



ENQual

European research Network on Quality
management in health care

NON-OFFICIAL PAPER:

THE LEGAL STATUS OF CLINICAL PRACTICE GUIDELINES

AN INTERNATIONAL LEGAL COMPARISON BETWEEN 11 EU-MEMBER STATES

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Summary

Since the early eighties the amount of Clinical Practice Guidelines has increased enormously. The European Commission underlines the great importance of clinical practice guideline use as part of quality improvement systems. Clinical Practice Guidelines can have legal implications when their use is regarded as an evaluation tool. This study is an international comparison of determinants for the legal binding character of Clinical Practice Guidelines. We regarded three determinants relevant for the legal binding character of Clinical Practice Guidelines, which are: the use of Clinical Practice Guidelines in court as a form of evidence, the presence of Clinical Practice Guidelines in law, or the authorisation by state appointed national bodies.

Experts in the field of Clinical Practice Guidelines and legal implications in health care set up a questionnaire. Subsequently, this questionnaire was sent out to the members of the ENQual network. The ENQual network is a collaboration network of research experts in Quality Assessment and Quality Management in European countries and is supported by the European Commission. The aim of the network is to facilitate the exchange of knowledge and expertise among European countries.¹ The countries which participate in the ENQual network are: The Czech Republic, Denmark, Finland, Germany, Hungary, Lithuania, Poland, Spain, The Netherlands, the United Kingdom, Italy, and Slovakia. The following countries returned the questionnaire and took part in this study: The Czech Republic, Denmark, Finland, Germany, Hungary, Italy, Lithuania, Poland, Spain, The Netherlands, and Slovakia.

Variations exist in the occurrence of legal aspects and implications of Clinical Practice Guidelines amongst countries. Only Germany Clinical Practice Guidelines have a strong legal status. In the other ENQual countries Clinical Practice Guidelines have some legal implications. In Germany, Poland, and Lithuania Clinical Practice Guidelines are mandatory by law for specific medical fields. When Clinical Practice Guidelines are mentioned in law in general, this is mostly for their development and/or implementation.

¹ For more information see: <http://www.nivel.nl/enqual> or <http://www.enqual.info> (28-3-2005).

Most ENQual countries have formal bodies for authorisation of Clinical Practice Guidelines. When Clinical Practice Guidelines are used in court they can be used as autonomous evidence in some countries.

The legal status of Clinical Practice Guidelines is expressed by several legal aspects and implications, which are: formal authorising bodies for Clinical Practice Guidelines, mentioning of Clinical Practice Guidelines in law, and the use of Clinical Practice Guidelines in court as evidence in case of medical malpractice.

In conclusion, variations in the occurrence of legal aspects and implications of Clinical Practice Guidelines exist amongst countries. Clinical Practice Guidelines have a strong voluntary character in the Czech Republic, Hungary and Denmark. In most of the other countries Clinical Practice Guidelines have a compulsory character, because they either are mandatory by law, or can be used in court as evidence in case of medical malpractice.

1 Introduction

Since the early eighties the amount of Clinical Practice Guidelines (CPG's) has increased enormously. CPG's are a part of quality management now and are used to assure and improve the quality of care.²

According to the Council of Europe CPG's are of great importance to assure and improve the quality of health care. It recommends the EU member states to "create policies and structures that support the development and implementation of 'quality improvement systems', i.e. systems for continuous assurance and improvement of the quality of health care at all levels".³ In the appendix of its recommendation the Council states that medical guidelines (read CPG's) should be implemented as a part of essential features of quality improvement systems.

CPG's are intended to provide professionals with a guidance tool, which has proven to be the best medical care a patient can get in given circumstances. This enables a professional to make the best choices in a short period of time and leads to health care of high quality and high efficiency. Since CPG's reflect the state-of-the-art in clinical practice they have potential legal significance and can be used as an evaluation tool⁴ as well as a tool to determine whether a medical professional has acted according to the instructions which are given in a CPG for certain circumstances. Not following these instructions can result in legal consequences in some countries.⁵

As CPG's are a form of self-regulation⁶ by the medical profession this leads to the question whether CPG's are voluntary or compulsory tools to be used by professionals in the European countries.⁷ And whether they are used as an evaluation tool with legal implications in these countries.

² Burgers et al. 2003, p. 148; Baker & Feder 1997, p. 399.

³ Council of Europe, RECOMMENDATION No. R (97) 17

⁴ Gevers & Biesart 1999, p. 2630.

⁵ Buijsen 2000, pp. 22-25; Hart 2000, p. 12; Hyams et al. 1995, p. 450; Schwartz et al. 1999, p. 1154.

⁶ Hart 2000, p. 5.

⁷ Hart 2000, p. 9; Gevers 1999, pp. 301-302; Hurwitz 1999, p. 661.

The legal status of CPG's depends on the authority of CPG's themselves or the authority of organisations who develop or use these CPG's. For this study we considered the use of CPG's in court as a form of evidence, the presence of CPG's in legislation,⁸ or the authorisation by state appointed national bodies⁹ as determinants for the legal status of CPG's.

This report firstly elaborates on the background of this study, the ENQual network. Subsequently, chapter 3 reflects the method and materials which have been used to conduct this study. Chapters 4-6 present the results of this study. These results are discussed in chapter 7. Chapter 8 draws the final conclusion on the basis of the discussion of chapter 7. Finally, chapter 9 looks back on the process of this study.

⁸ Gevers 1999, p. 302.

⁹ Van Reijssen 1999, pp. 250-251.

2 Background

The ENQual Network

European countries differ in the quality policies they pursue and consequently differences exist in the extent of quality management in health care organisations per country. The ENQual network is a thematic network on quality policy and quality management in health care, funded by the European Commission, and is a part of the Quality of Life programme “Public Health” (generic activities, area 10), to improve the health of European citizens by analysing “health policy initiatives and variations in health care models”, and “the effectiveness of health interventions”. The ENQual network was established in January 2003 to facilitate and to coordinate the exchange of information and expertise on similarities and differences among European countries in the national quality policies, and research methods to assess quality management in health care organisations at a national level. Both quality policy and quality management are rather new phenomena in health care. As a consequence, variations between the countries exist in many respects. For example, new quality acts have been issued in some countries, while other countries follow a non-legislative approach. The ENQual network consists of member-countries, which are represented by a key person in the field of quality management in health care. To gain insight into the quality policy and implementation of quality management in the participating countries three workshops were organised. During the first workshop 10 countries participated in the ENQual network, at this moment the ENQual network consists of 12 member-countries. These countries are: the Czech Republic, Finland, Denmark, Germany, Hungary, Lithuania, Spain, Poland, the Netherlands, the United Kingdom, Italy, and Slovakia. At first sight this seems an arbitrary selection of countries. However, the underlying thought of bringing these countries together is to get a mix of some Mediterranean countries, Scandinavian countries, Central European countries, and Western European countries.

Quality Management Systems and Clinical Practice Guidelines

The rationale of a quality management system is that it can improve the performance of an organisation by facilitating more effective and efficient processes and by improving the collaboration between health care professionals. Thus, a quality management system can

be described as the organisational structure, responsibilities, processes, procedures, and resources used to control, assure and improve the quality of care. Continuing quality improvement is one of the basic elements of a quality management system and implies the systematic monitoring and improvement of (parts of) the process of care through the quality cycle or the feedback procedures.¹⁰

CPG's are documents, which lead to more efficient provision of care according to the latest knowledge of medical science. They are to assist the professional as well as the patient in making choices for the best available treatment for a certain disease. CPG's are either based on consensus amongst professionals or evidence-based medicine. As a result CPG's provide professionals the best available and efficient treatment in certain circumstances. Therefore CPG's form a part of quality management systems.

The Three ENQual workshops

Core element of the ENQual network is international exchange of knowledge. Therefore, three workshops were organised. During these three workshops the ENQual members had to give a presentation about a given topic. After each presentation discussions took place to find out about the differences and similarities amongst the ENQual countries. The results of the three workshops are published on the ENQual website.¹¹

The first ENQual workshop was held in November 2003 in Utrecht, the Netherlands, and was hosted by the Netherlands Institute for Health Services Research (NIVEL).¹² Theme of the first ENQual workshop was the health care quality policies of the participating countries. A National Quality Policy is the policy of the Government and other authorities to stimulate Quality Management in health care. The objective of the first ENQual workshop was to exchange information on National Quality Policies in the participating countries and to discuss similarities and differences in these National Quality Policies.

In many countries the national governments have initiated an explicit quality policy in health care. This is in line with one of the World Health Organisation's targets, that all countries should establish effective mechanisms for ensuring quality of patient care within

¹⁰ Wagner 1999, p. 61.

¹¹ For more information see: <http://www.enqual.info> (30-3-2005).

¹² For more information see: <http://www.nivel.nl> (30-3-2005).

their health care system. The national quality policies are aimed at protection of patients, reduction of medical errors and the promotion of quality management by health care providers.

In order to get an overview of these policies each of the network members presented the characteristics of the health care Quality Policy in his/her country and the way in which it has been developed since 1990.

The second ENQual workshop was organised in April 2004 in Helsinki, Finland, and was hosted by the National Research and Development Centre for Welfare and Health (STAKES).¹³ Theme of the second ENQual workshop was quality management activities, which are performed in hospitals in the participating countries. The objective of the second ENQual workshop was to develop a clear understanding of Quality Management by discussing similarities and differences in activities and the extent of implementation in health care organisations in the participating countries.

The basic concept of quality management activities in hospitals is that they will reduce the occurrence of medical errors and adverse events, and that they will result in appropriate and safe health care. Quality management is a collective term encompassing all the procedures explicitly designed to monitor, assess and improve the quality of care. To that end, new concepts have been introduced, for example peer review, satisfaction and need surveys, best practice, accreditation, certification, CPG's and internal audits. Within and between countries the exact definitions of these concepts appear to vary, and clarification is needed.

The third ENQual workshop was organised in November 2004 in Budapest, Hungary, and was hosted by the Centre for Public Affairs Studies Foundation of the Budapest University of Economic Sciences and Public Administration. Theme of the third ENQual workshop was the Research methods to assess the implementation and effectiveness of Quality Management.

Recently, many European countries have expressed the desire for a national overview of the extent to which Quality Management activities are implemented into their health care organisations. Policy makers are in need of such information to evaluate the effectiveness

¹³ For more information see: <http://www.stakes.fi> (28-3-2005).

of their quality policy. In some countries, such overviews already exist, and in other countries researchers are involved in the development of research methods to assess the implementation and effectiveness of Quality Management.

During the third ENQual workshop the participating countries made an inventory of research methods and instruments, which can be used to assess quality management in health care organisations. The network members made an overview of research methods and instruments in their respective countries. These results were discussed at the third workshop. The members exchanged information on the suitability of the different research methods.

A related topic of discussion during the workshop was the possibility of adjusting the existing measurement instruments, in order to develop a generic instrument, which can be used in a number of European countries to assess the extent to which Quality Management has been implemented in health care organisations. It was agreed upon that the questionnaire, which was used for the ENQual hospital pilot, could be a good instrument to measure the implementation and effectiveness of quality management activities in the participating countries.

Besides the exchange of knowledge, the ENQual workshops turned out to be excellent opportunities for networking activities. During the workshops the key persons formed a close group of colleagues and new possibilities for international research and cooperation amongst the members were planned.

3 Materials, Method & Definitions

International comparative research

International comparative research is a very interesting activity. The exchange of different approaches and the analysis of similarities and differences amongst different countries provide an opportunity to learn from each other's experiences. At the level of the European Union some endeavours are directed at harmonising quality requirements for health care among the member states. This makes it very important to learn from each other. A good way to exchange knowledge and experience on an international level on a certain topic is the use of a network consisting of key persons. Many examples of these networks exist. The three ENQual workshops have proven to be an effective and pleasant method to exchange knowledge when the topic is not too specific. More specific topics need more preparation and more guidance.

A study on a specific legal topic needs preparation and guidance in order to obtain data, which can be used in an international comparison. Therefore we used a structured questionnaire to conduct the study regarding the legal status of CPG's. This paragraph will elaborate on the development of this questionnaire.

Definitions: make sure you talk about the same thing

Particularly for international comparative research it is essential to make sure that all the respondents use the same definitions of the treated concepts. It is evident that it is not possible to compare oranges with apples. Therefore it is essential to make sure a questionnaire does not contain any ambiguous terms or concepts. Of course it is not always possible to use concepts, which are totally clear to all respondents. Consequently, it sometimes is necessary to give a definition of the used concept or to ask the respondents which definition for a certain concept they apply in their country. The use of the same definition by all respondents increases the validity of an international comparative study.

Definition of Clinical Practice Guidelines

The AGREE Collaboration¹⁴ uses the definition of the Institute of Medicine (IOM)¹⁵ to define CPG's as '*systematically developed statements to assist practitioners and patients decisions about appropriate health care for a specific clinical circumstances*'. Lohr et al.¹⁶ distinguish four concepts in this definition, which are: systematic development, assistance to both clinicians and patients, appropriateness of services, and specificity with respect to defined clinical problems.

This definition is agreed upon by Finland, Denmark, Hungary, Spain, Poland, The Netherlands, Italy, and Slovakia. Germany makes a distinction of CPG's between 'Leitlinien' and 'Richtlinien'. For this study the definition of 'Leitlinien' matches the definition which the AGREE Collaboration uses for CPG's and reads: '*Leitlinien (CPG's) are systematically developed statements to assist decisions about appropriate health care for specific clinical circumstances*'. In addition to this definition, 'Leitlinien' are:¹⁷

- Scientifically based recommendations relating to clinical practice
- Regularly checked whether they are still up-to-date and updated where appropriate
- Representative for the consensus among a number of experts from various professional backgrounds and working fields (including patients where appropriate) concerning a particular clinical practice based on a well defined and transparent procedure
- Aids to orientation in the sense of 'corridors for practice and decision' from which deviations are possible or even mandatory in justified cases.

Also Lithuania and the Czech Republic agreed upon the definition of the AGREE Collaboration. However, in **Lithuania** there are no CPG's, which comply with the definition of the Agree Collaboration. They only have so called '*norms of health*', which are mostly for ambulatory care. Norms of health are approved by the Ministry of Health and are valid only for those health care providers who are working on the annual contract with the State

¹⁴ For more information see: <http://www.agreecollaboration.org> (20-12-2004).

¹⁵ Field & Lohr 1990.

¹⁶ Lohr et al. 1998, p. 5.

¹⁷ German Medical Association and National Association of statutory Health insurance physicians 1997; Ollenschläger et al. 2001, p. 474.

Sickness Fund. The norms of health are mentioned in art. 2 and 8 of the '*Law on the rights of the patients and compensation of the damage to their health*'.¹⁸

In the **Czech Republic** CPG's are elaborated into the Standard(s) of Efficient Medical Care (SEMC).¹⁹ The SEMC is a broader concept than CPG's and includes, next to CPG's, also baseline conditions and outcomes. More precisely SEMC's consist of input – process – output – outcomes. CPG's developed according to the SEMC-method are part of the 'process' section and assure standard medical care, which is measurable by the outcome quantified by key indicators of quality (e.g. mortality, frequency of complications, etc).²⁰

Although all ENQual countries agreed with the definition of CPG's we use for this study, the Czech Republic, and Lithuania use concepts which more or less deviate from the definition of the AGREE Collaboration. In the Czech Republic CPG's are part of a greater entity, the SEMC. In Lithuania, there are not such CPG's which meet our definition. Nonetheless, we received some relevant information from these countries and included this information, where possible, in this study.

Realisation of the questionnaire

The first step in setting up a questionnaire for an international comparative study is to determine what exactly should be studied. To achieve some inspiration and to gain knowledge about what already has been written on the topic it is advisable to perform a literature search. For this study we used PubMed,²¹ a service of the National Library of Medicine,²² including over 15 million citations for biomedical articles back to the 1950's, for a first orientation. The PubMed database was searched for literature describing CPG's in relation to legal and policy aspects. The found literature provided the opportunity to expand the literature search by checking the literature lists of these articles to get new relevant documents. This first orientation on the legal status of CPG's led to the following problem statement:

“What is the legal status of Clinical Practice Guidelines in the ENQual countries?”

¹⁸ New redaction came into force on 1-1-2005.

¹⁹ For more information see: <http://www.mediquali.cz/std/iga98/index.html>

²⁰ Bourek 2004, p. 3; Bourek 2000, pp. 436-439.

²¹ For more information see: <http://www.pubmed.com> (29-3-2005)

²² For more information see: <http://www.nlm.nih.gov> (29-3-2005)

The problem statement was translated into the following research questions:

- 1 Did the ENQual countries set up formal national bodies to officially authorise CPG's?
- 2 Do the ENQual countries refer to CPG's in their legislation, and if so what do they mention about them?
- 3 Is the standard of good medical practice reflected in CPG's of the ENQual countries?
- 4 Do the ENQual countries use CPG's as evidence in court in case of medical malpractice?
- 5 What are the differences and similarities between the legal implications of CPG's between the ENQual countries?

Subsequently, these research questions, had to be translated into clear unambiguous questions. Especially for international comparative research it is advisable to make use of short multiple-choice questions with a possibility to elaborate on the answer. This makes it easy for the respondent to answer the question and if needed, to clarify his answer. As time is money, long and laborious questionnaires often end up in the dustbin.

The questionnaire²³ used for this study was set up in cooperation with experts in the fields of law, CPG's, and quality management activities.

The respondents were asked to answer the questions in respect of their country (see appendix I). The questionnaire firstly provides the respondents with the definition of CPG's, which is used by the Agree Collaboration. The AGREE Collaboration is an international collaboration of researchers and policy makers who seek to improve the quality and effectiveness of clinical practice guidelines by establishing a shared framework for their development, reporting and assessment. When a country uses a definition which deviates from the AGREE Collaboration's definition, the respondents were asked to give this deviating definition.

Subsequently the questionnaire elaborates on the question whether CPG's are mentioned in national legislation. If so, the respondents can elaborate on their answer. Because

²³ See appendix I.

CPG's should reflect the state-of-the-art in clinical practice the next part of the questionnaire asks the respondents to answer questions about the standard of good medical practice in their countries. One would expect that the standard of good medical practice is reflected in the CPG's. The next question of the questionnaire deals with the position of CPG's as evidence in court in case of medical malpractice.

Sending out the questionnaire and receiving response

Especially for international comparative research it is a challenge to obtain a high response rate.

Because the respondents are located in another country, they feel less pressure to participate in a study. In order to make sure they will respond a questionnaire it is important to personally involve the respondents in the study. The ENQual network proved to be a great tool to personally involve the key persons into international comparative studies regarding quality management activities in health care organisations.

The questionnaire was sent out during the first week of January 2005 to the 12 countries participating in the network. In the first week of February 2005 10 countries had given their response to the questionnaire. The following countries returned the questionnaire and took part in this study: The Czech Republic, Denmark, Finland, Germany, Lithuania, Poland, Spain, The Netherlands, Italy, and Slovakia. Hungary sent in the answers later. This leaves us with a response rate of 92%.

Analysis of the answers to the questionnaire

After the completed questionnaires were received, the multiple-choice answers were put into tables. This made it easier to get an overview which legal aspects of CPG's were present in the participating ENQual countries. Subsequently the answers were described in the result section of this paper. The answers to the multiple-choice questions formed the basis for the description of the answers to the open questions. After the description of the results it became clear what the legal status is of CPG's per country.

The legal status of CPG's per country formed the basis for the discussion, in which the comparison was made between the differences and similarities of CPG's in the ENQual countries.

To make sure this paper correctly reflects the legal status of CPG's per country, a draft version was sent to the key persons of the ENQual network. They reviewed the document

carefully and sent back their feedback. This feedback was incorporated into the document.

Finally, the document has been sent to the scientific deliberation group of NIVEL. This group consists of the researchers of NIVEL and is set up to review all scientific documents, which are meant for publication. The feedback of the scientific deliberation group has also been incorporated into the document and formed the final version.

Finally, it should be noted that the legal status of CPG's per country should be seen in the perspective of the legal system of that country. However, this study focuses on the role and function of CPG's in a medicolegal setting. In an over viewing article, such as this, it is not relevant to elaborate on these different legal systems.

4 National authorisation and development of Clinical Practice Guidelines

Guideline development is a form of self-regulation by the professional group.²⁴ In some countries CPG's are authorised by national formal bodies. These national bodies are organisations, which are officially appointed by the national government to supervise and authorise CPG's in a country.²⁵ Figure 1 gives an overview of the national authorisation and development of CPG's in the ENQual countries.

Figure 1 National authorisation and development of CPG's in the ENQual countries

	National Standard for CPG development	Formal CPG authorising body	Amount of CPG's authorised
Czech Republic	Yes, MediQuality (http://www.mediquali.cz - 28-3-2005 http://www.cls.cz/english/index.htm - 26-8-2005)	Yes, Ministry of Health and Czech Medical Association	>100
Finland	Yes, Käypä Hoito (Current Care)	Yes, Käypä Hoito (Current Care)	50-100
Denmark	Yes	Yes, Unit for CPG's of National Health Board	0-10
Germany	Yes	Yes, Federal Joint Committee and Federal Ministry of Health	0-10
Lithuania (Health Norms)	No	Yes, Ministry of Health	20-50
Spain	No	No	Not available
Poland	No	No	Not available
The Netherlands	No	No	Not available
Italy	Yes, National Program for Guidelines (http://www.pnlg.it - 28-3-2005)	No	Not available
Slovakia	No	Yes, NIKI – National Institute of	0

²⁴ Hart 2000, p. 5.

²⁵ Schwartz et al. 1999, p. 1154.

As figure 1 shows, there are no formal bodies for authorising CPG's in Spain, Poland, the Netherlands, and Italy. Medical associations in **Poland** authorise the CPG's they develop, but there is no formal body over-viewing CPG's development and implementation on a national level. In **Italy** healthcare is managed at a regional level since 2001: the 20 Italian regions may decide autonomously how to provide health and healthcare services to the citizens and, therefore, it is difficult to identify a national policy for health affairs. Nevertheless, a strategic committee was appointed by the Decreto Ministeriale of the 30th of June 2004 to promote the development of CPG's and to support their diffusion. Neither in the **Netherlands** there is a formal authorising body. However, the professional bodies are joined in the EBRO platform (evidence based guideline development, formerly known as Cochrane),²⁶ which prevents the fragmentation of activities by gearing the development and revision of CPG's to one another. The aim of this process is to develop and implement high-quality CPG's based on the principles of evidence-based medicine and the AGREE instrument. The EBRO platform can be seen as a Dutch version of the Guidelines International Network (G-I-N).²⁷

Official national bodies exist for authorising CPG's in the Czech Republic, Finland, Denmark, Germany, Hungary, Lithuania, and Slovakia. In **Germany** CPG's from various Medical Societies are published by the Association of the Scientific Medical Societies (AWMF). In 2002 a national guideline program (NVL) was issued by the German Medical Association, the National Association of Statutory Health Insurance Physicians and AWMF in order to develop multidisciplinary CPG's²⁸ for specific health conditions. According to the Health Care Reform Act the Federal Joint Committee and the Federal Ministry of Health are responsible for authorisation of CPG's since 2004.²⁹ This authorisation applies only for CPG's which are mandatory in disease-management-programmes for the patients insured through the Social Law Book V.

²⁶ For more information see:
<http://www.cbo.nl/product/richtlijnen/folder20050106151837/article20031112170254> (28-3-2005).

²⁷ For more information see: <http://www.g-i-n.net> (28-3-2005).

²⁸ For more information see:
<http://www.leitlinien.de/versorgungsleitlinien/index/dokumente/pdf/awmfvertragfinal.pdf> (19-7-2005)

²⁹ Based on §§ 91, 92, and 94 of the Social Code Book V (SGB V).

In **Finland** Käypä Hoito (which means 'current care') is the official, state-funded, independent guideline-producing organisation.³⁰ The authorising body for CPG's in **Denmark** is the Unit for CPG under the National Health Board. And the national body for authorisation in **Slovakia** is the National Institute of Quality and Innovations (NIKI). In Hungary CPG's are authorised by the Ministry of Health (based on suggestions from Professional Colleges)

In the **Czech Republic** CPG's are recommended by the Czech Medical Association (CZMA)³¹ and the respective professional bodies, which form a part under the umbrella of the CZMA. A very small number of CPG's (especially the management and implementation of screening programs, e.g. cervical cancer screening, pregnancy screening and management, breast cancer, colorectal cancer screening, and procedures relating to assisted reproduction), which are closer to 'protocols', are authorised by the Czech Ministry of Health.³² Plans are made to provide the Czech Society for Healthcare Quality with a competence as an authorising body. The Norms of Health, used in **Lithuania**, are authorised by the Ministry of Health.

In each country organisations exist, which are involved in the development and implementation of CPG's. In some countries these organisations are professional bodies, which are involved in the development and implementation of guidelines on a self-regulative basis. In other countries these organisations have a formal status and are entitled by their national governments to officially authorise CPG's.

³⁰ For more information see: <http://www.kaypahoito.fi> (28-3-2005).

³¹ For more information see: <http://www.cls.cz> (28-3-2005).

³² For more information see: <http://www.mzcr.cz> (28-3-2005).

5 Clinical Practice Guidelines in national legislation

A European trend is to issue CPG's based on statute law. These CPG's can be developed by State agencies (formal bodies) directly or on delegated legislation.³³ In Germany, Lithuania, Poland, Italy, and Slovakia CPG's are mentioned in their national legislation (see figure 2).

Figure 2 Are CPG's referred to in national law?

Czech Republic	No
Finland	No
Denmark	No
Germany	Yes, Social Law Code (SGB)
Lithuania	Yes, Norms of Health
Spain	No
Poland	Yes, CPG's of the National consultant in anaesthesiology and intensive care, 1997
The Netherlands	No
Italy	Yes, several laws
Slovakia	Yes, Law on Health Care providers nr. 578, 2004

In **Germany** CPG's are mentioned in the fifth book of the Social Law Code (Socialgesetzbuch V). CPG's are implicitly mentioned in §135a(1) in the context of quality management, and explicitly mentioned in §§ 137f and 139a(3) in the context of disease management programmes. §137f states that CPG's should be available for chronic diseases and during the treatment of these diseases the use of CPG's should be taken in consideration. Based on §139(3)a scientific institute (Institut für Qualität und Wirtschaftlichkeit im Gesundheitswesen, IQWiG) has been founded to, amongst others,

³³ Schwartz et al. 1999, p. 1154.

assess CPG's for epidemiological most important diseases – so far no CPG has been assessed by the IQWIG.

In **Poland** CPG's of the National Consultant in Anaesthesiology and Intensive Care (*Wytyczne Krajowego Konsultanta w Dziedzinie Anestezjologii I Intensywnej Terapii*)³⁴ are mandatory by law.

In **Italy** CPG's are mentioned in several legislative documents. The National Health Plan 1998-2000 and the Legislative Decree of 1999³⁵ both provide the general framework and define the objectives of the National Quality Program. The National program for CPG's, which is established by a Health Ministry Decree (Decreto Ministero della Salute)³⁶, provides operative tools to achieve the goals of the National Quality Program. The National Financial Act 1999, Law nr. 449 (Section one Healthcare), and Law nr. 662 identify the organisations which are entitled to develop CPG's.

In **Slovakia** CPG's are mentioned in the Law on Healthcare Providers.³⁷ Paragraph 9 of this act states that the provider is obliged to implement quality systems for quality assurance and quality improvement. The regulation of the Ministry, which will come into force on the 1st of January 2007, sets the details on quality system assessment. From 2006 on the use of therapeutical and diagnostical standards will be obligatory, due to the publication of the catalogue of procedures by the Ministry of Health in the governmental regulation 576/2004.

The **Lithuanian** Norms of Health are mentioned in articles 2 and 8 of the Law on the Rights of the Patients and Compensation of the Damage to their Health.³⁸ In these articles it is stated that a patient has the right to choose one of the possible Norms of Health during the diagnostic process or treatment.

When CPG's are mentioned in legislation, these laws mostly regulate the development and implementation of CPG's. More specifically, these laws regulate and stimulate the development of a quality system and state that CPG development and implementation are important contributions to these systems. Only in Germany, Poland, and Lithuania the use of specific CPG's are mandatory by law for specific medical fields.

³⁴ Published in the legal journal on 17-7-1997.

³⁵ Decreto Legislativo 229/1999.

³⁶ Version which came into force on the 30th of June 2004.

³⁷ Published under nr. 578, 2004.

³⁸ Version which came into force on the 1st of January 2005.

6 Clinical Practice Guidelines in national courts

In a legal setting (e.g. court) the standard of good medical practice is used as a tool to evaluate professional acting. So far, no internationally accepted definition of the standard of good medical practice exists. Figure 3 reflects the occurrence of the standard of good medical practice in CPG's in the ENQual countries. Taking into account the elements of the provided definitions we see that some aspects are more or less part of the definition in each country. These aspects are:

1. Patients in equal circumstances should be given the same medical treatment
2. The care provided should meet the standards of medical science, which are generally accepted by other professionals of the same medical category.

This first aspect corresponds to Lohrs' concept of specificity with respect to defined clinical problems. The second aspect corresponds to Lohrs concepts of 'systematically development' and appropriateness of services'. In other words, CPG's reflect the standard of good medical practice to a great extent. This is in accordance with the earlier findings of Gevers³⁹ and Hart⁴⁰, which are that CPG's are an elaboration of the standard good medical practice, aimed at improving the quality of medical care.

Figure 3 CPG's and the standard of good medical practice

	Standard of good medical practice in CPG's	Definitions of the standard of good medical practice
Czech Republic	Yes	SEMC, According to the SEMC the good medical standard should consist of: baseline conditions, CPG's, Measurable outcomes.
Finland	Yes	In their professional activities, health care professionals must employ generally accepted, empirically justified methods, in accordance to their training, which should be continually supplemented (Act on health care professionals 559/1994; finlex.fi) The patient must be treated in the manner that an experienced professional would have treated (patient injuries act 585/1986, amended 640/2000).
Denmark	No	The legal definition applies to an individual doctors conduct in a specific situation.

³⁹ Gevers 1999, p. 301.

⁴⁰ Hart 2000, p. 12.

Germany	Yes	<p>Good medical practice is defined in accordance with the state of the art in medical science and patients' needs. In the context of the statutory health insurance the SGBV guaranties the insured what is:</p> <ul style="list-style-type: none"> - sufficient (ausreichend) - necessary (notwendig) - useful (zweckmassig) - economic (wirtschaftlich) <p>Details can be found in art. 12, 28, 35, 70, 72, 92, 126, 135, 139 SGBV</p>
Lithuania	No	Not available
Spain	Yes	Not available
Poland	No	Not available
The Netherlands	Yes	<p>Defined by Leenen (1996, pp. 41-42) as: A doctor has to act carefully according to the understandings of medical science and experience, like a reasonably competent doctor from the same medical category in the same circumstances with the same means, which are in proportion to the concrete aim of the treatment, would act. See also Dute (2000 p.125), who points out that the professional standard is mentioned in art 7:453 Civil code, but not officially defined.</p>
Italy	No	<p>There is no specific legal definition of good medical standard in Italian legislation. The Italian Criminal Code requires that healthcare professionals have to act with diligence, prudence and skill. If he/she harms anyone by being negligent, imprudent or unskilled, he may be convicted (Italian Penal Code art. 43; Gerin, C., Medicina Legale a delle Assicurazioni, Roma 1977).</p>
Slovakia	No	Not available

The standard of good medical practice is reflected in CPG's in the Czech Republic, Finland, Germany, Spain, and the Netherlands. These are also the countries, which have a specific definition of the standard of good medical practice.

As CPG's mostly reflect the standard of good medical practice and are documents with state-of-the-art knowledge, they can be a useful evaluation tool in courts. Therefore, CPG's can be used in court as evidence for inculpatory as well as exculpatory purposes.⁴¹ Figure 4 reflects the use of CPG's in court as evidence in case of medical malpractice in the ENQual countries.

⁴¹ Hyams et al. 1995, p. 454.

Figure 4 Are CPG's used in court as evidence in case of medical malpractice?

Czech Republic	No
Finland	Yes, however they are always interpreted by clinicians in context of the court case
Denmark	Not available
Germany	Yes, experience from the use of CPG's in arbitration board decisions suggests that they will be used to define the 'minimal standard of care' rather than the 'optimal standard'
Lithuania	No
Spain	Yes, as well as protocols. Both documents are regarded as autonomous/independent evidence in court
Poland	Yes, professionals use CPG's in court to prove they have followed the art of medicine
The Netherlands	Yes, however to use a CPG as autonomous/independent evidence the judge has to verify the origin and authority of the CPG
Italy	Yes, CPG's can be used as standards of medical care by defending counsels, attorneys or expert witness appointed by the judge
Slovakia	No

In case of a malpractice trial **Polish** health care providers (hospitals/professionals) claim they have followed the art of medicine and proceeded according to the Act on the Profession of Physician (1995). This act obliges professionals to act according to the recent medical knowledge. This obligation is also expressed in the Code of Doctors' Ethics (2003).

In **Germany** CPG's are likely to become increasingly relevant in legal conflict. Claims for malpractice can be addressed in various ways in Germany:

- 1 'arbitration boards' of Medical Associations, based on medical professional law;
- 2 civil courts (legal constitutions, based on social law);
- 3 medical review boards (Statutory Health Insurance Funds);
- 4 direct regulation with insurance companies outside courts.

Plaintiffs as well as defendants can refer to CPG's in both cases. In the past, judges did almost exclusively rely on expert's reports. With the introduction of the CPG's in court

decisions may become more transparent and independent from a single expert's report. Experience from the use of CPG's in arbitration board decisions suggests that they will be used to define the '*minimal standard of care*' rather than the '*optimal standard*'.⁴²

In **Italy** a judge is completely autonomous in taking decisions (art 101 & 111 Italian Constitution) and he may appoint an expert witness to assist him in trials concerning specific technical fields (art 220 to 233 Italian Code of Criminal Procedures). The appointed expert witness can use CPG's as standards of medical care. Attorneys and defending counsels may refer to CPG's as standards of care as well.

Finland malpractice cases mostly do not go to court because other mechanisms are present to handle complaints. When a case comes to court CPG's can be used as evidence. However, they cannot be used without a clinician to interpret the CPG in the context of the court case. So far, there is no indication that the CPG's form a normative basis for court decisions.

In the **Netherlands** CPG's are used as evidence in court decisions. When this is the case the judge has to take into account the origin and 'authority' of the CPG.⁴³ Deviation of a CPG can have severe consequences on the one hand. On the other hand, a professional can decide to deviate from the CPG on the basis of good medical practice. In other words, he must have a considered reason to decide not to follow the CGP.⁴⁴

In **Spain**, CPG's are used in court as autonomous evidence. In **Denmark** court-cases vary. The specific complaints council has a court like function. Unfortunately no (more) detailed information was available from these countries. CPG's are not used in national courts in Lithuania, the Czech Republic, and Slovakia (see figure 4).

In short, because CPG's should reflect the state-of-the-art on specific fields of medicine they are used as a form of evidence in most ENQual countries. However there are countries where CPG's are not used in courts ever. Whether CPG's can be used as autonomous means of evidence or not, differs per country.

⁴² Berndt & Fischer 2000, pp. 1942-1944.

⁴³ Van Wijmen 2000, p. 112.

⁴⁴ Van Wijmen 2000, p. 69; Gevers 1991, p. 1281.

7 Discussion

Variations exist in the occurrence of legal aspects and implications of CPG's amongst countries. A summary of the results of this study is given in Figure 5.

Figure 5 Summary of the results of this study

	Formal authorising body for CPG's	CPG's in Law	CPG's used in court as evidence
Czech Republic	Yes	No	No
Finland	Yes	No	Yes
Denmark	Yes	No	Not available
Germany	Yes	Yes	Yes
Lithuania	Yes	Yes	No
Spain	No	No	Yes
Poland	No	Yes	Yes
The Netherlands	No	No	Yes
Italy	No	Yes	Yes
Slovakia	Yes	Yes	No

The results show that in general there are three ways for countries to deal with the legal implications of their CPG's

1. CPG's have no legal implications at all. They are voluntary tools.
2. CPG's have some legal implications. They are authorised by official bodies, or mentioned in law, or they are used in court. However, they are not used as independent evidence.
3. CPG's have legal status. Deviation of a guideline is not accepted unless there is a good motivation for it.

In only one ENQual country, Germany, CPG's have a strong legal status. In the other ENQual countries CPG's have some legal implications. As far as the Czech Republic, Hungary, and Denmark are concerned, CPG's have a minimum of legal implications and

do not play a role in court decisions at all. In the other ENQual countries the legal implications are stronger because CPG's are mentioned in law and/or play a role in court decisions. Thus, CPG's can serve legislators and/or health policy makers in regulating clinical activities or lawyers in a legal case in most of the ENQual countries.⁴⁵

Most of the ENQual countries have (national) organisations for developing and implementing CPG's. In some countries these organisations are officially appointed by the government as authorising bodies. CPG's from bodies with a formal legal authority seem to have more legal binding power than CPG's from other professional organisations because they comply with officially developed demands for CPG's.⁴⁶ Nevertheless, as regulations from professional bodies can obtain a legal binding character as well⁴⁷ one could ask oneself whether CPG's from professional bodies with formal self-regulating powers have less legal implications than CPG's from authorising bodies officially appointed by the government.

Only in Germany, and Poland CPG's are mandatory by law for specific medical fields. Nonetheless, CPG's are mentioned in law in other countries to regulate the development and implementation. Because CPG's are a form of self-regulation legislators should be careful going into detail too much regarding CPG's during the legislative process. Self-regulation creates a dynamic field with possibilities for improvement. When legislation is used to regulate CPG's this dynamic field is narrowed and limits the possibilities for improvement and further development of CPG's. Consequently, this would have a negative effect on quality improvement.

CPG's developed by bodies without formal authorising power or legal authority are not legally binding. Nonetheless, CPG's represent (or should represent) the state-of-the-art on specific fields of medicine and therefore have potential legal significance.⁴⁸ In medical malpractice cases judges generally verify whether the health care provider has acted appropriately, according to what one might have expected from the health care provider. In some countries this is called 'acting according to the standard of professional medical

⁴⁵ Schwartz et al. 1999, pp. 1153-1154.

⁴⁶ Walshe 2003, p. 166.

⁴⁷ Schwartz 1999, p. 1154.

⁴⁸ Schwartz 1999, p. 1153.

acting'. Therefore, most of the ENQual countries use CPG's as an evaluation tool in their courts.

8 Conclusion

The legal status of CPG's is expressed by several legal aspects and implications, which are: formal authorising bodies for CPG's, mentioning of CPG's in the law, and the use of CPG's in court as evidence in case of medical malpractice. There are variations in the occurrence of legal aspects and implications of CPG's amongst countries. Nevertheless, in most of the ENQual countries CPG's have at least some legal status. The legal status of CPG's is considered weakest in the Czech Republic, Hungary and Denmark, and strongest in Germany.

This leads to the conclusion that CPG's have a strong voluntary character in the Czech Republic, Hungary and Denmark. In most of the other countries CPG's have a compulsory character, because they either are mandatory by law, or can be used in court as evidence in case of medical malpractice.

9 Epilogue

Three years ago, in 2002 I conducted a study to find out whether something was mentioned in the legislation of EU-member states about quality management activities. While performing this study I found out that international research is not as easy as it seemed to me at the beginning (response rate 40% - 4 out of 10).⁴⁹ The most important problems which occurred during that study were mainly: co-operational problems and communicational problems. Now, in 2005, I conducted a similar study, which is described in this report (response rate 92% - 11 out of 12). Aim of this epilogue is to point out which factors are essential for performing a successful international study.

The first step in the process of international comparative research is to build up a network. The next step is to set up continuous communication between the researcher and the members of the network. This leads almost automatically to a higher response rate on the information you are asking from the network members. It was difficult to get the members of the ESQH network⁵⁰ involved in the first study. Probably the most important reason for this was that the ESQH network was not established for research, but as a formal network of European national quality societies to support quality improvement in the daily practice of health care organisations. Therefore, the ESQH did not have an infrastructure for research projects. This made it more difficult to motivate the members to participate in an international comparative research study. Besides that, the earlier study did not offer a direct advantage for the members at that time and the members of the network had not personally met the researcher. The study was not a part of a major project and there was not any similar project at ESQH at that time. When you wish people to participate in a study they must at least have the idea that they benefit from it. In the 2005 study the names of the participating members were listed as co-authors of the study and the members had met the researcher and discussed the topic several times.

⁴⁹ Coppen 2002, pp. 65-68.

⁵⁰ For more information see: <http://www.esqh.net> (30-3-2005).

For validity reasons it is important to make sure that the respondents from different countries use equal definitions for the same concepts. In the 2002 study it was not clear to the respondents what was expected from them. The questionnaire took too much time to complete and was based on Dutch concepts. The definitions of these concepts were missing in the questionnaire. Therefore it was difficult to complete the questionnaire. In the 2005 study clear, internationally accepted definitions were used.

Performing international (comparative) studies is an art of research which requires special skills. During the 'quality and law study' in 2002 I could only persuade four respondents to cooperate with me and to provide me the information I needed at that time to complete the study. During the 'legal status of CPG's study' respondents from eleven countries offered their cooperation and provided the information needed to complete the study.

This remarkable difference can be explained by the fact that during the past three years I have gained more experience in performing international comparative studies.⁵¹ Again, during these studies, it appeared that communication and networking are very essential aspects in performing international comparative studies.

My work for the ENQual network made it possible to develop a solid questionnaire and to make use of a network of dedicated persons with a lot of expertise on quality management activities in their country. This was a good basis for performing this study and in the end made the process of this study a lot easier than my first international comparative study.

To conduct an international study it is essential to have access to a solid thematic network consisting of dedicated experts.

⁵¹ Coppen et al. 2003; Coppen et al. 2005.

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Appendix

Questionnaire legal status of Clinical Practice Guidelines (CPG's)

Dear Enqual member,

The article topic I would like to write about is 'the legal status of Clinical Practice Guidelines'. I would kindly like to ask you to fill in this short questionnaire. I realise that some of the questions in this questionnaire are complex legal questions. If possible, maybe you can ask a (health care) lawyer to support you with answering some of these questions. When you use literature for answering the questions, please provide me this literature or a reference. In the attachment you will find the draft results for some countries I found in literature.

Thank you very much in advance for you cooperation,

Remco Coppen

Please tick for which country you are answering this questionnaire

- Czech Republic
- Finland
- Denmark
- Germany
- Hungary
- Lithuania
- Spain
- Poland
- The Netherlands
- United Kingdom
- Italy
- Slovakia

1. What is the definition of clinical practice guidelines that is commonly used in your country? (The Agree Collaboration defines guidelines as systematically developed recommendations to help care providers and patients to decide about the best care in a specific situation. Is this definition applicable in your country?)

.....
.....
.....
.....
.....

2. Are CPG's mentioned in the law?

- No
- Yes

- In which law(s) are they mentioned? (if possible, please give the specific location in the law were they are mentioned)

-
.....
.....
.....
.....

- What is mentioned about them?

-
.....
.....
.....
.....

3. What is the definition of the good medical standard in your country?

.....
.....
.....
.....
.....

4. Are CPG's used to lay down the norms of the good medical standard of your country?

- ⊖ No
- ⊖ Yes

5. Are CPG's used in court as a form of evidence in case of medical malpractice?

- ⊖ No
- ⊖ Yes

- To what extent does a judge attach an importance to CPG's in his court decision? Are CPG's used as autonomous/independent evidence?

.....

.....

.....

.....

6. Are court decisions for health care open to the public in your country?

- ⊖ No
- ⊖ Yes

- There are (on average) ... court decisions a year.
- The following organisation(s) provide(s) the access to the decisions:

.....

.....

.....

.....

.....

7. Is there any data available on how many times CPG's are used in court decisions?

- no
- 0-5 times a year
- 5-10 times a year
- 10 times a year

8. Is there a national body for authorisation of CPG's?

- No
- Yes, namely:
.....
.....
.....
.....

9. Is there a general (national) standard for guidelines development in your country?

- No
- Yes

10. How many guidelines are authorised by these bodies?

- 0-10
- 10-20
- 20-50
- 50-100
- 100

11. Is there anything more you would like to share (and we should know) regarding the legal status of CPG's?

.....
.....
.....
.....

Thank you very much for your time and efforts!

You can send the answers to this questionnaire to Remco Coppen