EUROPEAN COMMISSION

HEALTH & CONSUMER PROTECTION DIRECTORATE-GENERAL

HIGH LEVEL GROUP ON HEALTH SERVICES AND MEDICAL CARE

Document: Work of the High Level Group on health services and medical care during 2005	
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Action: For information. This is the final version of the 2005 report of the High Level Group, reflecting discussion at the meeting of 9 November. The guidelines agreed by the High Level Group for purchase of treatment abroad are attached as an annex.	

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Brussels, 18 November 2005
HLG/2005/16

HIGH LEVEL GROUP ON HEALTH SERVICES AND MEDICAL CARE

EXECUTIVE SUMMARY

This is the second report of the High Level Group on health services and medical care. The Group was established as a means of taking forward the recommendations made by the reflection process on patient mobility, and has made significant progress on all the topics identified as priorities. The report from the High Level Group sets out progress at this stage and orientations for future work in 2006 and thereafter.

The High Level Group has taken forward work through working groups involving interested Member States on particular topics, with regular reporting of their work to the full High Level Group. The work, that started in 2004, has been taken forward in 2005 in the following areas.

- Cross-border Healthcare Purchasing and Provision: The main focus of the work of the group in 2005 has been the development of guidelines for purchasers buying healthcare in other Member States, and these are attached as an annex to this report. We recommend that health ministers endorse these guidelines, and disseminate them within their health systems. We also recommend that these guidelines should be accompanied by a mechanism for exchanging best practice and experience regarding their implementation in practice. For 2006 work should be focused on the key topics of information for patients; the financial impact of patient mobility; monitoring cross-border healthcare purchasing and provision; and addressing issues of medical malpractice and liability.

- Health Professionals: Initial analysis of a pilot study of professional mobility in 6 Member States suggest that the current impact of health professional mobility is marginal. However, the data indicate a potential for significant impact in certain geographies and clinical specialisms. Accordingly it is proposed that the work of this pilot is developed in 2006. Throughout the year the group worked on continuing professional development for doctors and nurses, looking at the potential for a common EU standard, and this should be continued in 2006. Through a pilot project on health care professionals crossing borders, the group was closely involved in a project working towards a European certificate of current professional status. The group also considered the question of ethical recruitment between EU Member States and into the EU from other countries. It is suggested that this work is continued in 2006.

- Centres of Reference: The working group has developed general principles as a working concept for European networks of centres of reference, and proposes these for endorsement by health ministers. Subject to that endorsement, we invite the European Commission to test the feasibility of this approach for European networks of centres of reference in 2006 through the pilot project(s). In parallel with this pilot project(s), the working group also proposes to pursue its work during 2006 on issues which need further investigation, or which have not yet met a consensus, such as legal, financial and organisational issues raised by the designation of ENCR, including quality control and the general legal framework for European networks of centres of reference.

- Information and eHealth (including data protection): The long-term aim of information and eHealth should be to ensure full access to all necessary health-related data on a comparable and comprehensible basis by appropriate and authorised people whenever and wherever it is needed throughout the Union. However, realising this vision will take many decades, and we have therefore focused on concrete first steps that can bring short-term benefits as well as acting as building-blocks for the future. The High Level Group therefore recommends that building on existing activities within Member States and at European level, the Commission should, involving the member states, examine the feasibility of introducing a 'minimum data set' for patients to be available throughout the Union, and make any necessary proposals, using the knowledge of national organisations, involved in the implementation of national information and eHealht strategies. Second, Member States should consider including investment in the necessary eHealth structure and services as part of their health system development plans. And third, Member States and the Commission should consider including investment in eHealth in proposals for support from the structural funds, in particular with regard to the new Member States.

- Health Impact Assessment and Health Systems: By the end of 2006, the group aims to have an operational tool for assessing the impact of proposals on health systems, combining a methodology, operational manuals for use by officials evaluating specific proposals or policies, and a network of contact points able to provide information on health systems in the different Member States. This tool can then be integrated by the Commission into its general impact assessment to ensure that impacts on health systems are properly identified and taken into account, and would also be available for Member States to use in undertaking their own health system impact assessments where they wish. The High Level Group proposes to establish a network for health systems impact assessment across the Member States, who can act as contact points for information regarding their specific health system.

- Patient Safety: We recommend that health ministers undertake to establish patient safety programmes within their health systems, where these do not already exist. In order to support Member States in addressing patient safety, we recommend establishing an operational network between Member States' patient safety contact points (agencies, ministries or other competent authorities) at the European level, with an additional forum for involvement of civil society and other stakeholders.

During 2005, the High Level Group also made arrangements to involve observers from the EEA/EFTA-states and contributions from civil society, as set out in the 2004 Report (HLG/2004/21 FINAL). The Commission has also taken forward other recommendations from that report, in particular by financing the establishment of a European Network on Health Technology Assessment.

The High Level Group has also contributed to other work relevant to health services and medical care. As in 2004, the High Level Group has discussed the open method of coordination on healthcare and long-term care and provided input.

The work of the High Level Group has been practical and informal, using simple working methods and flexible structures in order to achieve rapid results, depending on the cooperation and contributions of senior representatives from the Member States and other stakeholders and reflecting the principles of better regulation. This has included representatives of civil society, who have provided expertise to specific working groups, and observers from the EEA/EFTA States. This approach has enabled the Group to make good progress on complex issues related to health services and medical care.

Subject to any comments, the High Level Group will work on the basis set out in this report during 2006 and thereafter, taking into account comments and suggestions from the Council and other stakeholders, and keeping the Council regularly informed and liaising with it on future work, including regular liaison with the Presidency.

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HEALTH & CONSUMER PROTECTION DIRECTORATE-GENERAL

Brussels, 18 November 2005
HLG/2005/16

HIGH LEVEL GROUP ON HEALTH SERVICES AND MEDICAL CARE

WORK OF THE HIGH LEVEL GROUP ON HEALTH SERVICES AND MEDICAL CARE DURING 2005

1. ISSUES ADDRESSED BY THE HIGH LEVEL GROUP

The High Level Group on health services and medical care was established in 2004 in order to take forward the recommendations made by the reflection process. In 2005 the High Level Group met in April, June, September and November.

The High Level Group decided to prioritise its first phase of work by focusing on few specific areas, each being taken forward by a working group. The High Level Group concluded its work on health technology assessment during 2004; this was taken forward by the establishment of a European network for health technology assessment financed by the public health programme. In 2005 the following areas were addressed:

- Cross-border healthcare purchasing and provision
- Health professionals
- Centres of reference
- Information and e-health (including data protection)
- Health impact assessment and health systems impact assessment
- Patient safety

Several issues relate to more than one working group. During 2006 the High Level Group will review the relationships between these different areas in order to continue to ensure coherence between the different strands of action and appropriate priorities for future work.

During 2005, the High Level Group also made arrangements to involve observers from the EEA/EFTA states and contributions from civil society, as set out in the 2004 Report (HLG/2004/21 FINAL).

2. WORK UNDERWAY AND RESULTS OF THE WORK IN 2005

2.1. Cross-border healthcare purchasing and provision (including patient rights)

2.1.1. Membership of Working Group

The working group on Cross-border Healthcare Purchasing and Provisions has met five times. The working group is now co-chaired by Ireland (Mr John O'Toole) and Malta (Mr John Cachia), following the retirement of the co-chair from the Netherlands (Mme Renee Wetters). The meetings of the working groups normally involve representatives from all EU Member States, as well as observers from the EFTA countries.

2.1.2. Issues addressed by the Group

The main focus of the work of the group in 2005 has been the development of **guidelines for purchasers buying healthcare in other Member States**, which are annexed to this report. The guidelines aim to assist commissioners of health care in the Member States by setting out some key issues that should be taken into consideration when drawing up agreements or contracts related to purchase of health care abroad. They aim to facilitate better commissioning and contracting arrangements, consistent with EU law and existing arrangements between Member States. Examples of existing contracts and bilateral agreements for cross-border healthcare have also been assembled.

Preparation of these guidelines has been greatly assisted by the **"Conference on Cross – Border Health care - Challenges and Perspectives"** that took place in Venice 26-27 October. The conference brought together major stakeholders and experts related to cross border care and provided valuable input to the work of the High Level Group.

The High Level Group recommends that health ministers endorse these guidelines, and disseminate them within the health systems of their Member States. Commissioners of health care could also be invited to review existing arrangements and provide information on them in the light of these new guidelines. These guidelines are only a start. They will need to be updated and adapted in the light of experience, and mechanisms will be needed to ensure exchanges of information and best practice between commissioners of health care as the guidelines are implemented in practice, and we recommend that the High Level Group review these guidelines after two years. We will also need to further consider issues related to medical malpractice and liability in order to provide solutions to these particularly difficult questions.

2.1.3. Outline plans for future work

For 2006, we propose to continue to focus on the key topics

- information for patients (including gathering information on patient rights entitlements and responsibilities in the Member States);
- financial impact of patient mobility;

- monitoring cross-border healthcare purchasing and provision:

taking account of the discussions of the meeting of health ministers of 20-21 October concerning information for patients. As described above, we will also consider solutions to the issues concerning medical malpractice and liability.

2.2. Health professionals

2.2.1. Membership of Working Group

UK, Hungary, Poland, the Netherlands, Italy, France, Belgium, Germany, Sweden, Lithuania and Estonia are members of the working group. The working group is co-chaired by the UK and Hungary. The Group has invited the Standing Committee of European Doctors (CPME), the European Federation of Nurses Associations (EFN), the European Hospital and Healthcare Federation (HOPE) as well as the European Health Management Association (EHMA) to join in their discussions.

2.2.2. Issues addressed by the Group

The Group is looking primarily at the potential impact of migration of health professionals around the European Union. It has decided to concentrate, at least initially, on doctors and nurses. The group has currently the mandate of reflecting on three related themes, namely: evidence of migration amongst the health professions, recruitment practices, and quality aspects with regard to the continuing professional development.

2.2.3. Importance and Added Value of the Work

The concerns about the impact on the health systems of "donor" countries relate to the creation of severe shortages in specialties where mobility is easy/demand elsewhere is high, and the impact of that on wage levels and overall cost. There are also serious concerns about the information receiving countries have about the quality of staff education and training, and what is known about it.

The Group identified various sources of data and information such as the Committee of Senior Officials on Public Health, EUROSTAT, projects carried out by non-governmental organisations and a project by UK on "health care professionals crossing borders".

2.2.4. Work undertaken

Health professionals mobility

The working group undertook a project to explore the impact of mobility of doctors and nurses across 6 Member States. This report identified that robust data related to migration is limited. However it did identify that the number of doctors and nurses who had the potential to migrate were relatively small in comparison to the health workforce as a whole for most , but not all, countries in this project.

Recruitment

The group has shared information on **recruitment practices / ethical codes**. It discussed ethical aspects which are a concern in many countries, both in the EU and globally.

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Continued professional development

The group exchanged information on arrangements and requirements for continuing professional development. It has discussed a survey undertaken by CPME on CPD for the medical profession. The survey focused on quality assessment and quality control. Introductory work has been undertaken for a similar survey on CPD for nurses that will be carried out by EFN at the beginning of 2006.

Healthcare Professionals crossing borders

The Health care professionals crossing borders project set initial standards for the exchange of information between competent authorities. An agreement was reached at the consensus Conference in Edinburgh, Scotland in November 2005.

2.2.5. Outline plans for future work

Health professionals mobility

It is recommended that future activities explore strategies to enable collection of data that demonstrates actual migratory pattens and explores underpining reasons for doctor and nurse migration. This could link to recruitment and retention strategies where external migration has a potential for a negative impact on health systems.

Recruitment

The working group is to explore best practice strategies and the use of ethical recruitment codes within the EU and in the global context..

Continued professional development

The working group will reflect further on surveys of doctors and nurses and discuss the need for a minimal European standard would be needed for continued professional development, especially on the aspects of CPD quality improvement but also quality assessment and quality control.

Healthcare Professionals crossing borders

The project needs to extend and implement the Agreement in the context of Directive 2005/36/EC to increase professional mobility across national borders and to safeguard patient safety across Europe. The implementation phase of the project will need to coordinate with the High Level Group and with the new DG Internal Market Committee for the implementation of Dir 2005/36/EC[1], in the context of future resourcing after UK EU Presidency.

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[1] Directive of 7 September 2005 on recognition of professional qualification. OJEC of 29/09 L 255 . 22

2.3. European networks of centres of reference

As set out in the 2004 Report of the High Level Group, European networks of centres of reference could provide healthcare services to patients who have conditions requiring a particular concentration of resources or expertise, in particular for rare diseases, in order to provide high quality and cost-effective care, and could also be focal points for medical training and research, information dissemination and evaluation.

2.3.1 Membership of the Working Group

The work so far clearly demonstrated that there is a significant added value of the cooperation at the European level in this area. In the 2004 report the High Level Group identified general principles and potential benefits of developing European collaboration on centres of reference. In 2005 the working group met four times and worked on the practical implementation of these general principles. This working group is chaired by France, with the involvement of Belgium, The Czech Republic, Denmark, Estonia, Finland, Germany, Hungary, Ireland, Italy, The Netherlands, Slovakia, Slovenia, Spain and Sweden.

2.3.1. Work undertaken

Following the recommendations and conclusions formulated in several reports and official documents[2] indicating special interest for ENCR in tackling rare diseases, taking into account the obvious EU added value and according to the progress already achieved in this area, the working group agreed to choose the field of rare diseases as a starting point for discussion and experimentation. However, the group nevertheless aims to develop a general concept for a European system of centres of reference not limited to the area of rare diseases.

The SANCO Task Force on Rare Diseases was mandated by the working group to provide a technical and scientific input for this experimental stage, including results of its mapping exercise on national centres of reference for rare diseases, and produced a valuable report. On the basis of this work, there was an agreement on the following characteristics of the European networks of centres of reference for the purpose of launching pilot projects:

General principles

The process of developing European networks of centres of reference should respect the following principles:

- "Hierarchy" between national (or regional) and European networks of centres of reference should be avoided.
- Networking of expert centres rather than isolated European centres of reference should be favoured.

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[2] Outcome of the reflection process (HLPR/2003/16 of 9/12/2003); Communication from the Commission (COM 2004 301 final of 20/04/2004); Report from the High Level Group to the Council (HLG/2004/21 final); Resolution of the European Parliament (2004/2148 INI of 29/04/2005); Markos Kyprianou's speech of 20/01/2005 on "The new European Healthcare Agenda" (speech/05/24).

- In principle, expertise (professionals, samples, information) should travel rather than patients themselves. However, it should be possible for patients to travel to centres where this is necessary.

Criteria to be fulfilled by the European centres of reference

European centres of reference should comply with the following criteria as defined in the final report of the SANCO Rare Diseases Task Force (HLG/COR/2005/11) and agreed by the working group

- appropriate capacities to diagnose, to follow-up and manage patients with evidence of good outcomes so far as applicable;
- sufficient activity and capacity to provide relevant services and maintain quality of the services provided;
- capacity to provide expert advice, diagnosis or confirmation of diagnosis, to produce and adhere to good practice guidelines and to implement outcome measures and quality control;
- demonstration of a multi-disciplinary approach;
- high level of expertise and experience documented through publications, grants or honorific positions, teaching and training activities;
- strong contribution to research
- involvement in epidemiological surveillance, such as registries
- close links and collaboration with other expert centres at national and international level and capacity to network
- close links and collaboration with patients associations where they exist.
- Although a ENCR should fulfil most of the above criteria, the comparative relevance of those various criteria will depend on the particular disease or group of diseases covered. The working group also noted this list could be revised with the outputs coming from the implementation and development of the expected 2006 pilot project(s) on ENCR.

Areas to be covered by a European network of centres of reference

Agreement at European level on the pathologies, technologies and techniques to be covered by European networks of centres of reference is needed, drawing on national experiences and existing lists, especially as many Member States do not currently have designated centres of reference at all, although they have expert clinics. The priority areas should be determined on the basis of the following indicators:

- Diagnosis (when the diagnosis is difficult and is necessary for informing clinical management, to prevent complications and to set up treatment).
- Therapeutics and management (when treatment requires expertise and specialised interventions).
- Outcome (when patients are at high risk of developing severe complications or disability which are preventable).
- Technology and therapeutic innovations.

Criteria for designation of a European centre of reference are set out above, however, their application to specific situations requires significant expertise and knowledge of the current international situation. Selection of such centres of reference would therefore need input from experts from relevant specialties in medicine, patients, representatives of the health authorities of Member States and the European Commission. Continued compliance with the designation criteria should also be ensured. This area will require further consideration during 2006.

2.3.2 Outline plans for future work

We recommend that health ministers endorse the above general principles, criteria and areas as a working concept for a European networks of centres of reference. On this basis, we invite the European Commission to test the feasibility of this approach for a European network of centres of reference in 2006 through one or more pilot projects.

Based on this 2005 Report of the High Level Group and on the conclusion of the Council, the pilot project(s) should be launched in 2006, in order to test the general principles, criteria, areas and process described above, to see how this approach could work in practical terms and identify any specific problems for further consideration. The field of rare diseases is recommended as a priority for 2006. The outcome of the pilot project(s) should not be prejudiced by expectations, but open to the evidence found in practice. The pilot project(s) should focus on demonstrating ways in which the principles outlined above for a European network of centres of reference could be applied in practice for a specific disease, group of diseases, group of Member States or other focal principles, building where appropriate on existing centres, expertise or networks. They should include mechanisms for evaluation of their activities and regular reporting to the High Level Group, in order to provide a basis for analysis and future proposals or alternatives. The Report from the expert group of the Rare Diseases Task Force (document reference HLG/COR/2005/11) also contains useful background information.

In parallel with this pilot project(s), we also plan to pursue our work during 2006 on issues which need further investigation, or which have not yet met a consensus, such as legal, financial and organisational issues raised by the establishment of European Networks of Centres of Reference, including process of identification, quality control and the general legal framework for European networks of centres of reference, as well as the involvement of the health authorities of the Member States in the areas of priority setting and process of identification.

For 2006, the working group also plans to investigate the possibility of launching future projects on ENCR in the coming years which could also cover other areas than rare diseases (e.g. technology and therapeutic innovations), depending on the result of the pilot projects. External experts on all these themes could also be usefully invited to feed the reflection on ENCR as well as the need to request further contribution from the Administrative Commission on Social Security for Migrant Workers on professional mobility for ENCR.

2.4. Information and e-health

Health systems across the Union are constantly seeking to improve quality and accessibility of care to reflect medical innovations and public expectations whilst respecting limits on available resources. Providing this high-quality healthcare depends

on having the right information accessible to the right people at the right time. Information and communication technologies in the health sector ("eHealth") have the potential to bring benefits throughout health systems, by improving the accessibility, quality, efficiency and effectiveness of healthcare for citizens.

2.4.1. Membership of the Working Group

In 2005 the working group met four times. The group is chaired by Germany, with the involvement of Austria, Belgium, Cyprus, the Czech Republic, Estonia, France, Greece, Ireland, Italy, Latvia, Lithuania, The Netherlands, Slovenia, Spain, Sweden, and the United Kingdom.

2.4.2. Importance and added value of the work

Many initiatives on information and e-health are already underway within Member States. However, European cooperation on these issues can add value to national work. Ensuring that among others data is comparable at European level can also help to drive improvements through benchmarking and exchanging good practice throughout Europe. Quality of health can be improved and planning can be ameliorated by using automated processing of clinical data. For patients who move within or between Member States, it is vital to ensure that all relevant information is available where the patient is. Moreover, although there is great potential for information and communication industries within the EU, health-related systems are sufficiently specialised and complex that procurement for individual health systems can prove unviable or prohibitively expensive. A common approach to information and eHealth strategies within the health sector could help to ensure a critical mass of providers within the EU.

2.4.3. Outline plans for future work

The long-term aim of information and eHealth should be to ensure full access to all necessary health-related data on a comparable and comprehensible basis by appropriate and authorised people whenever and wherever it is needed throughout the Union. However, realising this vision will take many decades, and we have therefore focused on concrete first steps that can bring short-term benefits as well as acting as building-blocks for the future.

As a first step, we therefore propose to focus on defining a 'minimum data set' for patients and ensuring that this data is available throughout the Union. This would provide immediate benefits in terms of patient care and patient safety. However, it would also need mechanisms to be put in place for ensuring that data can be entered, stored and accessed securely between Member States; that patients and other relevant healthcare actors can be properly identified; and that the data will be fully understood when exchanged between systems, that privacy and data protection are secured. In short, it would be a test case for ensuring compatibility of operation between health systems in terms of their organisation; the definition and understanding of the data they exchange; and their technical systems.

2.4.4. Issues addressed by the Group

Much work has already been done in this area, both within Member States and at European level. The focus now should be on identifying what already exists, to reconcile and to fill gaps where necessary in order to put in place a workable system. This should cover areas including:

- Ensuring that relevant standards are developed, validated, tested, implemented, used and evaluated;
- Developing and implementing a framework and mechanisms for connecting different health systems and their various components;
- Ensuring compatibility with legal and professional requirements at national and European level, and identifying any necessary amendments;
- Involving competent authorities within Member States and other relevant stakeholders.

The High Level Group can provide overall political guidance to work in this area, but the detailed next steps should be taken forward by appropriately qualified experts in liaison with the relevant national authorities and other stakeholders. Concretely, this could take the form of a feasibility study to examine this approach and outline proposals for implementing it in practice.

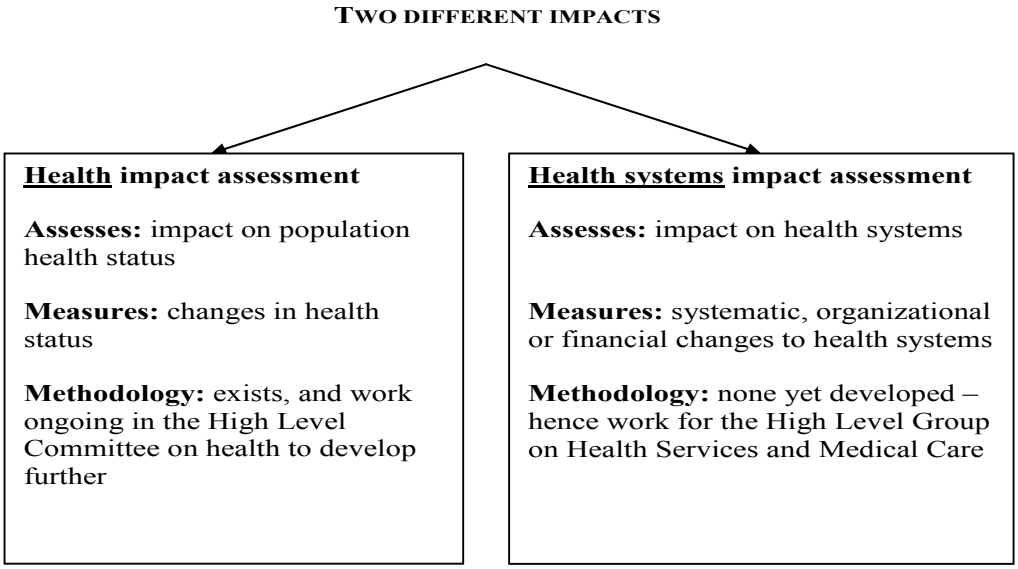
2.4.5. Recommendations

On this basis, the High Level Group recommends that:

- building on existing activities within Member States and at European level, the Commission should, using the knowledge of national organisations, involved in the implementation of national information and eHealth strategies, involving the Working Group, examine the feasibility of introducing a 'minimum data set' for patients to be available throughout the Union, and make any necessary proposals;.
- Member States should consider including investment in the necessary eHealth structure and services as part of their health system development plans and report conclusions to the High Level Group by June 2006; and,
- Member States and the Commission should consider including investment in proposals for support from the structural funds, in particular with regard to the new Member States.

2.5. Health impact assessment and health systems

As the Report of the High Level Group in 2004 set out, proposals may have a direct impact on the health of the population, or they may have an indirect impact through affecting health systems and thus their ability to achieve their objective of improving health.



Both these aspects are included in the Commission's guidelines for impact assessment (SEC(2005)791) updated on 15 June 2005). However, whilst methods have been developed for assessing direct health impacts, methods are not available for assessing health systems impacts. We proposed addressing this by developing a methodology in cooperation with an expert group, and this has been the main focus of work during 2005.

2.5.1 Membership of the working group

In 2005 the working group met four times. The group is chaired by Portugal, with the involvement of Belgium, Finland, France, Germany, The Netherlands, Sweden, the United Kingdom, Latvia and Lithuania.

2.5.2 Work undertaken

Expert input to develop this methodology has been provided by a technical group led by the WHO Observatory on Health Systems and Policies and including stakeholders representing purchasers, providers, ministries, academic experts and the European Commission. The methodology proposed aims to analyse the impact of proposals in different policy areas through a combination of the functions of health systems and the objectives that they seek to meet.

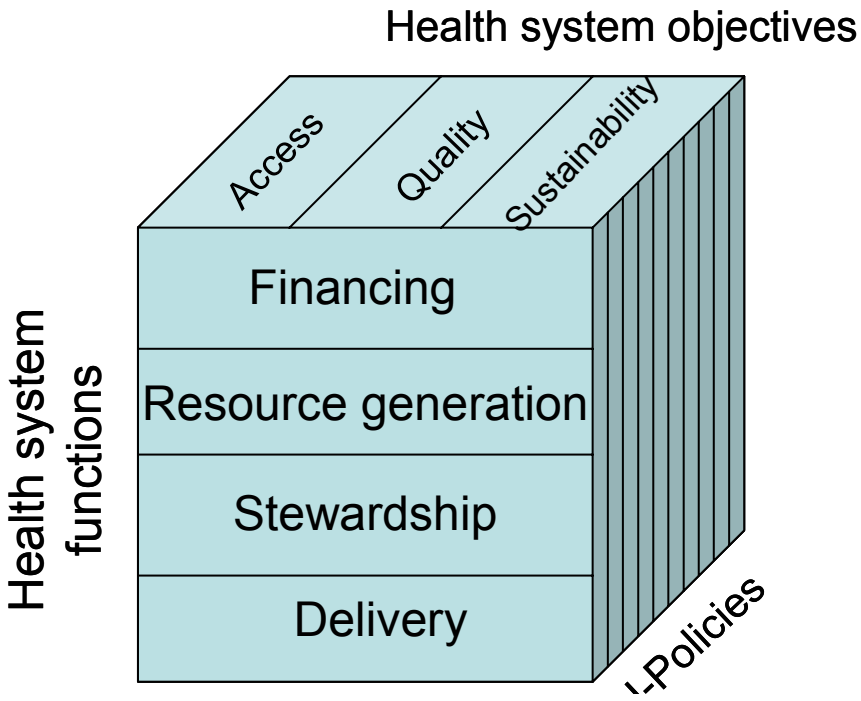
The functions of health systems can be broken down into four main areas:

- Financing of health systems (revenue collection, fund pooling and purchasing);
- Resource generation (including human resources, physical resources such as facilities and equipment, and knowledge)
- Stewardship (the oversight and policy formulation role of governments or other authorities responsible for health systems overall).
- Delivery (provision of services).

The overall objectives shared by European health systems agreed by the Barcelona European Council in March 2002 were:

- Accessibility of care for all, based on fairness and solidarity, taking into account the needs and difficulties of the most disadvantaged groups and individuals, as well as those requiring costly, long-term care;
- High-quality care for the population, which keeps up with medical advances and the emerging needs associated with ageing and is based on an assessment of their health benefits;
- Measures to ensure the long-term financial sustainability of this care and aiming to make the system as efficient as possible.

Impacts on health systems from any given proposal or policy area can therefore be assessed against a combination of these functions and objectives for health systems, as set out below. The common values of universality, solidarity and equity should also be taken into account when analysing the impact of the proposals in different policy areas.



The technical group is currently working to review evidence applicable to each of the functions and objectives set out above for different policy areas, including a seminar planned for later this year. Given the variety in different health systems across the Union, further information regarding particular health systems may also be needed. We therefore propose to establish a network for health systems impact assessment across the Member States, who can act as contact points for information regarding their specific health system.

2.5.3 Work plan and deliverables for 2006

The next stage during 2006 is to begin to assemble the evidence related to the elements outlined above and to pilot the proposed methodology through trial impact assessments. We plan to begin with the area of health and safety, and work is underway to assemble the necessary resources. We invite health ministers, perhaps through the Council Working party on public health meeting at senior level, to identify another topic which could be used to pilot this health systems impact assessment approach during 2006.

By the end of 2006, we therefore aim to have an operational tool for assessing the impact of proposals on health systems, combining a methodology, operational manuals for use by officials evaluating specific proposals or policies, and a network of contact points able to provide information on health systems in the different Member States. This tool should then be integrated by the Commission, the Council and the European Parliament into their general impact assessment to ensure that impacts on health systems are properly identified and taken into account, and would also be available for Member States to use in undertaking their own health system impact assessments where they wish.

2.6. Patient safety

2.6.1. Membership of the Working Group

The working group on patient safety brings together 24 Member States and representatives of the civil society to identify patient safety areas where European level collaboration and coordination of activities could bring added value. The working group is chaired by Sir Liam Donaldson from the UK and Dr Robida from Slovenia and it has met three times in 2005.

2.6.2. Importance and Added Value of the Work

Patient safety is a serious concern for the EU Member States. Although no accurate figures for Europe exist, recent rough estimates based on the best available research suggest that the number of hospital inpatient episodes in Europe which may result in some form of unintended harm is likely to be in the order of millions of cases every year. Around half of those incidents may be preventable.

In the increasing number of countries where research has been carried out, studies consistently show similar levels of health care errors, broadly in the order of 10% of hospitalisations. Analysing and discussing adverse events as well as reporting of adverse events are important steps in helping avoid preventable harm to patients from being repeated.

Today, the thinking on the safety of patients places the prime responsibility for adverse events on deficiencies in system design and organization, not on individual health professionals or products. A comprehensive approach is essential to enhance the safety of patients by preventing adverse events, making them visible and mitigating their effects when they occur.

There is considerable scope for collaboration in ensuring that patient safety is a priority healthcare issue for all Member States and to design and implement effective, national patient safety programmes. Furthermore, as people move more freely across borders, they expect that the care they receive in any EU Member State meets the same level of safety and quality.

Moreover, there is large amount of experience and knowledge on patient safety in the Member States as well as globally. In order to add value for European level activities in this field, the working group has involved key stakeholders in its work to avoid duplication of efforts and to achieve effective synergies. The World Health Organization (especially the World Alliance on Patient Safety) and Council of Europe as well as European associations for patients (EPF), doctors (CPME), nurses (EFN), pharmacists (PGEU) and hospitals (HOPE) have been actively involved in the working group. It is

essential that the main players collaborate and coordinate their work in this area to ensure highest level of patient safety and quality of care at the European level.

2.6.3. Issues addressed by the Group

Ensuring patient safety depends on effective and sustained patient safety policies and programmes being in place throughout Europe. We invite health ministers to agree to establish such programmes where they do not already exist.

The Commission can support governments in their patient safety objectives, in particular through patient safety reporting and learning systems at European level to enable EU-wide sharing of information on patient safety problems and solutions. We recommend that the Commission consider the following areas for initial action;

1. Develop mechanisms or tools to support Member States in establishing and developing national level patient safety programmes, encompassing areas such as governance and leadership.
2. Encourage and support Member States in establishing effective patient safety reporting and learning systems. This could pave the way in time for EU wide collation, analysis and sharing of information on patient safety problems drawn from national patient safety reporting systems.
3. Support an initiative on 'Design for Patient Safety' to bring together design expertise from a range of industries and disciplines to embed the best thinking in systems design in patient safety. Possible areas of focus include health care buildings, design and packaging of medicines and design of therapeutic equipment. Work could be taken forward through specific projects and strategies to influence other key players to improve design for safety.
4. Support research on the different key aspects of patient safety. The economic impact of patient safety problems and the financial costs and benefits of implementing improved systems to address patient safety issues is one key area where data and knowledge is currently insufficient.
5. Encourage development of a skills and knowledge framework for patient safety education, along with tools to support innovation and implementation. The initiative should encompass safety knowledge and performance of health care workers in training programs, as well as programs for staff in health care institutions. The possibility of promoting innovative approaches to education developed in other industries could also be considered.

2.6.4. Recommendations

The Member States developing and establishing patient safety policies and programmes could benefit from sharing of best practices and experiences in supporting each other in this process. For that purpose we recommend establishing an operational network between Member States' patient safety contact points (agencies, ministries or other competent authorities) at the European level.

A wide range of stakeholders have an important role in patient safety and especially in implementing patient safety measures in health systems. A separate forum or a task force should be established to facilitate their involvement. This task force or forum could be set up under existing mechanisms such as the EU Health Policy Forum.

If this proposed approach is agreed, the working group on patient safety will develop a work plan for 2006 to make proposals on how each of these priority areas could be taken

forward, as well as to consider other issues linked to patient safety such as healthcare associated infections and antimicrobial resistance.

3. CONTRIBUTION TO OTHER WORK RELEVANT FOR HEALTH SERVICES AND MEDICAL CARE

As set out in its 2004 Report, the High Level Group also provides a means for its members to contribute to other initiatives that are relevant for health services and medical care, whilst respecting the responsibilities of other bodies and institutions. In 2005 the High Level Group has provided comments on the draft Review on policy statements on health and long-term care of the Social Protection Committee and thus provided an input to the process of identifying of common objectives.

4. ORIENTATIONS FOR FUTURE WORK

The High Level Group has developed a good practical cooperation between Member States, which is already delivering concrete results. 2006 should see further steps, such as pilot projects on centres of reference.

Subject to the views of health ministers, the High Level Group plans to proceed on this basis during 2006 and thereafter, taking into account comments and suggestions from the Council and other stakeholders as well as providing regular updates on progress.

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GUIDELINES FOR PURCHASE OF TREATMENT ABROAD

09 November 2005

1. Introduction and scope of the Guidelines

The High Level Group on Health Services and Medical Care decided to encourage closer co-operation between authorities responsible for purchasing and provision of health care in the Member States and to develop these non-binding guidelines as a framework for the commissioners of health care to take into account when offering, purchasing or providing health care.

These guidelines cover only the situations related to relationships between commissioners of health care established or residing in different Member States involved in cross-border purchasing and provision of health care. These guidelines do not apply to purchasing of the health care by individual patients and in particular not to relationships already regulated by the applicable EU rules on coordination of social security schemes, existing arangements between Member States or existing agreements between commissioners of health care.

The detailed implementation of these guidelines may be further developed by Member States or commissioners of health care, and should take into account any applicable agreements between Member States. In any case, contracts should reflect the principles of universality, equity and solidarity.

2. Aim

These guidelines aim to assist all commissioners of health care in the Member States by setting out some key issues that commissioners of health care should take into consideration when drawing up or reviewing agreements/contracts.

3. Definitions

For the purpose of these Guidelines, the following definitions shall apply to:

Commissioners of health care: All of the entities involved in the regulation, purchasing and providing of health care (including ministries of health; national, regional, local or other public authorities; health insurance institutions; or hospitals).

Cross-border purchasing of health care: Concluding contracts concerning health care between commissioners of health care established or residing in different Member States.

Health care: Health services provided with involvement of a health professional as defined by the EU rules on the recognition of professional qualifications.

General guidelines: The general guidelines set out common elements defined in the national and EU legislation that should be reflected when determining the content of the specific guidelines.

Specific guidelines: The specific guidelines set out elements that should be included in a contract on healthcare purchasing.

4. General Guidelines

1. Applicable law. Contracts should stipulate the applicable law and jurisdiction and in particular should specify that medical care approved by the purchaser will be provided in accordance with the legal framework of the country of provision of care: however, the applicable law may not be the same for all the relevant legal issues.

2. Medical malpractice and liability. The relationship between the patient and the provider of health care should be determined according to private international law or any applicable public law. Commissioners of health care should ensure that liability insurance or other appropriate negligence coverage is in place for all health services provided under the contract.

3. Safeguard clauses. The responsibility for avoiding any conflict between the needs of domestic patients and patients from other Member States lies with the contracting parties, and should be considered before contracting.

4. Sharing of information. Commissioners of health care intend to share all information necessary, including patient information, to implement these guidelines in accordance with Directive 95/46/EC on the protection of individuals with regard the processing of personal data and on the free movement of such data. As regards health data, they may be shared

where this is required for the purposes of medical diagnosis, the provision of care or treatment (including continuity of care and follow-up) or the management of health care services, and where those data are processed by a health professional who is subject to the obligation of professional secrecy or by another person also subject to an equivalent obligation of secrecy. Other data may also be shared where the data subject gives their explicit consent and the law of their Member State allows them to give such consent.

5. Price. The price of the health care should be agreed in the contract between the commissioner of health care and the provider and may differ from contract to contract for care from the provider concerned. The price should reflect the tariffs of the country of provision, where such tariffs exist, but may be varied where this is objectively justified.

   Most commissioners of health care, and the contracts they enter into, are governed by national or European public procurement rules. Directive 2004/18/EC on the coordination of procedures for the award of public works contracts, public supply contracts and public service contracts sets rather limited requirements to procurement of health services. The contracting authorities are, none the less, bound to comply with the fundamental rules of the EC Treaty. This implies in general, the principle of non-discrimination on the ground of nationality and more particularly for public procurement an obligation of transparency which consist in ensuring, for the benefit of any potential tenderer, a degree of advertising sufficient to enable the services market to be opened up to competition and the impartiality of procurement procedures to be reviewed.

6. Administrative procedures. Commissioners of health care should inform the relevant public authorities. All parties concerned should seek to restrict administrative procedures to what is strictly necessary.

5. Specific guidelines

Taking into account the general guidelines the contracts on the purchasing of medical care should contain provisions concerning at least the following:

(i) the types of health care covered by the contract such as number of bed days, procedures, diagnosis, treatment

(ii) the indicative number of patients, treatments or procedures covered by the contract.

(iii) the duration of the contract and mechanisms for renewal and termination of the contract.

(iv) a provision that the following types of information are **exchanged between commissioners of health care** and providers in the following phases:

- in the contracting phase e.g. information about infection rates, quality, clinical criteria's, description of methodology

- in the case of admission e.g. preparations, pictures, blood, location

- in the case of treatment e.g. personal and clinical data

- in the case of follow up e.g. special requirements, journey, frequency of controls, medication, time limits for exchange of medical records

- in the case of complications and possible malpractice e.g. description of cause and consequences, recommended treatment controls

- in the cases where treatment deviate from initially agreed e.g. information on clinical criteria

(v) a provision on the responsibility for provision of clear and understandable **information and communication to patients** in the following phases:

- admission e.g. what to bring, diagnostic results

- treatment e.g. how to prepare, what will be undertaken

- travel e.g. how to get to the provider in another Member State

- financing e.g. what the patient and purchaser are expected to pay

- follow-up and exchange of information with the patient's doctor in their Member State;

(vi) Information and definition of one responsible contact point at both sides, available for patients and commissioners of health care, and mechanisms for updating the contact point. There should be arrangements in place for clinicians on both sides to discuss the clinical arrangements under the contract.

(vii) the financial arrangements

- when the payment will take place e.g. after the treatment takes place, when the patient returns, regularly,

- what is included and how the payment is calculated e.g. length of stay, procedure, cost of capital, medication, overhead costs

- what the patient is charged e.g. medication, medical devices, meals, telephone, travel expenses, changes to planned treatment

- and arrangements for accompanying persons

(viii) the administrative arrangements

- Define a responsible party through the entire process of diagnosis, treatment, journey and follow up.

- Specify the possibilities for accompanying persons e.g. facilities, accommodation, visiting hours.

- The languages of the contract should be agreed between the commissioners of health care.

6. Review of the common guidelines

These guidelines should be kept under constant review.

7. Appendix

Examples of existing contracts and bilateral agreements are available at the following site:

http://forum.europa.eu.int/Members/irc/sanco/hsermedcare/library?l=/&vm=detailed&sb=Title