reasons to change practice by decision maker, health professionals and the general public. Here, international comparative studies will be needed.
6. It has been suggested that "the pressure for more effective and efficient implementation of research findings is likely to grow" [Haines & Donald 1998]. Evidence is still incomplete but it is likely that no single strategy will to be successful and different strategies in combination may best contribute to achieving the desired change [Haines & Donald 1998]. To gain more information on what combinations of implementation strategies is most successful in obtaining the desired change sets the agenda for further research on the European agenda.

4.8 Monitoring the impact of Best Practice

The previous chapter has been concerned with the implementation of best practice evidence into clinical and policy practice. Best practice monitoring in this chapter is referred to as the evaluation of impact of best practice activities. In the previous chapter it was mentioned that information was rare, and this is even more so on the issue of impact evaluation ('monitoring'). According to the concept of the best practice framework, the outcome domain integrates the monitoring approach as a prerequisite for the continuity of the iterative loop. From monitoring the impact of best practice, information is obtained that will allow to critically re-appraise the research and all methods that constitute best practice. However, a number of unsolved problems occur with this approach, which already have been mentioned. For example, outcomes, such as safety, effectiveness, costs and cost-effectiveness, are not always strictly attributable to a health related intervention. Thus, it is not necessarily possible to draw a new conclusion for best practice in health. In most cases, it will furthermore have to be respected, that health-related

interventions (policy, clinical practice and consumer behaviour) are not only evidence-based. Preventive and health promotion measures taken at the community level will even have to consider cultural, social, political and ethical issues. Thus, on an international scale, evaluation of measures will cause methodological problems but provide the opportunity to learn from the experience of the different countries. Implementation strategies could be evaluated by means of comparing cross-national approaches. Therefore, information-sharing should be promoted in regard to the experience of Member States on the effects of implementation of strategies for best practice evidence. This eventually will increase knowledge and expertise gained throughout translation of best practice evidence into a variety of health care system organisational and financial structures including sharing of the successful and unsuccessful experience with it.

Alongside this statement on information sharing, there is very limited literature available on the evaluation of best practice evidence implementation. It has been recognised that such evaluations are often extremely difficult to carry out for example in Technology Assessment activities [Jacob & McGregor 1997]. It might not be easy to solve the question first of all in regard to who should carry out evaluation. However, the EUR-ASSESS subgroup on dissemination has stated clearly that "technology agencies should rigorously evaluate the impact of their dissemination and implementation activities" [Granados et al. 1997]. Funding again might become a limiting factor when public agencies concentrate on receiving ex ante recommendations. Evaluation is recommended at three levels: (1) change, maintenance or innovation of a policy (e. g. within a legislative analysis proposed by Granados et al. 1997); (2) distribution and utilisation; (3) effect on health and cost-effectiveness outcomes.

A growing number of studies is undertaken into the evaluation of practice guidelines that tend to focus however on the medium term impact on health care practice, rather than on health outcomes. Under the Changing Professional Practice programme, a number of studies has been funded by the European Union. Most of the studies are focused on identifying changes in ambulatory care practice and again have been related to factors influencing the successful introduction of guidelines:

1. the development process (with high probability of being effective when users are targeted in the development process, and lower probability with external local and even more so national external developmental strategy);
2. dissemination (with high effectiveness in the context of a specific educational programme and lower probability when published in professional journals and higher probability with local or institutional identifies);
3. implementation (with higher effectiveness probability of patient specific reminders as implementation tools and lower effectiveness probability with general reminder guidelines) [Grimshaw and Russel 1993; Feder 1997]. Continuous evaluation is enabled when targets are set on each level of guidelines development and implementation.

There is evidence that multiple dissemination and implementation strategies produce a higher change in clinician behaviour [Davies et al. 1995]. Limitations of existing studies conducted to evaluate the effectiveness of clinical practice guidelines, constitute to the short term duration of studies, the deficiency to address the growing role of nurses in guidelines trials, the limited studies into cost-effectiveness of guidelines programmes.

With EUR-ASSESS and HTA Europe, HTA activities have moved towards a standardised process. Systematic reviewing within the review group activities in the Cochrane Collaboration also have standardised the procedure for conducting systematic reviews. There is growing activities into an exchange of information between those concerned with the development of local and national guidelines, as well as between countries. The actual formulation of clinical guidelines will have to take into account local circumstances, health needs and preferences of those that are affected by the guidelines, and thus actual formulation of guidelines will have to be a decentralised process. However, there are many arguments already put forward for more information sharing and co-ordination of the process of obtaining evidence by systematic literature work. In this context, methods need to be improved that allow for the evaluation of the performance of evidence synthesising structures. Growing direction towards standardisation of HTA, EBM, and CPG development activities will help to evaluate the performance of activities. Evaluation inevitably includes implementation and thus will have to be left to the local site. Neither the state of standardisation nor multiplication of activities, however, will be conclusive in information on the effect of health care activities, given that activities are implemented into practice. The evaluation of best practice activities ultimately will have to consider medium term effects on health care practices and consecutively long term effects of population health outcomes.

4.9 Conclusion

None of the activities to organise research findings, and disciplines, methods and tools provides an all embracing-concept to maximise value to health. Each activity has to be supplemented with others. The choice of combination depends on the nature of the problem, the perspective of the decision and the availability of evidence. As these activities are primarily policy and provider oriented, there are now powers to increase the use for and strengthen the role of consumers in health care decision-making.

5 STATE OF BEST PRACTICE IN THE EU MEMBER STATES

5.1 EBM institutions

5.1.1 Cochrane Centres

One of the most developed database for countries of the European Union is the Cochrane Database of Systematic Reviews, maintained by the international Cochrane Collaboration (CC) which was founded in 1993 [Spinner & Antes 1998]. The purpose of the collaboration is to prepare, maintain, and promote the accessibility of systematic reviews of the effect of health care interventions in all areas of health care. The Cochrane Centres (CC) offer methodological support within the countries they are assigned to (co-ordination of membership, support of Cochrane Review Groups [CRGs], support of hand searching, co-ordination of national contributions to an international register for RCTs, support in systematic review activities, support in public information, organisation of workshop and training units) [Spinner & Antes 1998]. The Cochrane database is focused on clinical issues, but increasingly extended for evidence on the effect of organisational and financial structures on health. The first Cochrane Centre has been established in Oxford, United Kingdom, in 1992. Further European Centres have since then been instituted in Italy, The Netherlands, France, Denmark, Germany and Spain (Table 6).

Table 6: Cochrane Centres in the European Union

Location	Estab-lished	(Specific) Objective	Reference Centre	Main Funding Sources
France (Lyon) (Centre Cochrane Francais - CCF)	February 1996	Institution of all Cochrane activities within French speaking countries; 'Groupe Synthese' institution throughout France	Europe: Bulgaria, France, French-speaking Belgium and Switzerland, Luxembourg, Monaco, Romania Elsewhere: Algeria, Chad, French Polynesia, Guinea, Ivory Coast, Morocco, Tunisia	Association pour la Promotion de la Recherche et de l'Evaluation en Therapeutique; European Union
Germany (Freiburg))	October 1997		Europe: Germany, Switzerland, Austria	
Italy (Milano) (AREAS-CCI)	July 1994	Institution of an Italian Cochrane Network with Universities and Health Care Centres (as a legal entity under the Italian law since July 1996)	Europe: Bosnia, Bulgaria, Croatia, Greece, Italy, Malta, Romania, Slovenia, Italian-speaking Switzerland Elsewhere: Angola, Burkina Fasu, Burundi, Chad, Congo, Ivory Coast, French Guyana, Gabon, Mali, Rwanda, Togo	European Union (Biomed II), Mario Negri Institute (Milano), Zeneca Italia
Netherlands (Amsterdam)	October 1994	Institution of all Cochrane activities within Dutch speaking countries	Europe: The Netherlands, Dutch speaking Belgium Elsewhere: Surinam	Academic Medical Centre, Amsterdam; Department of Clinical Epidemiology & Biostatistics, Amster-dam; Ministry of Health, Welfare & Sports; European Commission (BIOMED 1 & 2)
Nordic countries (Copenhagen)		Establishment of a Nordic Cochrane Network	Europe: Denmark, Finland, Norway, Sweden	Rigshospitalet, Danish Ministry of Health, BIOMED programme; Fonden til Laegevidenskabens Fremme
Spain (Barcelona)	December 1997	Institution of all Cochrane activities within Spanish speaking countries and systematic reviews of Spanish publications	Europe: Andorra, Portugal, Spain Elsewhere: Latin America (in collaboration with the Brazilian and San Antonio Cochrane Centres)	Consorci Hospitalari de Parc Taulí; Fundació Parc Taulí; Instituto de Salud Carlos III (ISCIII); Instituto d'estudis de la salud; Fondo de Investiga-ciones Sanitarias (FIS)
United Kingdom (Oxford)	December 1992	Original Cochrane Centre, establishment of the Coch rane Collaboration national and international; Information System supporting the NHS Research and Development Programme	Europe: United Kingdom and Ireland, Czech Republic, Hungary, Slovakia, Turkey Elsewhere: Bahrain, Egypt, Iran, Iraq, Israel, Jordan, Kuwait, Lebanon, Oman, Qatar, Saudi Arabia, Sudan, Syria, United Arab Emirates, Yemen	NHS R&D Programme, UK; Chief Scientists Office, Scottish Home & Health Department, Scotland; NHS Wales Office of Research & Development, UK; Dept. of Health & Social Services, Ireland, UK; NHS Anglia & Oxford R&D Programme, UK; European Union, BIO-MED; Nuffield Provincial Hospital Trusts, London, UK; Association of the British Pharmaceutical Industry

Main structural elements of the CC are the CRGs, Cochrane Fields and the Steering Group. The Review G roups are responsible for identification and evaluation o f Randomised Controlled Trials and systematic reviews according to a standardised p rotocol. Cochrane Fields work on areas of the health care system beyond medical care. The Steering Group has the responsibility to set the principle direction for the work within the CC.

5.1.2 Further EBM Institutions[1]

- In the United Kingdom, the Research & Development Programme supports the adaptation of principles of evidence-based medicine since 1991. The National Health Service (NHS) has a Centre for Review and Dissemination (CRD) in York for producing and disseminating (e. g. by Effective Health Care Bulletins, pamphlets and patient information leaflets) systematic literature reviews (on 2-4 topics per annum). CRD employs a number of 20 people and obtaining a budget of 1.5 million £. The Centre for Evidence-Based Medicine in Oxford was instituted in 1995 at the Radcliffe Hospital in Oxford. The Centre is with more than 100 affiliates one of the largest institutions for Evidence-Based Health Care, the focus of the Centre is on research, practice and training in systematic review processing and such of randomised controlled trials. Particular tools are postgraduate and undergraduate courses, workshops, an internet communication group, and the development of the software package: CAT-Maker for clinicians.
- The Centre for Evidence-Based Child Health, London, was founded in 1996 and is located at the Institute of Child Health. The focus is on education and training for critical appraisal and systematic reviews of scientific literature in Evidence-Based Child Health.
- The Centre for Evidence-Based Pharmacotherapy, Nottingham, is an interdisciplinary centre with a focus on assistance on design and implementation of primary studies in pharmacotherapy, located at University of Nottingham.
- The centre of Evidence-Based Dentistry was initiated by a group of dentist practitioners in 1995 and established in Oxford. The main focus is on establishing an evidence-based evaluation culture in Dentistry. Main instruments are workshops for training in evidence-based dental care is offered to dentists.
- The Academic Medical Centre, Amsterdam, was founded in 1996 and is located at the University clinic of Amsterdam, co-ordinated by the Department of Epidemiology and Biostatistics. The focus is on education and training in EBM, critical appraisal techniques of scientific literature and systematic reviews.
- The Health Service Research Unit (HSRU), Oslo, instituted a unit for systematic reviews in 1996, following a consensus within a conference between different stakeholders in health care, researchers and politicians, to promote Evidence-Based Health Care in Norway. Main focus is on methodological training in systematic reviews.
- The Catalan Agency for Health Technology Assessment in Barcelona and the Institute of Clinical Evaluative Science in North York are HTA-institutions with relevant activities into EBM in Europe.

[1] [Spinner & Antes 1998]

5.1.3 Non institutionalised EBM information resources in Europe[1]

- The Critical Appraisal Skills Programme Workshops was initiated 1994 in Oxford with the purpose to establish a model for EBHC. The Programme offers workshops for different stakeholders in the health care system.
- ScHARR Guide to Evidence-Based Practice is an initiative of the Sheffield University in Great Britain under which all EBM related activities are published on the World Wide Web.
- The Bandolier is one of the first publications in Evidence-Based Health Care, with a monthly edition published by the Oxford Anglia NHS Region in the UK [www:http://www.jr2.ox.ac.uk/Bandolier]. The content is about general topics in EBHC and publications of scientific evidence in health.
- Evidence-Based Health Policy and Management is mainly concerned with evidence in management, financing and organisation of health care. Information is published by comprehensive presentation of primary articles and systematic reviews following their assessment according to a standardised assessment procedure.
- Evidence-Based Medicine is a joint publication between the Centre of Evidence-Based Medicine (Oxford) and the BMJ. The journal presents primary literature in the form of abstracts following solid quality assessment of the primary literature.
- Evidence-Based Purchasing is a publication of the R&D Directorate, NHS Executive South & West, aiming at publishing evidence to the comfort of purchasers and providers of health care.
- The Nordic Newsletter on Evidence-Based Health Care is published by the Health Service Research Unit of the National Institute of Public Health in Norway.

5.2 HTA activities[2]

Austria: Small HTA activity is reported in the National Academy of Sciences, with some studies and analyses performed.

Belgium: Some studies and analyses are performed, however with little impact on policy reported.

Denmark: A national programme is in operation since 1997 that is being organised in 1998. The Danish Institute for Health Technology Assessment has been established in 1997 at the Danish Institute for Health Services Research and Development. Denmark has a longer tradition of studies and analyses performed, with a small number having had considerable policy

[1] [Spinner & Antes 1998]
[2] Adopted among other sources from HTA Europe, final report, Leiden 1998.

impact. Between 1982 and 1992, 17 economic evaluations have been conducted in Denmark, where 12 have been directed at health policy decisions and 5 at the clinical decision-making level. The impact of the results on decisions was evaluated by looking at the change of behaviour among the decision-makers [Alban 1994]. It was found that within the observation period, 9 studies either led to a change of behaviour of the decision-maker, or at least reached the target group.

Finland: A long-standing history of interest is reported with a national programme established in 1995. At the National Research and Development Centre for Welfare and Health (STAKES), the Finnish Office of Health Technology Assessment (FinOHTA) is in charge with co-ordinating research, by disseminating information and by giving methodological and financial support to research projects.

France: In France a National Agency (Agence Nationale pour le Dévelopment de l'Évaluation Médicale, ANDEM) was established in 1989. After the agency broadened its mandate to hospital accreditation, the name was changed to Agence National pour l'Accreditation et l'Evaluation dans la Santé (ANAES) in 1997. HTA is instituted within the HTA department to provide various institutional partners (including the General Health Directorate, the Ministry of Health and the National Health Insurance Funds) assistance in the policy decision-making process by synthesising information on safety and efficacy of health technologies and its dissemination and financing decisions. ANAES is also a dominant information source for coverage decisions of the social insurance system. A pioneer of a prospective technology evaluation in terms of policy impact was the 1971 Programme Périnatalité, under which priority was given to the programmes with best ratio to cost-effectiveness in preventing preterm birth and reducing perinatal mortality among 60 possible interventions [Davies et al. 1994]. Cost-effectiveness has lately enjoyed increasing interest. ANAES also develops CPGs and evaluation activities in the public and private hospital sectors and the ambulatory settings. In addition, ANAES provides formal and continuing medical evaluation training.

Germany: There is substantial and growing interest reported in Germany with support of the Ministry of Health to institutionalise HTA within academic institutions and the Medical Documentation Centre (DIMDI) in Cologne. In ambulatory care, the incorporation of HTA is increasingly used for coverage decisions [Perleth et al. 1999]. Among about a dozen HTA-related initiatives few are dealing exclusively with HTA. Table 7 summarises a qualitative overview of these initiatives and current trends of activity. Until recently, health technology assessment activities were predominantly related to the societal and ethical impact of technologies. Established and emerging medical technologies became only in the last two years the focus of systematic assessments by some of the groups. Apart from the work of the German Scientific Working Group of Technology Assessment in Health Care, health technology assessments are produced in a growing number by other working groups and institutions [Bitzer et al. 1999].

Table 7: Initiatives by Type of Assessment in Germany

Type of Assessment	Federal Level	Research Centres	Academic Working Groups	Private Institutes and other Working Groups
Political and Other Determinants of Health Technologies	-	++	++	+
Societal, Legal and Ethical Impact Assessment	+	++	++	++
Analysis of Diffusion and Utilisation	+	-	-	-
Analysis / Monitoring of Technology Trends	+	-	+	-
Systematic Review with or without Cost-Effectiveness Analysis	++	-	-	+

(Source: Perleth et al. 1998)

Greece: There are some studies and analyses reported, but a 1997 law provided for the institution of a national HTA agency which is currently being implemented.

Ireland: There are plans to establish a national committee while there is growing interest reported into HTA.

Italy: There is a growing number of studies and analyses performed in Italy but a considerable low institutional infrastructure at the national and regional level. In the past, HTA is considered to have little impact on health policy [France 1994] with more recent indication on growing impact [HTA Europe 1998].

Luxembourg: There is only little HTA activity reported in Luxembourg, although interest may be growing.

The Netherlands: The Netherlands have a long history of HTA activities. A National Fund was established in 1988. Policy studies are performed - among others - by the Dutch Health Council who identifies technologies that warrant further evaluation and prepares the decision-making regarding coverage of technologies within the scope of the Hospital Provision Act. The Hospital Provision Act regulates in section 18 performance of a number of about 15 procedures with ministerial permission. These include transplants, invasive cardiac procedures, dialysis and neonatal intensive care. The Health Insurance Funds Council (Ziekenfondsraad) funds in its Investigative Medicine programme primary research studies after they have been selected in a process of priority setting and extensive review. They are considered as HTA because the study results assume a fundamental role in coverage decisions. Accordingly, they often contain also economic evaluations. The currently funded studies are the result of the "126 List", a needs-based list of technologies published in 1994, for which cost-effectiveness should be established. However, despite substantial activity, HTA in the Netherlands has been regarded as

insufficiently co-ordinated [Banta et al. 1995, Dutch Ministry of Health 1996]. Furthermore, HTA reports seem not always have the desired impact. Van den Heuvel et al. (1997) e. g. examined four cases of HTA commissioned by the Dutch government, namely breast cancer screening, serum alpha feto protein screening, in vitro fertilisation and lung transplantation, in which outcomes of HTA did not substantially affect the decision-making process.

Norway: A national HTA agency was established in 1997.

Portugal: Growing interest is reported and some studies and analyses performed.

Spain: Within Europe, Spain has developed substantial HTA activities both at a national and provincial as well as at an international level. An Advisory Board on High Technology was established in 1984 in Catalonia which eventually led to the Catalan Agency for Health Technology Assessment. The Basque Country Office for Health Technology Assessment was established in 1992.

Sweden: Sweden has substantial HTA activities on all levels of health care. SBU employs a staff of 23 people and has a yearly budget of 35 million SEK. It is the national agency for technology assessment, established in 1987 with a continuous expansion of mandate and budget to encompass all aspects (including financial and organisational) of health and dental care. The policy impact of studies and analyses is growing. Since 1989, SBU has produced more than 30 systematic reviews on the effectiveness of medical interventions, between 3 and 5 per year. Examples of reviews produced in the past are treatment for back pain, for mild hypertension, prevention of disease by antioxidants, prevention by lifestyle interventions, prevention by smoking cessation and by screening for bone density and preventive. SBU also provides training for HTA. Since 1997, an "early warning" programme for early detection of emerging technologies is in operation.

United Kingdom: There is substantial HTA activity on all levels of health care and the NHS R&D programme mentioned above funds more than one hundred research projects within its HTA programme since its inception in 1993. Investment in HTA is substantial and growing. Great attention is being paid to HTA priority setting and dissemination of results. The UK has several important institutions, including the National Coordinating Centre for Health Technology Assessment, the UK Cochrane Centre, the NHS Centre for Reviews and Dissemination, the Centre for Evidence-based Medicine, to name a few.

5.3 Guidelines development activities

Finland: The Finnish Medical Society Duodecim has since 1989 produced a collection of guidelines for primary care, the Physicians Desk Reference and Database as a computerised version and a book [Mäkela 1997]. The Guidelines are usually developed for a specific clinical

topic and edited by a team of general practitioners to suit the populations and working arrangements in primary care. The computerised version is updated every four months. In 1996, a national guidelines development programme was initiated to develop guidelines on systematic reviews and yearly updates. Dissemination is by the electronic database and publication in professional journals.

France: ANAES (formerly ANDEM) develops national clinical practice guidelines (based on the method developed by AHCPR) and Reférénces Médicales (and paramedicales) Opposables (RMOs) under the 'Clinical Guidelines and Medical References Programme'.[1] Databases: 1.) ANAES [http://www.anaes.fr]. 2.) S.N.F.G.E French National Society of Gastro-Enterology [http://www.snfge.asso. fr/indexa.html]. 3.) FNCLCC (Fédération Nationale des Centres de Lutte Contre le Cancer) [http://www.fnclcc.fr:80/-sci/sor.htm] [Maisonneuve et al. 1997].

Germany: After a call for more "standardisation" in clinical practice, the development of clinical practice guidelines has increased substantially over the past three years (Sachverständigenrat 1994). A number of about 300 guidelines were predominately developed by medical scientific societies and through an umbrella organisation (Arbeitsgemeinschaft der Wissenschaftlichen Medizinischen Fachgesellschaften, AWMF) through the internet disseminated. The poor quality of most of the guidelines currently available in Germany led to concerns regarding the developmental process of guidelines [Helou et al. 1998]. The Federal Agency for Quality Assurance took the lead for establishing recommendations for the development of guidelines, which are now widely accepted [Bloch et al. 1997, Ollenschläger et al. 1998a]. Increasingly, guidelines are also developed by quality circles in the ambulatory care sector [Gerlach et al. 1998].

In early 1998, the German Medical Association and the National Association of Statutory Health Insurance Physicians announced the development of a German Guideline Clearinghouse with the following aims: definition of quality criteria for guidelines; critical appraisal of guidelines; information on quality and effects of guidelines (Ollenschläger et al. 1998b).

[1] RMOs are regulatory medical references developed since 1994 and facilitated under the Medical Agreement (Convention Médicales) by the representatives of national sickness funds (Sécurité Sociale) and representatives of the medical professionals. Topics are chosen by the Medical Agreement parties and transmitted to ANAES. 243 RMOs have been developed for diagnostic tests and treatment on the basis of ANAES consensus recommendation identifying inappropriate care and discourage inappropriate practices by financial sanctions for individual doctors exceeding the threshold of treatments that are adverse to the RMOs. In addition, ANAES has developed 35 CPG, all of which have been developed throughout a systematic review and consensus of experts on the national level. Systematic reviews are performed within an individual protocol (the search being focused on and confined to MEDLINE, EMBASE and PASCAL database. There is limited co-ordination between the Cochrane Collaboration. Overall, ANAES has worked on 60 clinical topics between 1990 and 1998. Guidelines and RMOs do not consider cost aspects. They are either based on symptoms or clinical conditions. Regional dissemination of guidelines is encouraged throughout the media, a high degree of acceptance by the medical professions, and supported by audits (by official 'medical inspectors') and regulatory measures. The national guidelines development programme in France is recognised for its exceptional professional acceptance and impact on clinical practice (evaluated by surveys among medical professionals).

The Netherlands: Between 1991 and 1996, 53 guidelines have been produced by the Dutch College of General Practitioners in expert groups. The development process involves 16 steps and drafts for guidelines are sent to 50 general practitioners selected at random. Topics have been acne, diabetes, diarrhoea, migraine, subfertility, urinary tract infections and others. The process includes updating, but no systematic literature review. Dissemination is supported by background leaflets. For the hospital sector, National Organization for Quality Assurance in Hospitals (CBO) has since 1982 more than 60 (mainly consensus-based) guidelines in co-operation with Dutch medical scientific societies developed.

Spain: Guidelines are developed by the health institute of the Ministry of Health for primary care (mostly expert panels guiding preventive and public health measures) and scientific societies for consensus conferences in specialised care. Most guidelines are developed on the national level. Some guidelines have been produced by communities and few on an institutional and local level.

Sweden: A number of SBU reports has been disseminated as guidelines, with some (e. g. guidelines on preoperative routines) being evaluated and related to cost savings [Mäkela 1997].

United Kingdom: There is substantial activity reported within the NHS Research & Development Programme and 1.5 % of the NHS budget is devoted to the development of clinical practice guidelines. Professional guidelines are predominately developed by the Royal College of Physicians on the ground of explicit quality criteria.

Databases: 1.) SIGN (Scottish Intercollegiate Guidelines Network), UK 2.) Royal College of General Practitioners, GB (General Practice)[http://www.rcgp.org.uk/index2.htm] 3.) Centre for Health Services Research/University of Newcastle, UK [http://www.ncl.ac.uk /~ncenthsr/publicn/publicn.htm].

6 BEST PRACTICE MODEL CONCEPT ON CAROTID ARTERY STENOSIS

This model is intended to serves as an illustrative example for integrating heterogeneous pieces of evidence in order to complete the picture of what is known for a specific intervention in the whole spectrum of patients with a given disease. The model is therefore incomplete and not based on a complete, systematic literature search.

Specifically, the case study is determined to propose a compound utilisation strategy by health care activities in order to identify best practice in health care for categories patients with carotid artery disease.

Summary background information:

A. Priority setting for best practice: Stroke imposes a substantial socio-economic burden on the industrialised world, inducing up to 10-12 per cent of overall death. Moreover, stroke frequently causes serious impairment, disability and handicap, and is amongst the most common causes of adult disability in the developed countries. Indirect and direct costs are substantial (e. g. amounting to US$ 25 billion per year in the United States). Therefore, major interest exists to prevent stroke and stroke related disability. Ten per cent of all cases of stroke are caused by extracranial stenotic carotid artery disease.

B. Evidence-based information: A number of strategies has been developed to prevent ischaemic stroke. In the late 1980s six major co-operative prospective randomised controlled trials (RCTs) were undertaken to investigate the benefit of carotid endarterectomy (CEA) in reducing the risk of stroke in patients with symptomatic and asymptomatic carotid stenosis compared to medical management. These studies concluded that CEA is clinically efficacious for certain groups of good-risk patients with high-grade carotid stenosis [NASCET 1991, ECST 1991, VASCS 1993]. Surgery did not prove to be efficacious in patients with low grade symptomatic carotid stenosis [ECST 1991]. Evidence on the efficacy of CEA is not certain in patients with asymptomatic carotid stenosis because of conflicting evidence [ACAS 1995, CASANOVA 1991, VACS 1991, Strukenberg 1997]. Clinical benefit in moderate stenosis in symptomatic patients is also uncertain. A synopsis of these trials formed the basis for several clinical guidelines on CEA that commonly conclude a clear indication for CEA in symptomatic high-grade carotid stenosis for low risk patients and surgeons whose surgical morbidity and mortality rate is less than 6%, and issue that the treatment of asymptomatic patients by CEA is uncertain [AHA 1994, Findlay et al. 1997].

Stenting for carotid artery disease is subject to randomisation within one RCT. There is no evidence data available to date.

As alternative interventions, several medical therapies are reported suitable for the prevention of stroke. Warfarin medication is effective for stroke prevention in patients with nonvalvular atrial fibrillation which accounts for a non-major cause of patients suffering from stroke [Gage et al. 1995, Gage et al. 1996]. Costs and side effects have limited the use of Ticlopidine, although it remains useful for patients who are hypersensitive to aspirin [Oster at al. 1996]. Aspirin is the preferred medication for medical stroke prevention, in spite of increasing evidence of its varying efficacy with etiologic subtypes of stroke.

For asymptomatic patients, a recent meta-analysis of five trials which enrolled a total of 2.440 patients showed a moderate reduction of 2% in about three years of the absolute risk of ipsilateral stroke after carotid endarterectomy [Benavente et al. 1998].

In spite of some remaining uncertainty in evidence of CEA for a number of indications, we are not aware of a systematic review with the exemption of one meta-analysis of RCTs for symptomatic patients [Goldstein et al. 1995].

Economic analysis has shown that CEA is a cost-effective strategy. Results in asymptomatic patients have indicated that CEA is a less cost-efficacious intervention, or sensitive to a number of parameters [Jakubowski et al. 1998; Kuntz et al. 1995].

C. Complementing information by observational studies: A number of information can be obtained by studies evaluating the effectiveness of CEA in the community setting, for example providing information that:

- Outcomes under community conditions are inferior to the outcomes of trial participants from large scale Randomised Controlled Trials as far as documented by Medicare administrative databases [Strukenberg 1997, Wong 1996].
- Advanced age, however does not seem to be a significant risk factor in carotid surgery [Kerdiles et al. 1997, Strukenberg et al. 1997].
- Results by appropriateness ratings and other appropriateness studies indicate that procedures might be uncertain in up to 30 % of cases and inappropriate in up to 30% [Winslow et al. 1988]. Most studies have related inappropriate or uncertain performance of the procedure to high perioperative and medium term risks by centres and patients and diagnostic criteria indication for the intervention.
- Decision analysis has brought attention to the coexistence of coronary artery disease [Sarasin et al. 1995]
- Database information and appropriateness ratings have provided information on the relation between effectiveness of CEA and co-morbidity factors [Kerdyles 1997]

All activities are based on evidence but for individual patients or groups of population, complementary information has to be obtained (e. g.: is Ticlopidine effective in patients with a

lower compliance?). A more detailed perspective could be obtained by further subdivisions for example of patient group 2 (see Figure 9) into a number of age groups.

Conclusion:

To further develop this integrative approach, databases with different sources of evidence (e. g. from efficacy trials, economic evaluations, administrative databases, appropriateness studies) need to be linked. One way to establish integrated models is to build interdisciplinary networks that exchange data and develop methods for (statistical) integration of different types of data. Since this approach is disease-specific, priorities could be set in order to meet the needs of a changing morbidity and mortality patterns of the European population.

Fig. 9: Evidence-Based Health Care activities within the three compartments

7 RECOMMENDATIONS FOR EUROPEAN CO-ORDINATION

Within the context of best practice in health care, the scope for European-wide support and co-ordination of public health related activities can be identified in the following areas:

I. Research into best practice-related activities, related disciplines, methods and tools.

II. Development of public health policy-related activities that aim to improve decision-making along the lines of best practice in health care.

7.1 Recommendations for research into best practice-related activities, related disciplines, methods and tools

The recommendations concerning research and development of the different areas of best practice rely on the issues depicted in each chapter.

The most important recommendation focuses on quality and quantity of evidence of the various actions of health care policy, health system organisation and financing and health care provision in their effects on health, and health system effectiveness and cost-effectiveness. The factors of interest include aspects on safety, efficacy and effectiveness, cost-effectiveness, appropriateness, necessity, satisfaction, outcomes, social and ethical implications. The most important factor is health outcome. Areas in which the European Union should initiate action are collection and provision of evidence from primary and secondary studies, dissemination and implementation of findings and evaluation of best practice activities.

Integrative approaches (such as systematic reviews of heterogeneous pieces of evidence) need support from networks which allow for exchange of different types of data. At the EU level, interdisciplinary networks for specific high-priority diseases should be supported that develop models for integrating different sources of evidence. Based on the experience of the preliminary concept presented in this report, such an approach seems to be feasible.

The research recommendations are summarised in table 8.

Table 8: Research Recommendations

Area	Data	Methods
Primary Data/Basic Information	Improve and increase quality and quantity of primary research: ξ Stimulate and launch prospective studies, including economic evaluations alongside clinical trials ξ Improve access to conducted studies ξ Include industry producing trials ξ in particular promoting prospective studies to obtain primary data/basic information in how system financing and organisation arrangements effect the public's health and the impact of consumer choices, personal behaviour and socio-economic factors on health	Information technology: ξ Promote (compulsory) registration of all RCTs and (mandatory) publication of results in order to minimise publication bias ξ Indexing integrated sources ξ understanding sources of bias, impact of bias Increase transferability of results from randomised controlled trials: ξ conduct large *simple* trials in community settings and modify units of randomisation (e. g. randomising patients to different practices or geographic areas)
Synthesis	Increase number and quality of systematic reviews: ξ refine and standardise literature retrieval, assessment and synthesis methods in order to minimise bias in systematic reviews	Pooling Information from different designs and sources: ξ in particular in regard to Public Health interventions such as prevention (including immunisation, screening), health protection and promotion, and health education ξ establish disease-specific integrative networks
Dissemination and Implementation	Increase quantity and quality of studies on dissemination and implementation methods and barriers: ξ Developing a systematic methodology to address barriers on all executive areas of health policy and service provision for implementation of EBHC and consequently promote research into this area. This research should also cover transferability of results from studies. ξ Collect evidence on the most effective ways of dissemination and implementation (experimental studies , observational studies) ξ Exploration of the potential of mass media to promote information for consumers and patients.	Measurement optimisation: ξ prospective studies into barriers to change clinical and policy from 'practice' to 'good' (or best possible) practice
Monitoring / Evaluation	Conduct studies on the effects of best practice activities: ξ increase activities into studies addressing the actual impact of HTA results into health policy making	Develop criteria to measure impact of research findings on policy and practice

7.2 Development of public health policy-related activities that aim to improve decision-making along the lines of best practice in health care

The development of European public health policies should focus on three directions:

1. Improve availability and use of evidence.
2. Promote existing activities in best practice.
3. Promoting a register system for European Public Health.

7.2.1 Improving availability and use of evidence (including systematic reviews)

A. The European Union should promote that the findings of HTA and EBM from across the world are readily available across all countries of the European Union. This also applies to the applicant Member States and could be associated with a database that collects systematic reviews conducted in the Member States.
B. There is a need to promote education in how to access and practice EBHC throughout the European Union. An educational initiative at the European level should gather experts from the Member States with the aim at setting criteria and standards of what constitutes best practice skills at the managerial and political. This could lead to recommendations which could assist existing educational programmes and courses in improving their curricula, and could be the basis for planning of new programmes.

7.2.2 Promote existing activities in best practice

A. **HTA:** The recent HTA Europe Report has already concluded to four main areas of support which shall be shortly summarised in this context: (a) A board or steering body representing all Member States; (b) an administrative centre to support all activities of the network; (c) a mechanism to assure full use of the relevant expertise and commitment of different programmes and individuals on Europe; (d) funding to cover the activities inherent in a European programme of work. These recommendations are also directly related to the concept of best practice and should therefore be supported.
B. **Guidelines development:** The report has indicated some scope for developing guidelines at the European level in regard to health promotion and disease prevention. To promote the guideline development process in disease prevention, a mechanism to assure full use of the relevant expertise and commitment of different programmes and individuals in Europe

would have to be set to work, equivalent to the proposals in the HTA Europe project. In all other areas, the guideline formulation process should remain within the domain of the individual Member States. However, matter of consideration could be to promote a common process for the systematic literature review, while consensus processes would have to be undertaken in the individual countries. There is no scope at present for a common developmental process for clinical guidelines or a European Clearinghouse for example in regard to the diagnosis or therapy of diseases, as these areas do not comply to the legal competence of the Community. However, a European guideline database could enable to identify examples of successful development and implementation of clinical practice guidelines. In areas where the Union has an explicit competence for joint action (disease prevention, health promotion), a joint expert and monitoring process of a guidelines development process would comply with the Maastricht Treaty. For this purpose, suitable Public Health areas needed to be identified.

C. **EBM:** Established international databases should be supported. Support should be directed towards co-ordination of efforts of organisations, working groups and networks on order to avoid unnecessary duplication of work. Also of importance is the provision of resources to establish a dissemination strategy of these databases.

D. **Methods:** Established international databases on services and technologies for safety, efficacy, and effectiveness should be further extended for appraised studies on health outcomes, equity, cost-effectiveness, appropriateness, necessity, satisfaction, quality, cost-effectiveness, and social and ethical effect.

E. **Health Economics:** Research should be promoted to gain information on the effect of for example health services volume, co-payment systems and user charges, global budgets, provider payment systems, contracting arrangements, priority setting, skill-mix and institutional sizes on health outcomes. Current deficits in economic analysis of health interventions and health system organisational and financial structures support the argument in favour of a policy database in the European Union. In this respect, the existing infrastructure (e. g. NEED in York) should be supported.

7.2.3 Promoting information systems for European Public Health

A. Establishment of a European Health Policy Information System: A European health policy information system should be promoted to provide a foundation for evidence-based policy making on the European level. This database would add value to existing systematic reviews which primarily focus on clinical matters for individual and public health. Database information of a European Health Policy Information System should integrate the micro level approach (e. g. evidence on the efficacy of treatments in clinical practice in EBM) with the macro level approach (i. e. evidence on the effect of budgets on health outcomes) and

should be gathered on matters explicitly stated in the Treaty of Amsterdam (preventing human illness and diseases, in particular major health scourges; obviating sources of danger to human health; promoting research into the causes, transmission and prevention of diseases; health information and education; measures to combat diseases related to drug dependence, including information and prevention). The database would include interventions preferably evaluated by RCTs and systematic reviews.

B. Establishment of a European Public Health Information System: With regard to the freedom of movement of individuals, goods, services and capital, there is a need for more information sharing on the health of the Europeans. This could be realised within a health status monitoring system at the European level which already has been initiated (e. g. for cancer indicators). More work has to follow into the establishment of comparable key indicators of health status by public health experts and epidemiologists. This activity should be co-ordinated with already existing activities (for example the Organisation of Economic Co-operation and Development and the World Health Organization, Regional Office for Europe).[1] Details of such a monitoring system are beyond the scope of this project. However, it should be noted, that a register for health indicators is a prerequisite for examining effects of health-related policies and interventions along the line of best practice activities. In addition, it has been shown in the past, that health threats might emerge in the way that rapid evidence-based policy making is needed (i. e. re-epidemic of tuberculosis, slow virus diseases, viral infections). A health status monitoring system is needed for early detection of emerging health scourges and the development of policies assisted by best available evidence.

C. Making the concept of EBHC for Community action more explicit in areas of Public Health:

There are two initiatives that could follow from these recommendations.

1. Independent bodies could be set up specifically to provide summaries of scientific evidence on health promotion and disease prevention within a “European Task Force on Health Promotion and Disease Prevention". The US Preventive Services Task Force and the Canadian Task Force on the Periodic Health Examination could serve as prototypes.
2. A consumer information system for matters of public health (‘Consumer Library for Public Health’) to enable them to make consumers more aware of their share in promoting and maintaining public health.

[1] A **legal** provision for the establishment of statistic registers in the member states on the basis of such indicators would be up to the mandate of the European Parliament.

7.3 The following step

The purpose of this project was to develop a framework for Community action in the field of Public Health. The framework was developed in the way that activities and methods constituting best practice have been collected within an international, interdisciplinary collective effort. The summary has been used to synthesise the state of art in best practice, and at the same time to identify deficits in which the European Union should launch further research. A second conclusion was the translation of the findings into concrete policy recommendations for a joint effort at the Community level. For the practical purpose of translating the recommendations into a new policy for public health programmes in the future European Union, the next step should be ***to identify specific priority areas for European Public Health actions.*** This would require an international expert team (mainly epidemiologists and public health experts) which should be set up to form a concerted action to identify those preventable diseases of major burden to the Europeans (for example cardiovascular diseases or certain types of cancer). Such a team should provide public health expertise throughout the European Union and should also provide oversight over the public health situation and epidemiology of preventable diseases in the candidate Member States to the European Union.

8 REFERENCES

1 Aday LA, Begley CE, Lairson DR, Slater CH (1998) Evaluating the Healthcare System. Effectiveness, Efficiency and Equity. Chicago, Illinois: Health Administration Press 1998.

2 Alban A (1994) The role of economic appraisal in Denmark. Soc Sci Med 38: 1647-1652

3 Alpert HR, Emanuel L (1998) Comparing utilization of life-sustaining treatments with patient and public preferences. J Gen Intern Med. 13: 175-81

4 Andrade SE, Walker AM, Gottlieb LK, Hollenberg NK, Testa MA, Saperia GM, Platt R (1995) Discontinuation of antihyperlipaemic drugs - do rates reported in clinical trials reflect rates in primary care settings? N Engl J Med 332: 1125-31

5 Angood PB, Merrel RC, Hardy JR, Ivy ME (1997) Benchmarking for best practice in critical medicine: can it realistically be done? Best Pract Benchmarking Healthc 2:154-161

6 Audet AM, Greenfield S, Field M (1990) Medical practice guidelines: current activities and future directions. Ann Int Med 113: 709-714

7 Banta HD (1997) Evaluation in Health Care. In: Long AF and Bitzer E (eds.) Health Outcomes and Evaluation: Context, Concepts and Successful Applications. European Clearing House on Health Outcomes, Nuffield Institute for Health, University of Leeds. p. 23-31

8 Banta HD, Oortwijn WJ (1998) Health Technology Assessment in Europe: the challenge of coordination. Final Report of the HTA Europe Project. TNO Prevention and Health: Leiden 1998

9 Banta HD, Oortwijn WJ, Van Beekum WT (1995) The organization of health care technology assessment in the Netherlands. Rathenau Institute: The Hague

10 Banta HD, Perry S (1997) A history of ISTAHC. Int J Technol Assess Health Care 13: 430-453

11 Beaumont M (1994) Understanding "best practice" in health & community services. Aust Nurs J 1: 32

12 Benavente O, Moher D, Pham B (1998) Carotid endarterectomy for asymptomatic carotid stenosis: a meta-analysis. BMJ 317: 1477-1480

13 Bernstein SJ, Hofer TP, Meijler AP, Rigter H (1997) Setting standards for effectiveness: a comparison of expert panels and decision analysis. Int J Quality Health Care 9: 255-263

14 Berwick DM (1994) Eleven worthy aims for clinical leadership of health system reform. JAMA 272: 797-802

15 Birch S, Gafni A (1992) Cost-effectiveness/utility analyses: did current decision rules lead us where we want to be? J Health Econ 11:279-296

16 Bitzer EM, Busse R, Kohlmann T, Lühmann D, Perleth M (1999) Health Technology Assessment im internationalen Kontext: Wo steht Deutschland? Z ärztl Fortbild Qual sich 93:33-38

17 Black N (1996) Why we need observational studies to evaluate the effectiveness of health care. BMJ 312: 1215-1218

18 Bloch RE, Lauterbach K, Oesingmann U, Rienhoff O, Schirmer HD, Schwartz FW (1997) Bekanntmachungen: Beurteilungskriterien für Leitlinien in der medizinischen Versorgung Beschlüsse der Vorstände von Bundesärztekammer und Kassenärztlicher Bundesvereinigung. Dt Ärztebl 94: A-2154-2155

19 Bond S, McColl E (1997) What is the difference between health status and health outcome? J Health Serv Res Policy 2: 63

20 Bradley MD, Sheldon TA, Watt IS (1997) Influenza vaccine and older people: an evidence-based policy? [editorial] Br J Gen Pract. 47: 271-2

21 Britton A, McKee M (1997) The implication of evidence-based medicine. Unpublished document, presented at the WHO Meeting on Reshaping Health systems towards health outcomes. Celle, Germany, 17.-19. December 1997

22 Britton A, McKee M, Black N, McPerson K, Sanderson CV, Bain C (1997) Choosing between randomised and non-randomised studies: a systematic review. Report to the NHS HTA Programme

23 Brook RH, Kosecoff JB, Park RE, Chassin MR, Winslow CM, Hampton JR (1988) Diagnosis and Treatment of Coronary Disease: Comparison of Doctors' Attitudes in the USA and the UK. Lancet 1: 750-3

24 Burack RC, Gimotty PA (1997) Promoting screening mammography in inner-city settings. The sustained effectiveness of computerized reminders in a randomized controlled trial. Med Care. 35: 921-31

25 Busse R (1996) Transferability of Results Across Health Care Systems. Unpublished results, presented at a WHO Meeting on the Evaluation of Cost Effectiveness in Health Care in Celle, Germany, 9.-11. December 1996

26 Busse R (1998) Anwendung und Weiterentwicklung von Konzepten und Methoden der Gesundheits system-forschung im deutschen Kontext. Habilitationsschrift. Hannover.

27 Butterfoss FD, Goodman RM, Wandersman A (1996) Community coalitions for prevention and h ealth promotion: factors predicting satisfaction, participation, and planning. Health Educ Q. 23: 65-79

28 Camp RC (1989) Benchmarking: The Search for Industry Best Practices that Lead to Superior Performance. White Plains, New York. Quality Research

29 Canadian Coordinating Office for Health Technology Assessment (1997) Guidelines for Economic Evaluation on Pharmaceuticals. 2nd edition, November 1997

30 Canadian Task Force on the periodic Health Examination (1979) Task Force Report: t he periodic health examination. Can Med Assoc J 121: 1-45

31 Candelora E, Pfeiffer E (1994) Screening for memory disorder: a best practice model. Tampa, Fla: National Institute on Long Term Care and Alzheimer's Disease.

32 Carnegie J (1994) Best practice and enterprise bargaining. Australian Health Review 17: 37-46

33 Carr-Hill R (1998) Evidence-based healthcare: flaws in the paradigm? J R Soc Med 91(Suppl. 35): 12-14

34 CASANOVA Study Group (1991) Carotid surgery versus medical therapy in asymptomatic c arotid stenosis. Stroke 22: 1229-1235.

35 Caspari AF (1996) The ambiguous relationship b etween p ractice variation and appropriateness of care: an agenda for further research. Health Policy 35: 247-265

36 Caspari SF (1998) Guidelines in Health Care. The Cost Effectiveness of Health Care Guidelines. Report of a WHO Conference. Schriftenreihe des Bundeministeriums für Gesundheit Band 104 . Baden-Baden: Nomos 1998

37 Chapuis PH, Killingback MJ, Anseline PF, Bell AM, Bokey EL, Chapuis PH, Cohen JR, Collopy BT, Ctercteko GC, Cunningham IG (1996) Best practice parameters for management of rectal cancer: recommendation of the Colorectal Surgical Society of Australia. Aust N Z J Surg 66: 508-514

38 Chen AM, Wismer BA, Lew R et al. (1997) "Health is strength": a research collaboration involving Korean Americans in Alameda County. Am J Prev Med 13(6 Suppl): 93-100.

39 Clancy CM, Kamerow DB (1996) Evidence-based medicine meets cost-effectiveness analysis. JAMA 276: 329-330

40 Cochrane A.L, St Leger AS, Moore F (1978) Health services input and mortality output i n d eveloped countries. Journal of Epidemiology and Community Health 32: 200-205

41 Collins JP (1997) 'Best Practice' in surgical management of breast cancer. Med J Aust 166: 620-621

42 Commission of the European Communities (1998) Communications from the Commission to the Council, the European Parliament, the ec onomic and social committee and the c ommittees of the regions on the development of public health policy in the European Community. Brussels, 15.04.1998 COM(1998) 230

43 Commonwealth of Australia, Department of Health and Family Services (1996) Australian h ealth organisations taking up b est practice c hallenge. The Best Practice in the Health Sector Program. Canberra, Australia: Australian Government Publishing Service 1996

44 Conrad KA, Rice S, Harmon MM (1996) Composing our future: a retrospective and forecast of a speciality practice's achievements in a best practice. Best Practice Benchmarking Healthc 1: 94-100

45 Cook DJ, Greengold NL, Ellroth AG, Weingarten SR (1997b) The relation b etween systematic reviews and guidelines. Ann Int Med 127: 210-216

46 Cook DJ, Guyatt GH, Laupacis A, Sacket SL (1992) Rules of evidence and clinical recommendations on the use of antithrombotic agents. Chest 102: 305S-311S

47 Cook DJ, Mulrow CD, Haynes RB (1997) Systematic reviews: Synthesis of best evidence for clinical decisions. Ann Int Med 126: 376-380

48 Coulter I, Adams A, Shekelle P (1995) Impact of vaying membership on ratings of appropriateness in consensus panels: a comparison of multi- and single disciplinary panel. Health Services Research 30: 577-591

49 Coyle D, Davies L (1993) How to assess cost-effectiveness: elements of a sound economic evaluation. In: Drummond MF and Maynard A (eds.): Purchasing and providing cost-effective health care. Edinburgh: Churchill Livingstone 1993

50 Crawford ED, Bennett CL, Stone NN et al. (1997) Comparison of perspectives on prostate cancer: analyses of survey data. Urology 50: 366-72.

51 Cuyler A.J (1995) Need: The idea won't do - but we still need it. Social Science and Medicine 40: 727-730

52 Cuyler AJ, Wagstaff A (1992) QALYs versus HYEs: A theoretical Exposition. Discussion Paper 99. York: Centre for Health Economics

53 Davidoff F, Haynes B, Sackett D, Smith R (1995) Evidence-based medicine. A new journal to help doctors identify the information they need. BMJ 310: 171-176

54 Davies L, Coyle D, Drummond M (1994) Current status of economic appraisal of health technology in the European Community: Report of the Network. Soc Sci Med 38: 1601-1607

55 Davies P, Howden-Chapman P (1996) Translating research findings into health policy. Soc Sci Med 43: 865-872

56 Davis DA, Taylor-Vaisey A (1997) Translating guidelines into practice. A systematic review of theoretic concepts, practical experience and research evidence in the adoption of clinical practice guidelines CMAJ 157: 408-16

57 Dixon S, Booth A, Perrett K (1997) The application of evidence-based priority setting in a District Health Authority. J Public Health Med. 19: 307-12

58 Donabedian A (1966) Evaluating the quality of medical care. The Milbank Memorial Fund Quarterly 44: 166-203

59 Donabedian A (1988) The quality of care: how can it be assessed? JAMA 260: 12

60 Drummond M, Torrance G, Mason J (1993) Cost-effectiveness league tables: more harm than good? Soc Sci Med 37: 33-40

61 Drummond MF (1989) Output measurement for resource allocation in health care. Oxfor Rev Econ Policy 5: 58-74

62 Drummond MF, Davies L (1991) Economic analysis alongside clinical trials. Int J Technol Ass Health Care 7: 561-573

63 Drummond MF, O'Brien B, Stoddart GL, Torrance GW (1997) Methods for the economic evaluation of health care programmes. Oxford University Press, Oxford 2 nd edition

64 Drummond MF, Stoddart G (1995) Assessment of health producing measures across different sectors. Health Policy 33: 219-231

65 Ducket S (1995) Best practice in the health sector. J Qual Clin Practice 15: 133-137

66 Dutch Ministry of Health (1996) Medical technology assessment and efficiency in health care. Rijswijk

67 Eddy DM (1991) Oregon's methods: did cost-effectiveness analysis fail? JAMA 266: 2135-2141

68 Egger M, Davey-Smith G, Schneider M, Minder C (1997) Bias in meta-analysis detected by a simple, graphical test. BMJ 315: 629-634

69 Egger M, Smith GD (1995) Misleading meta-analysis [editorial] BMJ 310: 752-754

70 Entwistle VA, Sheldon TA, Sowden A et al. (1998) Evidence-Informed Patient choice. Int J Technol Assess Health Care 14: 212-215

71 Epstein Am (1998) Rolling down the runway: the challenges ahead for quality report cards. JAMA 279: 1691-6

72 Epstein RS, Sherwood LM (1996) From outcomes research to disease management: a guide for the perplexed. Ann Int Med 124: 832-842

73 EUR-ASSESS (1997) Report from the EUR-ASSESS Project. Int J Technol Assess Health Care 13: 133-143

74 European Carotid Surgery Trialists' Collaborating Group *(ECST)* (1991) MRC European Carotid Surgery Trial: interim results for symptomatic patients with severe (70-99%) or mild (0-29%) carotid stenosis. Lancet 337: 1235-1243

75 Executive Committee for the Asymptomatic Carotid Arteriosclerosis Study *(ACAS)* (1995): Endarterectomy for Asymptomatic Carotid Artery Stenosis. JAMA 273: 1421-1428

76 Fahey T, Griffiths S, Peters TJ (1995) Evidence-based purchasing: understanding results of clinical trials and systematic reviews. BMJ 311: 1056-9

77 Fahey TP, Peters TJ (1996) What constitutes controlled hypertension? Patient based comparison of hypertension guidelines. BMJ 313: 93-96

78 Feder G (1997) Evaluation of health care practice guidelines: do they change practice? WHO Meeting on Guidelines in Health Care Practice. Schloß Velen, Germany, January 1997

79 Field MJ, Lohr KN (eds.) (1992) Guidelines for clinical practice: from development to use. Institute of Medicine. Washington D.C.: National Academy Press 1992

80 Findlay JM, Tucker WS, Ferguson GG, Holness RO, Wallace MC, Wong JH (1997) Guidelines for the use of carotid endarterectomy: current recommendations from the Canadian Neurosurgical Society. Can Med Assoc J 157: 653-659

81 Fink A, Kosecoff J, Chassin M, Brook RH (1984) Consensus Methods: Characteristics and Guidelines for Use. Am J Pub Health 74: 979-983

82 Florin D (1996) Barriers to evidence-based policy. Health promotion in primary care changes again. BMJ 313: 894-895

83 France(1994) Centralised versus decentralised funding of evaluative research: impact on medical technology policy in Italy. Soc Sci Med 38: 1635-1641

84 Fraser GM, Pilpel D, Kosecoff J, Brook RH (1994) Effect of panel composition on appropriateness ratings. Int J Qual Health Care 6: 251-5

85 Gage BF, Cardinalli AB, Albers GW, Owens DK (1994) Cost-effectiveness of warfarin and aspirin for prophylaxis of stroke in patients with nonvalvular atrial fibrillation. JAMA 274: 1839-1845

86 Gage BF, Cardinalli AB, Owens DK (1996) The effect of stroke and stroke prophylaxis with aspirin or warfarin on quality of life. Arch Intern Med 156:1829-1836

87 General Accounting Office (1992) Cross Design Synthesis. A new strategy for medical effectiveness research. Washington, D.C.

88 Gerard K, Mooney G (1992) QALY league tables: three points for concern – goal difference matters. Health Economic Research Unit Discussion Paper 04/92. Aberdeen: Departments of Public Health and Economics, University of Aberdeen

89 Gerlach FM, Beyer M, Römer A (1998) Quality circles in ambulatory care: State of development and future perspective in Germany. Int J Qual Health Care 10: 35-42

90 Gerlach FM, Beyer M, Szecsenyi J, Fischer GC (1998) Leitlinien in Klinik und Praxis. Deutsches Ärzteblatt 95: A-1014-1021

91 Getzen TG (1997) Health Economics. Fundamentals and Flow of Funds. New York: John Wiley & Sons 1997

92 Gibbs BF, Guzzetta VJ, Furmanski D (1995) Cost-effective carotid endarterectomy in community practice. Ann Vasc Surg 9: 423-427

93 Glazer WM (1994) What are "Best Practices?" Understanding the concept. Hosp Commun Psych 45: 1067-1068

94 Golledge J, Cuming R, Beattie DK, Davies AH, Greenhalgh RM (1996) Influence of patient-related variables on the outcome of carotid endarterectomy. J Vasc Surg 24: 120-126

95 Goodman C (1998) A framework for outcome measurement: definitions and dimensions. Un published paper presented at the HTA Europe-Meeting: 'Use of health outcomes information in health policy and health systems', Celle, Germany, January 30, 1998

96 Gorelick PB (1995) Stroke prevention. Arch Neurol 52: 347-55

97 Grady GF, Wojner AW (1996) Collaborative practice teams: the infrastructure of outcomes management. AACN Clin Issues 7: 153-8

98 Granados A, Jonsson E, Banta D (1997) EUR-ASSESS Project subgroup report on dissemination and impact. Int J Tech Assess Health Care 13:220-286

99 Gray JAM (1997) Evidence-Based Health Care. New York: Churchill Livingstone 1997

100 Gray JAM, Haynes RB, Sackett DL, Cook DJ, Guyatt GH (1997) Transferring evidence from research into practice: 3. Developing evidence-based clinical policy [editorial] ACP J Club 126: A14-6

101 Gray SF, Bevan G, Frankel S (1997) Purchasing evidence: the corollary of evidence-based purchasing. J Public Health Med 19: 6-10

102 Grimshaw J, Eccles M, Russell I (1995) Developing clinically valid practice guidelines. J Eval Clin Pract 1: 37-48

103 Grimshaw JM; Russel IT (1993) Effect of clinical guidelines on medical practice: a systematic review of rigorous evaluation. Lancet 342: 1317-1322

104 Hadorn DC (1991) Setting health care priorities in Oregon: cost-effectiveness meets the Rule of Rescue. JAMA 265: 2218-2225

105 Haines A, Donald A (1998): Getting research findings into practice: Making better use of research findings. BMJ 317: 72-75

106 Hall JA, Dornan MC (1988) What patients like about their medical care and how often they are asked: a meta-analysis of the satisfaction literature. Soc Sci Med 27: 935-939

107 Halligan AW, Crump BJ, Homa PM, Naftaklin NJ, Taylor DJ (1997) Achieving best practice in maternity care. Br J Obstet Gynaecol 104: 873-875

108 Ham C (1997) Priority setting in health care: learning from international experience. Health Policy 42: 49-66

109 Ham C, Hunter JD, Robinson R (1995) Evidence-based policymaking. BMJ 310: 71-72

110 Hammermeister KE, Shroyer AL, Sethi GK, Grover FL (1995) Why it is important to demonstrate linkages between outcomes of care and processes and structures of care. Med Care 33(Suppl.): OS5-OS16

111 Hannan EL, Siu AL, Kumar D et al. (1995) The decline in coronary artery bypass graft surgery mortality in New York State. The role of surgeon volume. JAMA 273: 209-13

112 Hannan EL, Stone CC, Biddle TL et al. (1997) Public release of cardiac surgery outcomes data in New York: what do New York state cardiologists think of it? Am Heart J. 134: 55-61

113 Hawe P (1994) Measles control: a best practice challenge in public health. Aust J Public Health 18: 241-243

114 Haynes B, Haines A (1998) Barriers and bridges to evidence-based clinical practice. BMJ 317:273-276

115 Heitman E (1996) The public's role in the evaluation of health care technology. Int J Techn Assess Health Care 12: 657-672

116 Helou A, Perleth M, Bitzer E, Dörning H, Schwartz FW (1998) Methodische Qualität ärztlicher Leitlinien in Deutschland. Ergebnisse einer systematischen Untersuchung. Z ärztl Fortbild Qual sich 92: 421-428

117 Herrin J, Etchason JA, Kahan JP, Brook RH, Ballard DJ (1997) Effect of panel composition on physician ratings of appropriateness of abdominal aortic aneurysm surgery: elucidating differences between multispeciality panel results and speciality society recommendations. Health Policy 42: 67-81

118 Hicks N (1997) What are the policy implications of evidence-based medicine? WHO Meeting on Reshaping Health Systems towards Health Outcomes. Celle, Germany, 17-19 December 1997

119 Hicks N (1998) Evidence-Based Health Care. Bandolier 39-9

120 Hobsborn RW, Weiss DG, Fields WS, Goldstone J, Moore WS, Towne JB, Wreight CB and the Veterans Affairs Cooperative Study Group ***(VASCS)***: Efficacy of Carotid endarterectomy for asymptomatic c arotid stenosis (1993). N Engl J Med 328: 221-27

121 Hope T (1996) Evidence-Based Medicine. In: Hope T (ed.) Evidence-Based Patient Choice. London: Kings Fund 1996.

122 Hornberger J, Wrone E (1997) When to base clinical policies on observational versus randomized trial data. Ann Intern Med 127: 697-703

123 Hyams AL, Shapiro DW, Brennan TA (1996) Medical practice guidelines in malpractice litigation: an early retrospective. Journal of Health Politics, Policy and Law 21: 289-314

124 Jacob R, McGregor M (1997) Assessing the impact of health technology assessment. Int J Technol Assess Health Care 13: 68-80

125 Jadad AR (1998) Randomized controlled trials. London: BMJ Publishing Group

126 Jakubowski E, O´Sullivan J, Busse R, Sassi F, Schwartz FW (1998): Ökonomie der Carotisendarteriektomie: Eine Kosten-Nutzwert-Analyse. Langenbecks Arch Chir 383(Suppl. II): 1668

127 Johanneson M (1995) Ecomic evaluation of health care and policy making. Health policy 33: 179-190

128 John J (1997) Auswirkungen von Entgeltsystemen und Versorgungsverträgen auf die ärztliche Versorgung und deren Ergebnisqualität. Unpublished document, presented at the the WHO Meeting on Reshaping Health Systems towards Health Outcomes. Celle, Germany, December 1997

129 Johnston ME, Langton KB, Haynes RB, Mathiew (1994): The effects of computer based clinical decision support systems on clinician performance and patients' outcome: a critical appraisal of research. Ann Intern Med 120: 135-142

130 Kahan JP (1997) Defining Appropriate Health Care. Unpublished document, presented at the WHO Meeting on Reshaping Health Systems towards Health Outcomes. Celle, Germany, December 1997

131 Kahan JP, Bernstein SJ, Leape LL (1994) Measuring the necessity of medical procedures. Medical Care 32: 357-365

132 Kahan JP, Park RE, Leape LL, Bernstein SJ, Hilborne LH, Parker L, Kamberg CJ, Ballard DJ, Brook RH (1996) Variations by specialty in physician ratings of the appropriateness and necessity of indications for procedures. Med Care 34: 512-23

133 Kahn Jr CE, Michalski TA, Erickson SJ, Foley WD, Krasnow AZ, Lofgren RP, Quiroz FA, Rand SD (1997) Appropriateness of imaging procedure requests: do radiologists agree? Am J Roentgenol 169: 11-4

134 Kahn KL, Park RE, Brook RH, Chassin MR, Kosecoff J, Fink A, Keesey JW; Solomon DH (1988) The effect of comorbidity on appropriateness ratings for two gastrointestinal procedures. J Clin Epidemiol 41: 115-122

135 Kahn KL, Parl RE, Vennes J , Brook RH (1992) Assigning appropriateness ratings for diagnostic upper gastrointestinal endopscopy using two different approaches. Medical Care 30: 1016-1028

136 Kerdiles Y, Lucas A, Podeur L, Ferte P, Cardon A (1997) Results of carotid surgery in elderly patients. J Cardiovasc Surg 38: 327-334

137 Kitchiner D, Davidson C, Bundred P (1996) Integrated care pathsways: effective tools for continuous evaluation of clinical practice. J Eval Clin Pract 2: 65-69

138 Klarman HE (1967) Present status of cost-benefit analysis in the health field. Am J Public Health Nations Health 57: 1948-53

139 Kotler P (1984) Social Marketing of health behaviour. In: LW Frederiksen, LJ Solomon, KA Brehony (eds.) Marketing health behaviour: Principles, techniques and applications. New York, Plenum Press 23-39

140 Krakauer H, Lin MJ, Schone EM, Park D, Miller RC, Greenwald J, Bailey RC, Rogers B, Bernstein G, Lilienfeld DE, Stahl SM, Crawford 3rd RS, Schutt DC (1998) 'Best clinical practice': assessment of processes of care and of outcomes in the US Military Health Services System. J Eval Clin Pract. 4: 11-29

141 Kravitz RL, Laouri M, Kahan JP, Guzy P, Sherman T, Hilborne L, Brook RH (1995) Validity of criteria used for detecting underuse of coronary revascularisation. JAMA 274: 632-638

142 La Croix-AZ, Newton KM, Leveille SG et al. (1997) Healthy aging. A women's issue. West J Med. 167: 220-32.

143 Lam E (1994) Benchmarking best practice. Nursing Times 90: 48-51

144 Langley C, Faulkner A, Watkins C (1998) Use of guidelines in primary care--practitioners' perspectives. Fam-Pract. 15: 105-11.

145 Lauterbach KW, Lubecki P, Oesingmann U, Ollenschläger G, Richard S, Straub C (1997) Konzept eines Clearingverfahrens für Leitlinien in Deutschland. Z ärztl Fortbild Qual sich 91: 283-288

146 Leape LL, Park RE, Kahan JP et al. (1992) Group judgements about appropriateness: The effect of panel composition. Qual Assur Health Care 4: 151-159

147 Lee AJ, Huber J, Stason WB (1996) Poststroke rehabilitation in older Americans. The Medicare experience. Med Care 34: 811-25

148 Leidl R (1994) Health Economics as a discipline. J Public Health 2: 131-148

149 Leidl R (1997) Der Effizienz auf der Spur: Eine Einführung in die ökonomische Evaluation. In: Schwartz FW, Badura B, Leidl R, Raspe H, Siegrist J (eds.) Das Public Health Buch. München; Wien; Baltimore: Urban & Schwarzenberg 1998

150 Leidl R (1997) Health Policy Implications of Evidence-based medicine approaches. Unpublished document, presented at the WHO Meeting on Reshaping Health systems towards health outcomes. Celle, Germany, 17-19 December 1997

151 Lerner JC (1998) The National Patient Library. Evidence-based information for consumers. Int J Technol Assess Health Care 14: 81-96

152 Liles JH, Donaldson LJ, Barton AG (1995) How effective are best practice guidelines at changing clinical practice of surgeons? Annu Meet Int Soc Technol Assess Health Care 11, Abstract 13

153 Lohr KN (1994) Guidelines for clinical practice: Applications for primary care. Int J Qual Health Care 6: 17-25

154 Lohr KN, Eleazer K, Mauskopf J (1998) Health policy issues and applications for evidence-based medicine and clinical practice guidelines. Health Policy 46: 1-19

155 Luce BR, Elixhauser A (1990) Estimating costs in the economics evaluation of, medical technologies. Int J Technol Assess Health Care 6: 57-75

156 Lusted LB (1971) Decision making studies in patient management. N Engl J Med 284:416-424

157 Maisonneuve H, Cordier H, Durocher A, Matillon Y (1997) The French clinical guidelines and medical reference programme: development of 48 guidelines for private practice over a period of 18 months. J Eval Clin Pract 3: 3-13

158 Maisonneuve H, Matillon Y (1996) French regulatory references are criteria, not clinical guidelines. BMJ 321: 1306-1311

159 Mäkela M (1997) Strategies of health care guidelines development in Europe. WHO Meeting on Guidelines in Health Care Practice. Schloss Velen, Germany, January 1997

160 Mant J, Hicks N (1996) Health status measurement and the assessment of medical care. Int J Qual Health Care 8: 107-109

161 Margiotta P(1994) Best practice in infant feeding. Health Visit 67: 420

162 Mayberg MR, Wilson SE, Yatsu F, Weiss DG, Messina L, Hershey LA, Colling C, Eskridge J, Deykin D, Winn R, and the Veterans Affairs Cooperative Studies Program 309 Trialist Group ***(VETERANS)*** (1991) Carotid endarterectomy and prevention of cerebral ischemia in symptomatic carotid stenosis. JAMA 266: 3289-2394

163 Maynard A, Bloor K (1995) Help or hindrance? The role of economics in rationing health care. Br Med Bull. 51(4): 854-68

164 Maynard AK (1991) Developing the health care market. The Economic Journal 101: 1277-1286

165 Maynard AK (1997a) The search for evidence on the impact on health care organisation and regulation and health outcomes. Unpublished document, presented at the WHO Meeting on Reshaping Health Systems towards Health Outcomes. Celle, Germany, December 1997

166 Maynard AK (1997b) Evidence-based Medicine: an incomplete method for informing treatment choices. Lancet 349: 126-128

167 Maynard AK, Godfrey C (1994) Alcohol policy--evaluating the options. Br Med Bull 50: 221-230

168 McDonnell J, Meijler A, Kahan JP, Bernstein SJ, Rigter H (1996) Panellist consistency in the assessment of medical appropriateness. Health Policy 37: 139-152

169 McGlynn EA (1997) Six challenges in measuring the quality of care. Health Affairs 16: 7-21

170 McKeown T (1979) The role of Modern Medicine. Oxford: Blackwell, p. 50-54

171 McNair CJ, Leibfried KHJ (1992) Benchmarking: A Tool for Continuous Improvement. London: Harper Collins 1992

172 Mehrez A, Gafni A (1989) Quality-adjusted life-years, utility theory and healthy years equivalents. Med Decision Making 9: 142-149

173 Miller M (1996) Best Practice in wound assessment. Community Nurse 2: 41-42

174 Mitchell JB, Ballard DJ, Whisnant JP, Ammering CJ, Matchar DB, Samsa GP (1991) Using physician claims to identify postoperative complications of carotid endarterectomy. Health Serv Res 31: 141-152

175 Moore WS, Barnett HJM, Beebe HG, Bernstein EF, Brener BJ, Brott T, Caplan LR, Day A, Goldstone J, Hobson RW, Kempczinski RF, Matchar DB, Mayberg MR, Nicolaides AN, Norris JW, Ricotta JJ, Robertson JT, Rutherford RB, Thomas D, Toole JF, Trout HH, Wiebers DO (1995) Guidelines for Carotid Endarterectomy. A Multidisciplinary statement from the Ad Hoc Committee, American Heart Association. Stroke 26: 188-199

176 Mulrow C, Langhorne P, Grimshaw J (1997) Integrating heterogeneous pieces of evidence in systematic reviews. Ann Int Med 127: 989-995

177 Murphy MK, Black NA, Lamping DL, McKee CM, Sanderson CFB, Askham J, Marteau T (1998) Consensus development methods, and their use in clinical guideline development. Health Technology Assessment 2: i-iv, 1-88

178 Murray TS, Campbell LM (1997): Finance, not learning needs, makes general practitioners attend courses: a database survey. BMJ 315:353

179 Naylor CD (1995) Grey zones of clinical practice: some limiots to evidence-based medicine. Lancet 345: 840-842

180 NHS Centre for Reviews and Dissemination (1996) Hospital volume and health care outcomes, costs and patient access. Effective Care Bulletin 2:8

181 Normand C (1997) Impact of management and organization of health care. Unpublished document, presented at the WHO Meeting on Reshaping Health systems towards health outcomes. Celle, Germany, 17-19 December 1997

182 North American Symptomatic Carotid Endarterectomy Trial Collaborators ***(NASCET)*** (1991) Beneficial effect of carotid endarterectomy in symptomatic patients with high-grade carotid stenosis. N Engl J Med 325: 445-451

183 Nuffield Institute of Health (1994) Implementing clinical practice guidelines: can guidelines be used to improve clinical practice? Effective Health Care 8:1-12

184 Nutbeam D (1996) Achieving 'best practice' in health promotion: improving the fit between research and practice. Health Educ Res 11(3) :317-326

185 O'Connor AM, Bunn H, Jacobsen MJ et al. (1998) Tools for Developing and Evaluating Evidence-Based "Decision Aids" for Patients and their practitioners. In: Tugwell et al. Toolkit on Health Technology Assessment. Ottawa, Canada: University of Ottawa, 1998

186 Oberer D, Auckman L (1996) Best Practice: clinical pathways for uncomplicated births. Best Practice benchmarking Healthc 1: 43-50

187 Office of Technology Assessment (1980) The Implications of Cost-Effectiveness Analysis of Medical Technology, OTA-H-126, Washington D.C.

188 Office of Technology Assessment (1994) Identifying Health Technologies that work: Searching for Evidence, Washington D.C.

189 Ollenschläger G, Helou A, Kostovic-Cilic L, Perleth M, Raspe H, Rienhoff O, Selbmann HK, Oesingmann U (1998a) Die Checkliste zur methodischen Qualität von Leitlinien. Ein Beitrag zur Qualitätsförderung ärztlicher Leitlinien. Z ärztl Fortbild Qual sich 92: 191-194

190 Ollenschläger G, Oesingmann U, Thomeczek C, Kolkmann FW (1998b) Ärztliche Leitlinien in Deutschland - aktueller Stand und zukünftige Entwicklung. Z ärztl Fortbild Qual sich 92: 273-280

191 Onel E, Hamond C, Wasson JH et al. (1998) Assessment of the feasibility and impact of shared decision making in prostate cancer. Urology. 51: 63-6.

192 Oster G, Huse DM, Lacey MJ, Epstein AM (1996) Cost-effectiveness of ticlopidine in preventing stroke in high-risk patients. Stroke 25: 1097-1098

193 Penniment M (1997) Best Practice Parameters for management of rectal cancer: recommendations of the Colorectal Surgical Society of Australia. Aust N Z J Surg 67: 215-216

194 Perler BA, Williams GM (1996) Carotid endarterectomy in the very elderly: Is it worthwhile? Surgery 11: 479-483

195 Perleth M (1998) Wann ist Verlaß auf medizinische Leitlinien? Münch med Wochenschrift 140: 82-86

196 Perleth M, Busse R, Schwartz FW (1998) Rapid development of HTA in Germany - Results of national survey. Annu Meet Int Soc Technol Assess Health Care 14: 100

197 Perleth M, Busse R, Schwartz FW (1999) Regulation of health-related technologies in Germany. Health Policy 46:105-26

198 Phelps CE (1993) The methodologic foundations of studies of the appropriateness of medical care. N Eng J Med 329: 1241-1245

199 Power EJ, Tunis SR, Wagner JL (1994) Technology Assessment and Public Health. Annu Rev Public Health 15: 561-79

200 Rettig RA (1997) Healthcare in transition. Health technology assessment in the private sector. Santa Monica: RAND

201 Rittenhouse BE (1996a) Is there a need for standardisation of methods in economic evaluations od medicine? Med Care 34 (Suppl.): DS13-DS22

202 Rittenhouse BE (1996b) The standardisation debate: What have we learned? Med Care 34 (Suppl.): DS5-DS10

203 Roos LL, Nicol JP, Cageorge SM (1987) Using administrative data for longitudinal research: comparisons with primary data collection. J Chron Dis 40: 41-49

204 Rovira J (1994) Standardizing economic appraisal of health technology in the European Community. Soc Sci Med 38: 1675-1678

205 Rovira J (1996) Standardization of the economic evaluation of health technologies. Med Care 34(Suppl.): DS182-DS188

206 Russell LB, Gold MR, Siegel JE, Daniels N, Weinstein MC (1996) The role of cost-effectiveness analysis in health and medicine. JAMA 276: 1172- 1177

207 Sachverständigenrat für die Konzertierte Aktion im Gesundheitswesen (1994) Gesundheitsversorgung und Krankenversicherung 2000 . Eigenverantwortung, Subsidiarität und Solidarität bei sich ändernden Rahmenbedingungen. Sachstandsbericht 1994. Baden-Baden: Nomos 1994

208 Sacket DL, Richardson WS, Rosenberg W, Haynes RB (1997) Evidence-based medicine: how to practice and teach EBM. London: Churchill Livingston 1997

209 Sackett D, Rosenberg WMC, Muir Gray JA, Haynes RB, Richardson WS (1996) Evidence-Based Medicine: What it is and what it isn't (Editorial). BMJ 311: 71-72

210 Sackett DL, Haynes RB, Guyatt GH, Tugwell P (1991) Clinical epidemiology: a basic science for clinical medicine. 2nd ed. Boston: Little, Brown 1991

211 Saracci R, Olsen J, Mc Michael A (1998) Europe's health research: getting the right balance. Preoccupation with technology mustn't erode public health research. BMJ editorial 7134

212 Sarasin FP, Bournameaux H, Bogousslavsky J (1995) Asymptomatic severe c arotid stenosis: Immediate surgery or watchfull waiting? A decision analysis. Neurology 45: 2147-2153

213 Satzinger W (1997) Arbeitsgruppe 'Sozialmedizin und Allgemeinmedizin' in der Deutschen Gesellschaft für Sozialmedizin und Prävention. Berichtsheft 7: 1-11

214 Schneider EC, Epstein AM (1996) Influence of cardiac-surgery performance reports on referral practices and access to care. A survey of cardiovascular specialists. N Engl J Med. 335: 251-6

215 Schulman KA, Glick H, Guzman G, Backhouse M, Bell L, Buxton M, Sculpher M, Kong J, Mauskopf J (1996) Results of the ec onomic e valuation of the first study. FIRST Investigators. Flolan International Randomized Survival Trial. Int J Techn Assess Health Care 12: 698-713

216 Serra-Prat M, Jovell AJ (1997) Concepts and methods in h ealth technology assessment. Efficacy versus effectiveness. Informatiu AATM (Catalan Agency for Health Technology Assessment) 10: 11-12

217 Shekelle PG, Kahan JP, Bernstein SJ, Leape LL, Kamberg CJ, Park RE (1998) The reproducibility of a method to identify the overuse and underuse of medical procedures. N Engl J Med. 338: 1888-95

218 Sheldon TA, Guyatt GH, Haines A (1998): Getting research findings into practice: When to act on evidence. BMJ 317:139-142

219 Silberfeld M, Grundstein-Amado R, Stephens D et al. (1996) Family and ph ysicians' views of surrogate decision-making: the roles and how to choose. Int Psychogeriatr. 8: 589-96

220 Sisk JE (1998) Introduction. Int J Tech Assess Health Care 14: 1-2

221 Sloan F (ed) (1995) Valuing health care. Cambridge: Cambridge University Press 1995

222 Soumerai SB, Ross-Degnan D, Fortess EE, Walser BL (1997) Determinants of change in Medicaid pharmaceutical cost sharing: does evidence affect policy? Milbank Q 75: 11-34

223 Spinner DM, Antes G (1998) Realisierungsmöglichkeiten eines Informationssystems Gesundheits ökonomische Evaluation. Deutsches Cochrane Zentrum, Freiburg, Germany

224 Staniforth P (1995) Audit-guidelines, policies, best practice or 'cookbook medicine'? Injury 26: 435-6; discussion 436-7

225 Strukenberg GJ (1997) Comparison of carotid endarterectomy outcomes from randomized controlled trials and medicare administrative databases. Arch Neurol 54: 826-832

226 Teixeira MP, Ribeiro V (1998) Nursing telematic education; a critical success factor to the 'best practice'. Stud Health technol Inform 51: 24-8

227 Thompson JW, Bost J, Ahmend F et al. (1998) The NCQA's Quality compass: Evaluating Managed Care in the United States. Health Affairs 17: 152-158

228 Thornton JG, Lilford RJ, Johnson N (1992) Decision analysis in medicine. BMJ 304: 1099-103

229 Tugwell P, Bennet K, Feeny D, Guyatt G, Haynes RB (1987) A framework for the evaluation of technology: The Technology Assessment Iterative Loop. In: Feeny D, Guyatt G, Tugwell P (eds.) Health Care Technology: Effectiveness, Efficiency and Public Policy. The Canadian Medical Association and The Institute for Research on Public Policy. pp. 56ff

230 Udvarhelyi IS, Colditz GA, Rai A, Epstein AM (1992) Cost-effectiveness and cost-benefit analysis in the medical literature. Ann Int Med 116: 238-244

231 UK Department of Health (1994) Guidelines for the economic evaluation of pharmaceuticals. Press Release 94/251

232 US P reventive Services Task Force (1998) Guide to clinical preventive services. An assessment of the effectiveness of 169 interventions. Baltimore

233 Van den Heuvel WJA, Wieringh R, Van den Heuvel LPM (1997) Utilisation of medical technology assessment in health policy. Health Policy 42: 211-222

234 Vasconcelos E, Seghatchian J (1997) Quality is a matter of mind: proposed quality improvement through the implementation of best practice. Transfusion Sc 18: 373-377

235 Visalli H (1997) Developing a best practice model for care of patients with polydipsia. J Nurs Care Qual 12: 53-62

236 Weinstein MC (1996) Theoretical foundations of cost-effectiveness analysis. In: Gold MR, Siegel JE, Russell LB, Weinstein MC (eds). Cost-effectiveness in health and medicine. New York: Oxford University Press 1996

237 WHO Meeting on Guidelines in Health Care. Schloß Velen, Germany, January 1997

238 WHO-conference on cost-effectiveness in health care. Celle, Germany. December 9-12, 1996

239 Wiley M (1997) Health service contracting and reimbursement: approaches and applications. Unpublished document, presented at the WHO Meeting on Reshaping Health Systems towards Health Outcomes. Celle, Germany, December 1997

240 Wilks J, Jones D, Wood M., Paul K, Barnes J (1997) Managing patient records and documenting service delivery: the results of a 'best practice' remote area nursing program. Aust J Rural Health 5: 153-157

241 Williams AH (1985) Economic of coronary artery bypass grafting. BMJ 291: 326-329

242 Williams B (1994) Patient satisfaction: a valid concept? Soc Sci Med 38: 509-516

243 Williams SV, Finkler SA, Murphy CM, Eisenberg JM (1981) Improved cost allocation in case-mix accounting. Med Care 20: 450-459

244 Wojner AW (1996) Outcomes management: an interdisciplinary search for best practice. AACN Clin Issues 7: 133-45

245 Wolf AMD, Nasser JF, Wolf AM, Schorling JB (1996) Impact of informed consent on patient interest in prostate specific antigen screening. Arch Intern Med 156: 1333-1336

246 Woolf SH (1992) Practice Guidelines, a new reality in medicine. II. Methods in developing guidelines. Acrh Int Med 152(5):946-52

247 Woolf SH (1997) Shared decision-making: the case for letting patients decide which choice is best. J Fam Pract 45: 205-8

248 Woolf SH (1998) Do clinical practice guidelines define good medical care? Chest 113(Suppl.): 166S-171S

249 Woolf SH, DiGuiseppi CG, Atkins D, Kamerow DB (1995) Developing evidence-based clinical practice guidelines: Lessons learned by the US Preventive Services Task Force. Annu Rev Public Health 17: 511-538

250 Zaiuri M, Matthew A (1995) An evaluation of TQM in pimary care: in search of best practice. Int J Health Care Qual Assus 8: 4-13

APPENDIX

A.1 Persons involved in the project

A.1.1 Project Partners

Prof. D. Banta
TNO Prevention and Health
Division of Technology in Health Care
Sector Medical Technology Assessment
2301 CE Leiden, The Netherlands

Dr. Nicholas Hicks
Department of Public Health
Oxfordshire Health Authority
Old Road, Headington
Oxford OX3, United Kingdom

Dr. Hervé Maisonneuve
ANAES
Medical Reference Program
159 Rue Nationale
Paris 75640 Cedex 13, France

Professor Alan Maynard
Health Economics Consortium
University of York
Heslington
York YO1 5DD, United Kingdom

A.1.2 Reviewers of the project report

Dr. G. Antes
German Cochrane Center
University of Freiburg
Albertstr. 21a
D-79104 Freiburg, Germany

Prof. D. Banta
TNO Prevention and Health
Division Technology in Health Care
Sector Medical Technology Assessment
NL-2301 CE Leiden, The Netherlands

Dr. N. Hicks
Department of Public Health
Oxfordshire Health Authority
Old Road, Headington
UK-Oxford OX3, United Kingdom

Prof. E. Jonsson
SBU – The Swedish Council on Technology
Assessment in Health Care
Tyrgatan 7
S-11486 Stockholm, Sweden

Prof. J. Kahan
RAND – Europe
Landbergstraat 6
NL-2628 CE Delft, The Netherlands

Prof. G. Ollenschläger
Ärztliche Zentralstelle Qualitätssicherung
Aachener Str. 233-237
D- 50931 Köln, Germany

Dr. C. Riley
Country Health Policies and Regions for Health
WHO Regional Office for Europe
8 Scherfigsvej
DK- 2100 Copenhagen, Denmark

A.1.3 Experts that have provided comments on specific topics

Prof. J. Kolodinsky
University of Vermont
Community Development and Applied Economics
Morrill Hall
Burlington, VT 05405, USA

Dr. C. Krauth
Hannover Medical School
Dep. Epidemiology, Social Medicine and Health System Research
Carl-Neuberg-Straße 1
D-30623 Hannover, Germany

Dr. L.A. Levin
Tema Health and Society
Center for Medical Technology Assessment
Linköpin University
S-58183 Linköpin, Sweden

Prof. G. Würzberg
Professor in communication and consultant in corporate communications
Jörgensmühle
D-39688 Wippersfürth, Germany

G. Van Wyk
Commonwealth Department of Health and Family Services
Canberra ACT 2601
Australia

Dr. H. Zöllner
Health Economics and Policy Analysis
WHO Regional Office for Europe
8 Scherfigsvej
DK-2900 Copenhagen, Denmark

A.2 Workshop

Hannover, June 16, 1998

A.2.1 List of Participants

Dr. G. Antes
German Cochrane Center
University of Freiburg
Albertstr. 21a
D-79104 Freiburg, Germany

Prof. D. Banta
TNO Prevention and Health
Division Technology in Health Care
Sector Medical Technology Assessment
NL-2301 CE Leiden, The Netherlands

Dr. B. Gibis
Dep. Epidemiology, Social Medicine,
Health System Research
Hannover Medical School
Carl-Neuberg-Straße 1
30623 Hannover, Germany

Dr. N. Hicks
Department of Public Health
Oxfordshire Health Authority
Old Road, Headington
UK-Oxford OX3, United Kingdom

M. Hübel
European Commission
Public Health and Safety at Work
Directorate - DG V/F
L-2920 Luxembourg

Dr. E. Jakubowski, MSc.
Dep. Epidemiology, Social Medicine a nd
Health System Research
Hannover Medical School
Carl-Neuberg-Straße 1
30623 Hannover, Germany

Dr. Th. Kohlmann
Medical University Lübeck
Institute for Social Medicine
St. Jürgen Ring 66
23564 Lübeck, Germany

Dr. H. Maisonneuve
Agence Nationale d Àccréditation
et d'Evaluation en Santé (ANAES)
159, rue Nationale
75640 Paris CEDEX 13, France

Dr. B. Merkel
European Commission
Public Health and Safety at Work
Directorate - DG V/F
L-2920 Luxembourg

Dr. M. Perleth, MPH
Dep. Epidemiology, Social Medicine,
Health System Research
Hannover Medical School
Carl-Neuberg-Straße 1
30623 Hannover, Germany

A.2.2 Original workshop programme

MORNING SESSION: 'BEST PRACTICE' IN HEALTH CARE

9:00	WELCOME FROM HANNOVER (Dr. Jakubowski and Dr. Perleth)
9:20	WELCOME FROM DG V/F (Dr. Merkel, M. Hübel)
9:30	THE CONCEPT OF 'BEST PRACTICE' IN HEALTH CARE (Dr. Jakubowski)
9:50	DRAFT COMMENTARIES (Prof. Banta, Dr. Hicks, Dr. Maiso nneuve)
10:20	DISCUSSION
11:00	***Coffee Break***
11:30	WORKSHOP: BEST PRACTICE CRITERIA (chair: Prof. Banta)
12:30	WORKSHOP: IMPLEMENTATION AND EVALUATION (chair: Dr. Hicks)
13:30	***Lunch***

AFTERNOON SESSION: BEST PRACTICE RECOMMENDATIONS TO THE EU

14:45	DISCUSSION: BEST PRACTICE RESEARCH
15:30	DISCUSSION: BEST PRACTICE IMPLEMENTATION
16:15	***Coffee Break***
16:30	DISCUSSION: BEST PRACTICE EVALUATION
17:15	CONCLUDING REMARKS (Dr. Jakubowski)
17:30	***Closing***

A.3 Additional Material

A.3.1 European Community mandates for health

A.3.1.1 Maastricht Treaty (in summary)

Article 3 [Activities of the Community]:

ξ o) contribution to achieve a high level of health protection

Article 129
(1)

ξ preventing diseases, in particular major health scourges including drug dependence

ξ promoting research into the causes and transmission of diseases

ξ health information and education

ξ incorporation of health protection requirements in the Communities other policies

(4)

ξ exclusion of any harmonisation of the laws and regulations of the Member States

A.3.1.2 Treaty of Amsterdam (in summary)

Article 3 :

ξ p) contribution to achieve a high level of health protection

Article 152:

(1)

ξ incorporation of health protection requirements in the Communities other policies

ξ improving public health

ξ preventing human illness and diseases, in particular major health scourges

ξ promoting research into the causes, transmission and prevention of diseases

ξ health information and education

ξ measures to combat diseases related to drug d ependence, including information and prevention

(4)

ξ exclusion of any harmonisation of the laws and regulations of the Member States

A.3.2 Example of a ‘best clinical practice’ approach

Krakauer H, Lin MJ, Schone EM, Park D, Miller RC, Greenwald J, Bailey RC, Rogers B, Bernstein G, Lilienfeld DE, Stahl SM, Crawford 3 rd RS, Schutt DC (1998) 'Best clinical practice': assessment of processes of care and of outcomes in the US Military Health Services System. J Eval Clin Pract. 4: 11-29

Objective: ‘the active, on-going monitoring and improvement of the effectiveness and efficiency of the care provided to a broad population’.

Analytic activities: ‘(1) identification by clinical panels of conditions and procedures of interest; (2) collection of data from electronic repositories and from charts to characterize the patients, how they are managed, the clinical outcomes they experience, the resource costs their care entails, and, from questionnaires, their functional status and level of satisfaction, and (3) generation of 'report cards' that inform organizational units down to the level of the hospital of the characteristics of their patients, their practices, and the risk-adjusted outcomes they achieve. The patterns of care employed by the hospitals that obtain the best risk-adjusted outcomes and resource utilization ('best clinical practice') are identified and made known. In addition, (4) a systematic process of developing outcomes-based practice guidelines has been devised.’ The expected outcome is: ‘to serve as a decision-support tool for clinicians.’

Case study: ‘the probable consequences of the application of this tool to operative interventions in childbirth. Use of the tool would result in a higher occurrence of elective Caesarean sections, a reduced rate of emergency Caesarean sections and much lower use of forceps, with an overall improvement in outcomes and lower resource costs.’

Prospect: to provide ‘(1) education of the clinical and administrative communities in the use of the data and the decision-support tools’ and the ‘(2) evaluation of the consequences of the use of the data by the clinical and administrative communities’.

A.3.3 Electronic communication with Gerry Van Wyk

(Commonwealth Department of Health and Family Services, Australia)

'On the specific research areas you mention:

This are of the Australian health department is responsible for clinical IT & IM, clinical practice guidelines and some involvement in evidence-based medicine. In the IT area we are doing development work on an electronic medical record, clinical decision support systems, electronic links between providers and automated performance measurement. Much of our initial work involves the consideration of standards and coding in the technical area, and privacy and confidentiality issues in the application of the technology. We are at an early stage of development and have looked at the Good European Health Record and associated material. We do not have any involvement with diagnostic technology, apart from an interest in electronic guidelines or decision support systems. Our work on clinical guidelines is mainly focused on implementation. It seems to us there is much information on guidelines available to clinicians that never gets used. This is because they are unsure of the evidence base, whether it is outdated, how to apply the mass of information within the clinical environment, how to test its effectiveness or how to respond to variations. There is also a strong aversion to "cookbook" approaches to medical practice.

We are attempting to overcome these issues by providing clinical teams with the skills and support necessary for them to apply evidence-based medicine, using a range of tools including guidelines, with the objective of improving and measuring the outcomes of care and providing quality care.

It seems to us we need to change the attitude and skills of clinicians, so they seek out and use guidelines and similar material. If we can demonstrate that they can significantly improve the provision of care, make consumers an active participant in deciding the best course of treatment and have the certainty that they can access information on evidence-based medicine, then guidelines become a desired source of clinical information.

In the longer term we would hope to improve the guideline delivery mechanism - on-line and interactive.

This Department provides support for the Australian Cochrane Centre, which coordinates research on evidence-based medicine. We hope it becomes a valuable source of information for guideline developers and users.'

A.4 Levels of Evidence scale of the U.S. Preventive Services Task Force

I	Evidence obtained from at least one properly designed randomised controlled trial
II-1	Evidence obtained from well designed controlled trials without randomisation
II-2	Evidence obtained from a well-designed cohort or case-control analytical studies, preferably from more than one centre or research group.
II-3	Evidence obtained from multiple time series with or without the intervention.
III	Opinions of respected authorities, based on clinical experience, descriptive studies, or reports of expert committees.

≥Woolf et al. 1995≅