CPME guidelines for **Telemedicine**

CPME
COMITÉ PERMANENT DES MÉDECINS EUROPÉENS
STANDING COMMITTEE OF EUROPEAN DOCTORS

Note

[1] An electronic and eventualy updated version of this publication is available from the CPME Secretariat, Avenue de Cortenbergh, 66 bte 2, B-1000 Brussels, Belgium, tel +32 2 732 72 02, telefax + 32 2 732 73 44, e-mail : secretariat@cpme.be

[2] Relevant CPME documents, identified in this publication by **this font** are available from the CPME Internet website : www.cpme.be

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Foreword

Electronic networks and computer technology have changed the world dramatically and continue to do so. Telemedicine is said to be the fastest developing area of medicine today, offering good opportunities for doctors to better serve their patients. New technology, however, carries many risks as well, and it is evident that the new culture must be developed on a sound ethical basis.

In order to give guidance to doctors in the use of this new technology, the Standing Committee of European Doctors (CPME) has developed guidelines on telemedicine, e-correspondence between doctors and their patients and on marketing of health services over the net. The CPME has also made a study in its member countries in order to evaluate in which way telemedicine is practiced and which problems have been encountered.

The problems and difficulties have been analysed and the CPME has developed policies and recommendations for solutions. The reader will find opinions of the medical profession on many practical aspects of telemedicine in this book. Quite evidently the legislation has not been able to cope with the pace of the development, wherefore these guiding principles are even more important.

The CPME publishes this book in order to help doctors, who consider practicing over the net, and to guide general development of this important and growing field.

The CPME greatly appreciates co-operation with the e-Health Working Group of the European Commission and would like to thank the Group and especially Mrs. Petra Wilson for their expertise and guidance during the development of this publication.

Reiner Brettenthaler Markku Äärimaa

■ The CPME

The Standing Committee of European Doctors (CPME) is the umbrella organization representing 1.6 million European doctors.

It is an international non for profit association under Belgian law composed of the National Medical Associations of the European Union / European Economic Area (Austria, Belgium, Denmark, Finland, France, Germany, Greece, Iceland, Ireland, Italy, Luxembourg, Norway, Portugal, Spain, Sweden, The Netherlands and the United Kingdom).

It has also associate members (Andorra, Bulgaria, Cyprus, Czech Republic, Estonia, Hungary, Latvia, Lithuania, Malta, Poland, Romania, Slovak Republic, Slovenia and Switzerland) and associated organizations which are the most representative, autonomous European medical organisations for doctors (AEMH, CIO, EMSA, FEMS, IFMSA, PWG UEMS, UEMO and WMA).

The aim of CPME is to promote the highest standards of medical training and medical practice in order to achieve the highest quality of health care for the people of Europe.
CPME is particularly concerned to promote public health, the relationship between patients and doctors and the free movement of doctors within the European Union.

To achieve its goals, CPME co-operates proactively with the European Union authorities. It works both by keeping its policy responsive to developments in Europe as well as by taking the lead in matters of importance and urgency for the profession and care of patients.

Because of its wide representation, CPME offers broad expertise in matters related to medicine and the medical profession.

The Standing Committee of European Doctors is directed by a Board elected by the General Assembly for two years. An Executive Committee is constituted within the Board

The CPME has 4 subcommittees :

- Medical training, continuing professional development and quality improvement
- Medical ethics and professional codes
- Organisation of health care, social security, health economics and pharmaceutical industry
- Preventive medicine and environment

Experts from each national member organizations, associate members and associated organisations participate in sub-committees meetings. Where necessary, subcommittees set up smaller working groups to concentrate on specific issues. The work of the subcommittees forms the basis of CPME policy as they are responsible for drafting CPME position statements to be submitted to the governing bodies.

Part 1
Guidelines approved by the CPME

Ethical guidelines in telemedicine

Definition

The term telemedicine refers to the practice of medicine over a distance. In telemedicine, interventions, diagnostic and treatment decisions and recommendations are based on data, documents and other information transmitted through telecommunication systems.

Authorisation - competence

Telemedicine is one way of practicing medicine which may provide opportunities and increase possibilities to effectively use available human and material resources. The possibilities offered by telemedicine must be open to all doctors over geographical borders.

Physicians practicing telemedicine must be authorised to practice medicine in the country or state in which they are located and must be competent in the field of medicine in which they are practicing it. When practicing telemedicine directly with the patient, the doctor must be authorised to practice medicine in the state where the patient is normally resident or the service must be internationally approved.

Patient - doctor relationship

The use of telemedicine must not adversely affect the individual patient-doctor relationship which, as in all fields of medicine, must be based on mutual respect, the independence of judgement of the doctor, autonomy of the patient and professional confidentiality. It is essential that the doctor and the patient can reliably identify each other in a telemedicine consultation.

Preferably, all patients seeking medical advice should see a doctor in a face to face consultation, and telemedicine should be restricted to situations in which a doctor can not be physically present within acceptable time. The major application of telemedicine is the situation in which the treating doctor seeks another doctor's opinion or advice, at the request of or with the permission of the patient.

Where a direct telemedicine consultation is sought by the patient, it should normally only take place when the doctor already has a professional relationship with the patient, or adequate knowledge of the presented problem, to such extent that the doctor will be able to exercise proper and justifiable clinical judgement.

In an emergency, such judgements may have to be based on less than complete information, but in these instances the danger to the health of the patient will be the determinant factor in providing advice or treatment.

The responsible physician

The doctor asking for another doctor's advice remains responsible for treatment and other decisions and recommendations given to the patient.

When practicing telemedicine directly with the patient, the doctor assumes responsibility for the case in question.

The doctor performing medical interventions via telemedical techniques is responsible for those interventions.

Quality, security and safety in telemedicine

A doctor practicing telemedicine is responsible for the appropriate quality of his/her services. He/she must not practice telemedicine without making sure that the equipment necessary for the required telemedical services is of sufficiently high standard and adequately operational.

The doctor must carefully evaluate the data and other information he/she has received. Medical opinions and recommendations can only be given and medical decisions made if the quality and quantity of data or other information received is sufficient and relevant for the case in question.

When performing medical interventions over a distance, the doctor must secure the presence of sufficient and adequately trained staff assisting the patient and his/her continuing care.

Patient documents

All doctors practicing telemedicine must keep adequate patient records and all cases have to be properly documented. The manner of patient identification shall be recorded, as well as the quantity and quality of data and other information received. Findings, recommendations and telemedical services delivered shall be adequately documented.

Medical ethics, patient consent and confidentiality

The principles of medical ethics which are binding on the profession shall also be followed in the practice of telemedicine.

Normal rules of confidentiality and security also apply to telemedicine documentation, storing or transmission methods may be used only where confidentiality and security can be guaranteed.

Patient data and other information may only be transmitted to a doctor or other health professional on the request or with the informed consent (permission) of the patient and to the extent approved by him/her. The data transmitted must be relevant to the problem in question

Good Practice Guide for marketing professional medical services over the net

Introduction

The directive 2000/31/EC, on certain legal aspects of information society services, in particular electronic commerce in the Internal Market (Directive on electronic commerce) shall be brought into force by member states before 17 January 2002. In its article 8 regulated professions are encouraged to draw up a Good Practice Guide at Community level for the marketing of professional services. The Standing Committee of European Doctors (CPME) has asked the Conférence Internationale des Ordres (C.I.O.) to set the principles for this purpose, which the C.I.O. adopted in December 2001. Based on these principles the CPME has adopted the Good Practice Guide for marketing professional medical services over the net.

Aim

The aim of this guide is to guarantee that all marketing of medical services is accurate and truthful in content and appropriate in form, to promote patient safety.

Scope

This Good Practice Guide is applicable to all marketing of professional medical services over the net, whether in the form of web-sites or by the use of other display models.

General principles

Any doctors publishing information about their services on the internet should make sure that the information is factual and verifiable and consistent with good practice guidelines covering other forms of advertising.

Specific areas

Identification of the providers

The providers of medical services must be clearly identifiable in all marketing.

The information displayed should include the name and contact information of the doctor giving the service or responsible for it.

The name, location and contact information of the body, which has granted the authorisation to practice medicine and/or to provide medical services must also be indicated. A link to the rules of professional conduct applicable to the Member State in which the doctor is established (i.e. the national code of Conduct of Medical Ethics) must be provided.

Content

It should be clearly displayed, how the service can be accessed. In case of telemedical services relevant contact information such as the e-mail addresses, telephone and fax numbers should be given, as well as estimated response times. In case of surgeries, the address and opening times in addition to the above contact information should be indicated.

Arrangements for responding to emergencies and access to out of hours health care services should be displayed if relevant.

Information on medical equipment and medical methods used may only be included, if this information has an obvious added value and the terms used are generally known by the public.

Comparative information – open or covered – is inappropriate. Any mentioning of therapeutic results of the provider of the service is inadmissible. Specifically, doctors publishing information must not make unjustifiable claims about the quality of their services. They must not, in any way, offer guarantees of cures, nor exploit patients' vulnerability or lack of medical knowledge. Information must not put pressure on the public to use a service, for example by arousing ill-founded fear about their future health.

Information about recognised quality assurance procedures can be given.

Titles used

Only recognised diplomas and professional qualifications, relevant for the services provided, should be displayed.

Marketing of products

Physicians must not participate in marketing of drugs or other products to the public.

Implementation

The CPME recommends that the national medical associations take appropriate actions to incorporate this Good Practice Guide in the rules of the association or appropriate national regulations.

CPME Guidelines for e-mail correspondence in patient care

Introduction

Communication between the doctor and his/her patient is the most essential part of a doctor-patient relationship. E-mail is already used for communication in health care where it provides a new and effective tool to transmit and receive information.

The use of electronic networks has provided new opportunities for telemedicine, treating patients over a distance. The Standing Committee of European Doctors has already given its ethical guidelines on the practice of telemedicine (**CPME 1997/33**).

E-mail is a useful tool in doctor-patient communication first and foremost as a supplement to, and not as a replacement for, face-to-face consultation. Complicated communication messages that may be difficult to understand, information that may be negative to the patient, or messages which otherwise require personal follow up or support, should preferably be given person to person.

Definitions

E-mail is mail in electronic form; the sender composes a message on his/her computer and transmits it via a communications network to the receiver's computer (European Commission: Telemedical Glossary 2001).

E-mail correspondence in patient care means in this context professional communication to assist the doctor and others

with whom he/she works to fulfil his/her professional obligations and to assist the patient to communicate with his/her doctor in the treatment or a follow-up of his/her condition or in the administration of health care.

Instant messaging means e-communication online.

The purpose of the Guidelines

The purpose of these guidelines is to give practical advice to doctors who establish practices and frameworks for e-mail communication with their patients and to the other health care staff required for patient care. These guidelines offer a minimum code of conduct in e-mail correspondence to help the doctor and other staff to ensure the quality and sound ethical basis of e-communication with their patients.

Benefits of usage of e-mail in health care

E-mail correspondence offers a rapid, cheap and versatile means of communication which is not tied to a certain place or time. Thus it offers time to patients and health care staff to consider the request or the response. For this reason it is recommended that e-mail correspondence be used instead of instant messaging in health care communication.

E-mail correspondence leaves behind a document. Thus, the patient avoids forgetting the response from the doctor or other health care staff. Conversely, the doctor (or other health care staff) has an exact document of the response. Written documentation increases the legal protection of both parties.

Risks of usage of e-mail in health care

Technical, legal and other problems may arise in e-mail correspondence. Examples are:

- interruption of e-mail
- lack of integrity
- destruction of data caused by technical failure or computer viruses
- threat to confidentiality
- lack of identification of the parties
- possible lack of liability insurance coverage
- problems related to cross-border practice of medicine with particular regard to jurisdiction, registration and indemnity.

Suitable issues for e-mail correspondence

E-mail must never be used for seeking emergency help or urgent therapy. In addition, the doctor must always guide the patient to seek a face-to-face consultation if the e-mail consultation sindicates a need for this.

Possible uses of e-mail consultation between the doctor and the patient include:

- communication about laboratory results and other objective measures
- follow-up of a chronic disease or a treatment (e.g. renewal or change in medications) when a face-to-face consultation is not necessary. Examples of such chronic diseases: asthma, diabetes and hypertension.
- guidance in non-acute conditions
- health promotion
- administrative matters such as making an appointment.

Practical guidelines

When considering e-mail correspondence with a patient, the doctor should weigh the benefits and risks of it. The doctor and the patient should, beforehand, discuss the appropriate use of e-mail consultation and agree on the issues to be communicated with it. The patient should also be informed about the security and technical aspects of e-mail correspondence. Written information about the appropriate use of e-mail correspondence should be given to the patient (e.g. Annex 2).

Working arrangements of the doctor

The doctor using e-mail for communication with his/her patients must have time allocated for that purpose and working conditions which enable effective use of e-mail correspondence.

The doctor must define a turnaround time for the e-mail correspondence he/she receives from the patients. The patients and all the relevant health care personnel of the clinic or hospital department concerned must be informed of this turnaround time.

A doctor must inform the patients when he/she cannot be reached by e-mail. If arrangements for another doctor or other medical professional to respond to the e-mail are made for this time period, the patient must give his/her consent beforehand.

In particular there must be a clear agreement about the management of e-mail correspondence during the doctor's absence.

A doctor must establish the protocols of e-mail correspondence to be followed in his/her own practice. These terms of practice

must include the issues mentioned in these guidelines and, where they exist, local guidelines adapted to the individual practice.

Doctors should consider the form in which they distribute information about their own particular practice. They may choose a paper form and or an electronic form for the terms of practice, and this document must be distributed to the interested parties such as patients and the relevant staff at the clinic or hospital department where the doctor practices. A checklist for e-mail correspondence is presented in Annex 1.

Equipment

Before offering consultation services via e-mail, the doctor must ensure that the networks, hardware and software that are being used are functioning as required to run the service reliably. Both hardware and software need to be regularly updated. In particular, up-to-date virus protection is essential.

When choosing the e-mail software it is essential to obtain program which:

- confirms when a message has been delivered
- confirms when a message has been opened
- uses encryption techniques for transfer of the data
- provides an audit trail.

E-mail correspondence as a part of the patient's health record

E-mail correspondence between doctor and patient is a part of a patient's health record. It also has legal significance and must be treated in accordance with the current regulations for medical records. A reliable method must be used to back up all electronic patient data.

E-mail correspondence in health care is comparable to any other communication of health care. The liability of care should thus be the same as in all other forms of professional communication.

Privacy and confidentiality

The doctor must safeguard the confidentiality of e-mail correspondence with his/her patients, just like that of any other form of doctor-patient communication.

E-mail correspondence between doctor and patient must be considered confidential like any other communication between doctor and patient.

There must be a defined e-mail account for the e-mail correspondence. User names and passwords must be regarded as confidential information.

The computer used for communication with the patients must be placed so that the screen is not visible/readable by others than the doctor. If the doctor has to leave the room, he/she must either sign out from the account or use a password-protected screen saver. If the e-mail is printed, the paper form must be treated like any other document from the patient's health record.

The server that is used for e-mail communication must be kept in a safe place, where only authorised persons can access it. Access should be supervised.

E-mail cannot be provided on an entirely safe basis: this should be acknowledged by all the parties involved. Safety-improving protocols must be discussed with the patients and with other parties involved.

Identification of the parties

To ensure correct identification, doctors and patients must each use their defined e-mail accounts whenever possible. The doctor must make sure that the e-mail account of the patient is accessible by the patient only. A defined e-mail account does not, however, ensure the identity of the user of that e-mail account. The doctor cannot be responsible if data is read by other persons through the patient's e-mail account.

Electronic identification, i.e. electronic signature, must be used for identification of both patient and doctor whenever possible. It is recommended that e-mail should not be used for communication between a doctor and a patient if either side has doubts about possibilities to identify the other.

Style and content of e-mail : the doctor

As in all communication with patients, the doctor must avoid any possible misunderstanding. He/she must not use professional slang. All the statements must be relevant and presented in a neutral tone. The subject line of the message should be filled in to indicate the topic whenever possible and in a neutral tone. For clarity, the answer should be positioned above the previous message. The e-mail from the doctor should contain the following information

- name and other identification if possible
- procedure for obtaining a face-to-face contact
- details of the place of practice (address, telephone, fax) and office hours

Style and content of e-mail : the patient

The e-mail from the patient should contain the following information:

- name and other identification
- contact information in a case the doctor needs to reach the patient rapidly.
- all other relevant information

Invoicing and reimbursement

E-mail correspondence between doctor and patient must be treated like any other form of health care service in respect of reimbursement. Invoicing may be done by electronic or other means and must be carried out according to the national laws and regulations.

The doctor must inform the patient beforehand of the charges and of how the patient may get the charges reimbursed.

ANNEX 1 :

Checklist for the doctor

Consider carefully for which purpose and with which patients e-mail correspondence could serve you and your patients.

1. Schedule the time required to respond to your patients' e-mails.

2. Check the equipment for e-mail correspondence with your patients. Maintain the updating of your hardware and software. Ensure you have an up-to-date virus protection.

3. Prepare methods for billing and reimbursing.

4. Make sure that you practice e-mail correspondence according to the local legislation and that your liability insurance covers e-mail correspondence with your patients.

5. Remember that e-mail correspondence with a patient is a part of the patient's health record. You must therefore file it as such. Consider also the method of filing your patient's e-mail addresses.

6. Use a neutral subject heading

7. Define those persons who will have access to your e-mail account and who are needed for processing the e-mail from the patients. Discuss the arrangements required in your absence with your staff and colleagues

8. Prepare an information sheet for your patients and distribute it to them and to your staff and colleagues who are involved.

ANNEX 2 :

Information for the patient - a standard model for a form to be distributed to patients

You can use e-mail for communication with your doctor on certain agreed subjects. The following are usually suitable for e-mail correspondence:

- laboratory and other results
- follow-up of certain conditions (like blood sugar, blood pressure etc.)
- follow-up of medication
- results of certain treatments
- administration queries (appointments etc.)
- other subjects:....

E-mail correspondence is not suitable in emergency situations, in which you should contact the emergency services.

1. Your doctor will reply to your e-mail in .... days

2. If your doctor is out of office, the arrangements will be as follows: .....

3. Your e-mail will be processed by using the data security methods required by law. No one other than your doctor and the health care staff necessary to provide care can access your information. The e-mail correspondence is a part of your normal health record.

4. It is your responsibility to ensure that the equipment you use for e-mail correspondence is reliable and that you use your e-mail account in a secure manner. You are recommended always to use the same e-mail account with your doctor. Make sure that only you or those who you allow can have access to your e-mail.

5. While drafting your e-mail to your doctor, bear in mind the following:

6. Give your full name and date of birth, and also your contact information in case the doctor wants to communicate with you directly.
   Use a neutral subject heading
   Supply only information relevant to your question.
   Avoid e-mailing on matters that are particularly personal and sensitive.

7. Charges for the doctor's e-mail response: ....

8. Billing method

9. Reimbursement of the doctor's charges for e-mail response

10. Your doctor will make every effort to keep the correspondence confidential, but for technical and other reasons the confidentiality of your data cannot be totally guaranteed.

Part 2
The practice of telemedicine in Europe

Analysis, problems and CPME recommendations

The following section, the Practice of Telemedicine in Europe, is based on a study carried out by CPME in 2001. In order to analyse the present practice and difficulties of telemedicine in European countries, a questionnaire was prepared. In this process comments and suggestions were received from the e-health group of the European Commission.

The questionnaire was sent to the CPME members and associated members. Response was received from medical associations of Austria, Belgium, Denmark, Finland, France, Germany, Greece, Iceland, Italy, Netherlands, Norway, Portugal, Spain, Sweden, the UK and Slovenia.

The analysis of the answers was presented to the Board of CPME in November 2001. Recommendations in relevant problem areas were drafted and CPME recommendations were approved by the Board of CPME in March 2002.

In the following report the analysis is divided under 11 headings. Each of these items is presented under the following subheadings when appropriate:

- Definitions
- Description of the topic
- Results of the study
- Relevant EU regulations
- CPME policy




1.
The extent of the practice of telemedicine

Definitions

As defined by the CPME telemedicine is practice of medicine over a distance. The definition does not restrict purposes for which telemedicine is used, or methods which can be applied. As a matter of fact, letters, telefaxes and telephones have been used for decades to give medical assistance. Modern electronic telecommunication has boosted the development, as well as innovations in e.g. video conferencing and robotics, which have also made remote operations possible. Today telemedicine can be used in many different fields of medicine; in radiology, in pathology and psychiatry telemedical methods already belong to routine practice in some areas.

Description of the topic

In order to determine the current situation in the EU countries we studied:

- in which countries telemedicine is practiced.
- for which purposes telemedicine is used.
- the differences between public and private health care in the use of telemedicine.
- whether telemedicine is practiced in a country and internationally

Results of the study

Extent of use

Telemedicine is practiced in all the countries of the EU/EEA and Slovenia. Austria stated that it will use telemedicine for the transfer of medical data whenever the use of telemedicine is not possible in the direct doctor-patient relationship.

Notice: Information was not obtained from Ireland and Luxembourg.

Purpose of the use

Telemedicine is used for:

- diagnosis and treatment (11 countries),
- occupational health (5 countries; e.g. Netherlands specified this as health services given to sailors at sea. Other countries were Belgium, Finland, Iceland and Spain),
- insurance medicine (3 countries; France, Iceland and Spain),
- other purposes indicated by the 6 countries : education (Norway, Sweden), consultation (Sweden), second opinion (Slovenia, Sweden), and to provide health information (Netherlands), and community health (UK, a pilot scheme).

Use in public/private health care

Telemedicine is practiced by public health care in most countries (12/14): Finland, France, Germany, Greece, Italy, Iceland, Netherlands, Norway, Portugal, Spain, Sweden and the UK as well as by private health care (13/14): Belgium, Finland, France, Germany, Greece, Iceland, Italy, Netherlands, Norway, Portugal, Slovenia, Spain and Sweden.

According to these results telemedicine is used exclusively in public health care in the UK and exclusively in private health care in Belgium and Slovenia.

Use within a country/cross border

Public health care services are mainly performed within the country (9/9): Finland, Germany, Greece, Iceland, Italy, Netherlands, Portugal, Spain and Sweden, but in some countries also internationaly (4/8): Greece, Italy, Iceland and France.

Private telemedicine services are mainly delivered within the country (11/12: Belgium, Finland, Germany, Greece, Iceland, Netherlands, Norway, Portugal, Slovenia, Spain, and Sweden), but also internationaly (6/12): Finland, France, Germany, Greece and Iceland.

Notice: There were some controversial answers like Italy which has private telemedical services, but stated that private service is neither given within the country nor internationaly.

Relevant EU regulations

Treaties establishing European internal markets set four principles: free movement of goods, services, labour and capital. These freedoms can be easily exploited by telemedicine, with which medical services can be effortless sold and bought over the national borders. European secondary legislation realises these principles of the internal markets. So called directives ensure Europe-wide recognition of medical diplomas and ensure the possibility of doctors to practice in another EU country. Europeans have the right, based on Community legislation, to be employed, to be established and to provide services in another country. Citizens have the right to obtain services from other member countries of the EU. According to the principle of subsidiarity, member states can restrict the freedom of buying medical services abroad. Tertiary legislation of the Community, i.e., interpretation of Community legislation by the European Court of Justice (ECJ), has clarified the freedom of buying medical services over the borders. According to recent rulings of the ECJ, both ambulatory and institutional medical services are commercial services, which should be freely available for patients to buy over national borders. Restrictions can be imposed only in order to maintain the national health care

[1] EU Directives mentioned in this document are available by their number from: http://www.europa.eu.int/eurlex/en/search/search_lif.html

system or to economise it. Restrictions must however not harm the patient causing for example undue delay. ECJ rulings are suggestive and a slow means to provide answers for indistinctness. They are done case by case and later on interpreted nationally.

Directive 2000/31/EC[1] on certain legal aspects of information society services, in particular electronic commerce, in the internal markets, expresses that EEC Member States cannot restrict the freedom to provide information society services established in another Member State (if they comply with the applicable provisions of that Member State). Exception is possible e.g. for protection of public health (Article 3.1.-2.).

The position of the telemedicine in European legislative framework, whether and where the Community legislation or national legislation applies, will have an indicative impact, when the case of DocMorris, Dutch online pharmacy, is judged by the European Court of Justice. DocMorris took advantage of the price divergence between the Netherlands and Germany and sold pharmaceuticals, also non-authorised products, via internet to German consumers. It delivered the goods via mail, this act being against German law. DocMorris was sued by the German Pharmacist Association and several drug companies, and sentenced by several German provincial Courts. However, the regional Court of Frankfurt took the case of DocMorris into the European Court of Justice. The questions asked for interpretation of Community law apply to the fundamental rights of internal market: Freedom of movement of goods.

Several EU legislations (and rights) could be restricted for the safety of public in the near future, what will happen to this type of online service raises several unsolved questions when it is practiced in the virtual and real world. Certainly

the Court's attitude will be suggestive for other types of telemedical service.

CPME policy

The practice of telemedicine should be encouraged, also over national borders. In order to make it safe and feasible international rules or rules between concerned countries should be established to guide appropriate practices.




2.
The practice of telemedicine

Description of the topic

In general, legislation on the practice of medicine is relevant also for the practice of telemedicine. Additional legislation is however required to cover special aspects of telemedicine. Use of non-legislative measures, such as guidelines and codes of conduct are essential to complete the framework offered by legislative measures. International co-operation in a regulative framework for telemedicine is necessary to ensure functioning and safety of cross border practice.

We studied:

- whether special legislative measures are applied to the practice of telemedicine
- whether special legislative measures are applied to the equipment used

Results of the study

Special legislation on telemedicine

Four countries informed that telemedicine was recognised by laws or regulations. In Finland legislative measures were applied to electronic prescriptions; In Germany regulations on teleradiology were under preparation. Portugal said that telemedicine was recognised by legislation establishing health information net and emergency care; Norway did not specify the legislation. Of the remaining 11 countries, 4 stated that general legislation on health care applied to telemedicine. These countries were: Denmark, Netherlands, Spain and Sweden. This is probably the case in all of the countries.

Telemedical equipment

No specific legislation on the quality of telemedical equipment exists any of the countries. Iceland stated that other laws and regulations applied to telemedicial equipment such as Act on Medical Devices NO 16/2001. The quality of transfer of data in telemedicine was specifically legislated in 2 countries, Belgium, France; while the rest of the countries, 10 together, stated that there were no specific legislation on this issue. Some of them said that general legislation applied. This is likely to be the case in the other countries, too.

Relevant EU regulations

Several EU directives and regulations are relevant for the practice of telemedicine. The two directives establishing a framework for telemedical services are:

Directive 2000/31/EC on certain legal aspects of information society services, in particular electronic commerce, in the internal market.

Directive 1997/7/EC on the protection of consumers in respect of distance contracts.

Individual data protection in electronical communication, applying also data processed in telemedicine:

Directive 1995/46/EC on protection of individuals when processing personal data and on free movement of such data.

Directive 1997/66/EC on processing of personal data and protection on privacy in telecommunications sector.

Council Directive 93/42/EEC of 14 June 1993 concerning medical devices establishes quality requirements standards and procedural measures prior to placing the equipment onto the internal market. All the devices have to fulfil requirements to gain a common CE-mark.

CPME policy

Conventional health care legislation shall be reviewed and, if found insufficient, extended to cover telemedicine. The CPME should identify areas where further guidance is required for safe and high quality practice of telemedicine.




3. Guidelines for the practice of telemedicine

Description of the topic

Professional associations have shown concern on the practice of telemedicine. Gaps in legislation and the uncertainty of rules applying cross-border practice pose a legal risk for both the doctors and their patients. International professional organisations have developed codes of conduct for the practice of telemedicine to guide individual doctors. CPME established its ethical guidelines on telemedicine in 1997. Later on in 1999 the World Medical Association (WMA) developed its ethical guidelines for the practice of telemedicine, the point of view being the same as in the CPME's. A few national medical associations have adopted these guidelines and some have even produced their own guidelines.

The problem with non-legislative measures such as guidelines is that they are not legally binding. In some countries their value may be higher and the medical supervising authorities respect the guidelines as a professional norm that has to be followed but this is not the case in all the countries.

We studied:

- whether non-legislative measures are adopted for the practice of telemedicine.

Results of the study

Guidance at national level

Three countries reported that legislative or non-legislative measures (guidelines) exist on national level for the practice of telemedicine. These countries were: Finland (used the CPME guidelines for telemedicine, adopted by the Finnish

Medical Association), France and Norway (did not specify the used measures). Denmark stated that the Ministry of Health currently studied telemedicine in order to offer official guidance. In Germany, Bundesärztekammer (German Medical Association) had an opinion on general questions on health telematics. Sweden and Iceland stated that general laws and regulations on health care applied to telemedicine; this view is probably the attitude of all the countries where telemedicine is used even though not mentioned by other countries

Professions guidance

National medical associations in five countries had accepted telemedicine guidelines produced by the CPME (5: Belgium, Finland, Germany, Slovenia and Spain), by the WMA (4: Belgium, Finland, Germany and Spain), produced by their own (4: Belgium, France, Germany, Spain) and other (3, Belgium, Slovenia (AEMH's guidelines) and Spain). All the four alternatives of guidelines were reported to be used in Belgium and Spain.

Relevant EU regulations

Directive 2000/31/EC on certain legal aspects of information society services, in particular electronic commerce, in the internal markets establish framework for information society services. The Directive defines 'information society service as any service normally provided for remuneration, at a distance, by electronic means and at the individual request of a recipient of services' (Art. 2a).

The Directive states a minimum for information about the service provider and about the contract the service provider has to offers to the service recipient.

The Directive also gives the possibility to professional bodies to establish Community level codes of conduct to determine the information that can be used in commercial communication (Art. 8.2). Member States are given the responsibility to supervise that regulated professionals follow professional rules when they offer information society services (Art. 8.1.).

CPME policy

National medical associations should adopt the "Ethical guidelines in telemedicine", (CPME 97/033).




4. Identification of the doctor and the patient

Description of the topic

Medical treatment is based on a doctor-patient relationship. Thus it is essential that both parties can identify each other. Identification is also necessary for many other practical and legal aspects of health care, like continuity of care, and in some instances identification is important to in order to solve questions related to responsibility and indemnity.

We studied:

- whether anonymous use of telemedicine is possible for doctors and patients.
- whether identification of doctors/patients is regulated.

Results of the study

Anonymous provision of medical services

Anonymous provision of telemedicial services is not possible for doctors in 8 countries out of 13: Finland, France, Germany, Greece, Italy, Norway, and Sweden. Anonymity was possible in Belgium, Iceland (probably), Netherlands, Portugal, Spain and the UK the reason being lack of mechanisms such as legislation to prevent anonymity (Netherlands, Portugal).

Anonymous use of services

Anonymous use of telemedicine is not possible for patients in only two countries, Finland and Italy. Anonymity was possible in 10 countries out of 12: Belgium, France, Germany, Greece, Netherlands, Norway, Portugal, Spain, Sweden and the UK and probably in Iceland.

All together, anonymous use of telemedicine is possible for both the doctors and patients in 5 countries: Belgium, Netherlands, Portugal, Spain and the UK.

Measures for identification of doctors

Identification of doctors is regulated by legislation in 9 countries out of 15: Belgium, Denmark, Finland, France, Iceland, Germany, Greece, Norway, Spain and Sweden. Recommendations are used in 5 countries, Belgium, Finland, Greece, Italy and Sweden.

Measures for identification of patients

Identification of patient is regulated by legislation in 6 countries: Denmark, Finland, Germany Italy, Norway and Sweden and also by recommendations in Finland, Germany and Sweden.

Notice : Finland and Germany answered to these questions only in respect of telemedicine and the aspect of the countries answering 'no legislation/no recommendations' (Belgium, France, Greece, Netherlands, Portugal and Slovenia) is not known.

Relevant EU regulations

Directive 2000/31/EC on certain legal aspects of information society services, in particular electronic commerce, in the internal markets sets the minimum for the information the service provider has to offer to the service receiver about him/herself (Article 5): name, geographical address of

establishment, other contact information, the registrative body, supervising authority, possible identification number for value added tax. In addition, regulated professionals, such as doctors, also have to indicate their professional title and the body and the member state which registered their authority. Access to Professional rules in that state must be displayed.

Thus, in European Community anonymity of the service provider in e-commerce is not recommended.

Directive 1997/7/EC on the protection of consumers in respect of distance contracts, applies to contracts concluded by means of distance communication such as telephone, telefax, videotext with keyboard and e-mail. According to this Directive, the supplier has to offer the consumer his/her identity and address in case of advance payment prior to the contract (Article 4).

CPME policy

Anonymous use of telemedicine should be allowed neither for doctors nor for patients regardless of the status (commercial or non-commercial) of the service

5. Supervision of the practice of telemedicine

Description of the topic

Supervision of medicine is usually performed nationally, where the doctor is located or service provider established. However, telemedicine brings new aspects to the supervision as it can be and it is practiced across the borders. International co-operation is needed to offer safety for practice of telemedicine and to ensure that there are commonly accepted rules when measures are needed. The study sought the various mechanisms of the national countries in this area.

A. Supervision of telemedicine

We studied:

- which authorities (medical associations/ministries/others) supervise doctors practicing telemedically
- which authorities investigate cases of malpractice in telemedicine if the doctor and the patient were in the same/different country
- where a possible trial took place if a case of malpractice was taken into a court if the doctor and the patient were in different countries.

Results of the study

Supervision of telemedicine

Supervision of telemedicine is performed by:

- Medical association in 5 countries: Belgium, France, Germany, Greece and Portugal.
- Ministry in 6 countries: Finland, France, Greece, Norway, Slovenia and Sweden.

- Other: institution/body in 6 countries: Denmark (Danish National Board of Health), Finland (provincial governments), Germany (public health care service), Iceland (Directorate of Health) Portugal (Health Department (General Inspectorate for Health, Courts, National Commission for Data Protection)), Sweden (National Board of Health and Welfare)

Investigation and measures for malpractice

In a case when a supervising authority receives information about malpractice in telemedicine performed by a doctor, and

both the patient and the doctor are within the same country :

- Authorities will investigate the case in 14 countries (Belgium, Denmark, Finland, France, Germany, Greece, Iceland, Netherlands, Norway, Portugal, Slovenia, Spain, Sweden and the UK). The only exception was Italy stating that no authority would perform investigation.
- Conventional consequences of the misconduct were applicable in 10 countries (Belgium, Finland, France, Greece, Iceland, Netherlands, Norway, Portugal, Spain, Sweden and the UK).
- Only in one country of the 14 one case of malpractice in telemedical contact was observed: This was a case of inaccurate diagnosis in Norway (undefined skin malignoma was mistaken for solar keratosis, a pre-carsinoma of the skin).

doctor is in the country of complaint and the patient is abroad:

- authorities would study the case in 12 countries (Belgium, Denmark, Finland, France, Germany, Greece, Iceland, Netherlands, Norway, Portugal, Slovenia, Spain, Sweden) and would not investigate the case in two countries (Italy and the UK).

- Normal consequences were the case in 8 countries (Finland, France, Germany, Greece, Iceland, Norway, Spain and the UK) i.e., in all the countries that answered this question.
- In Germany there had existed a case of malpractice, which was not specified.

doctor is abroad and the patient is in the country of complaint:

- authorities of the country of complaint would investigate the case in 6 countries (Austria, Belgium, France, Greece, Portugal and Spain) and would not investigate the case in 7 countries (Finland, Germany, Iceland, Italy, Norway, Sweden and the UK). Denmark and Slovenia did not know acts in such case.
- Eight countries would contact the supervising authority in that country (Austria, Belgium, Finland (quite likely), Germany, Greece, Iceland, Netherlands, Portugal and Slovenia). Italian authorities would not contact the respective authority.

Place of the trial

In a case where a patient from abroad sues a doctor for malpractice, the trial could take place in:

- the country of the patient: 3 countries (Greece, Netherlands, Slovenia)
- the country of the doctor: 9 countries (Belgium, France, Greece, Iceland, Netherlands, Portugal, Slovenia, Spain and Sweden)
- was thought to be possible in both the countries in 6 countries: Greece, Iceland, Netherlands, Portugal, Slovenia and Sweden

In a case where the doctor is abroad, and the patient turns to the supervising authority, the trial could take place in:

- the country of the patient: 5 countries (Greece, Netherlands, Portugal, Slovenia and Spain)
- the country of the doctor: 5 countries (Austria, Belgium, France, Greece and Slovenia)
- was thought to be possible in both: 5 countries (Greece, Iceland, Netherlands, Portugal and Slovenia)

Relevant EU regulations

Directive 93/16/EEC to facilitate the free movement of doctors and the mutual recognition of their diplomas, certificates and other evidence of formal qualifications (Medical Directive) establishes the process for recognition of doctor's profession, the process being in theory automatic in many cases. Practice of telemedicine would require the recognition of the doctor in the country where the service is given. Thus the country may be other than the country of establishment and recognition by the national authority concerned may be necessary. However, in telemedicine the service is transferred instead of the professional moving which was the actual scope of this directive. It is however not clear weather the Medical Directive really gives the authority to practice telemedicine over national borders.

Council Regulation (EC) No 2001/44 on jurisdiction and recognition and enforcement of judgements in civil and commercial matters states that jurisdiction in consumer contracts allows the consumer to bring proceedings against the other party of the contract in the domicile of the consumer or in the domicile of the defendant when the contract has been made in the domicile of the consumer and the defendant has performed commercial or professional activities in that country. The Regulation also

states that other EU Member States have to recognise the accordingly given judgement and enforce the judgement if it has been recognised in that country due to the application of the interest party.

The Regulation means that in case of a trial due to a harmful effect in telemedicine the consumer(patient) can choose the country for the trial. Thus, it should be possible for the consumer to start the procedure and make the complaint of the service accordingly to the authority system of the chosen country.

B. Recognised problems of telemedicine

We studied :

- whether illegal practice in telemedicine has been recognised
- whether there exist recognised problems in telemedical practice (quality of service/liability/other)

Results of the study

Illegal practice

None of the countries acknowledged any illegal practice of telemedicine (14/14). Some problems in the practice of telemedicine were however, recognised, such as:

Quality of service (1 country)

Germany listed problems as relating to technical aspects of 3-dimentional images; time lacks, reliability of networks, qualifications of participants.

Liability (3 countries)

Belgium stated that a clinical anamnesis and examination is missing in telemedical services.
Germany said that basic questions were still unsolved. Norway mentioned that there existed a case of a false diagnosis.

Other (8 countries)

Lack of standardisation and legislation, security, authenticity, identification etc.

Relevant EU regulations

Directive 2000/31/EC on certain legal aspects of information society services, in particular electronic commerce, in the internal markets establish a legislative framework for the practice of information society services. Member states are required to establish means for supervision of the implementation of the Directive and shall co-operate with other member states when necessary.

EU has taken measures to promote safer use of the Internet. Decision no 276/1999/EC adopted a multi-annual community action plan on promoting safer use of Internet by combating illegal and harmful content on global networks. It is based much on non-legislative measures to regulate Internet.

CPME policy

The aim of the directive 93/16/EEC is to make it possible for doctors who are authorised to practice medicine in one country, to practice their profession also in other member countries. As specific regulations for telemedicine do not exist, the directive must be understood so that doctors who are authorised to practice medicine in one EU country, can provide telemedical services over national borders within the EU without further authorisation.

Appropriate mechanisms for international supervision of telemedicine should be investigated by the CPME together with the CIO. International agreements of the supervision should be developed and the possible need for international registration of doctors practicing telemedicine internationally shall be evaluated.




6. Regulations on the protection of confidentiality

Description of the topic

Confidentiality of patient data has always been essential for the practice of medicine and it has been recognised by both the law and by ethical norms. Use of electronic means for the transfer and processing of patient data has brought new problems that have not been faced in traditional medicine. Fear for breaches of medical confidentiality has inhibited the development of telemedicine. The European Union has harmonised legislation on data protection and also made arrangements to ensure sufficient confidentiality of the data transferred between the EU and the USA. This is particularly important when telemedicine is practiced with countries outside the EU. For example, in Greece some private hospitals consult experts in the USA.

We studied:

- whether the existing legislation is sufficient and relevant for data protection in telemedicine.
- whether existing guidelines and recommendations are sufficient and relevant for data protection in telemedicine.
- which are the mechanisms used for the protection of such data (encryption/other).
- whether the patient is allowed by law/regulations to access his/her own data

Results of the study

Legislation

Seven countries, Finland, Greece, Iceland, Italy, Netherlands, Portugal, Slovenia and Sweden, replied that special legislation on security and confidentiality in telemedicine does not exist, but general legislation on health care or data

protection was relevant also for telemedicine. Seven countries, Belgium, Denmark, France, Germany, Norway and Spain, stated that there exists special legislation on telemedicine, such as legislation on e-signatures.

Recommendations

Recommendations on security and confidentiality in telemedicine exists in Belgium, introduced by Ordre des Medecins and in Germany. Italy reported to use generally applied practises.

Regulated or recommended mechanisms for the protection of data

Encryption is used in 8 countries out of 11 (Belgium, Finland, Germany, Greece, Italy, Norway, Sweden and the UK). Other methods are used in Germany (digital signature, firewalls etc.), Denmark (closed networks) and Spain. Netherlands data protection authority was preparing guidelines for the issue.

Patient's access to his/her information was guaranteed by legislation in 12 countries out of 13: Belgium, Finland, France, Greece, Iceland, Netherlands, Norway, Portugal, Slovenia, Spain, Sweden and the UK and also by recommendations in 3 countries, Greece, Italy and Sweden.

Relevant EU regulations

Directive 1995/46/EC on protection of individuals when processing personal data and on free movement of such

data aims to protect the fundamental rights and freedoms of individuals and their right to privacy when their personal data is processed. The Directive establishes that personal data has to be processed for specified and legitimate purposes at adequate extent and updated when necessary (Art.6). The data subject has to consent to the processing of his/her individual data as well as information about the data collector and the purposes the data is collected. According to the Directive the data subject has the right to access the registered data and in some circumstances demand to update or delete the data (Art. 7, 10, 12). Processing of certain individual data (such as health or sexual orientation related issues) is forbidden unless for medical purposes and even then processed by a health professional (Art.8). The Directive demands the Member States to ensure that the keeper of the register carries out the data processing by confidential and secure means within Europe and to third countries.

Member states have adopted divergent interpretations of this Directive when applied on deceased persons.

A 'Safe Harbour' agreement between the US and the EU was approved by the EU in the year 2000 as a consequence of the demand stated in Directive 95/46 EC on personal data protection when (electronically) transferred to third states. The Directive forbids the transfer of personal data outside the EU unless confidential processing of data has been ascertained in the destination. The US companies can voluntarily participate in the 'Safe Harbour' agreement, but it is a necessity if they want to continue co-operation with their European partners.

Directive 1997/66/EC on processing of personal data and protection on privacy in telecommunications sector establishes responsibilities to the service providers on

telecommunication networks and the Member States to ensure confidentiality of the service in telecommunication networks.

CPME policy:

Instructions given in the Ethical Guidelines on Telemedicine (CPME 97/033) shall be followed.
The CPME should study whether the European legislation is sufficient and applicable for telemedicine. The CPME shall evaluate weather new recommendations ensuring the confidentiality and secrecy in telemedicine should be given




7
Liability and patient insurance

Definitions

Liability insurance protects the doctor from financial losses if sued or condemned for liability.

Patient insurance compensates the patient in case of an unexpected adverse outcome in a health care service, irrespective of liability.

Description of the topic

We studied:

- whether liability insurance is valid for telemedicine practiced within the country/abroad
- whether additional liability insurance can be obtained for telemedicine practiced within the country/abroad
- whether patient insurance is valid for telemedicine practiced within the country/abroad
- whether additional patient insurance can be obtained for telemedicine practiced within the country/abroad

Results of the study

Liability insurance in telemedicine

Liability insurance covers a doctor's liability in the practice of telemedicine within the same country in most of the countries (9/13) that replied: France, Germany, Iceland, Netherlands, Norway, Slovenia, Spain, Sweden and the UK. However, liability insurance covers doctor's liability to abroad only in 3 countries: France, Germany and Spain. In both cases, liability within the same country and to abroad could be extended if acquired, in Germany.

In those countries i.e., Belgium, Greece and Italy, where liability insurance doe not cover the practice of telemedicine within the country nor to abroad, as well as in Iceland additional coverage can be obtained in Belgium and Greece.

Patient insurance

Patient insurance covers accidents also in telemedicine in Finland, Iceland, Sweden and UK, if the patient is within that country and not abroad. In Finland, Iceland and the UK patient insurance covers accidents if the patient from that country is temporarily abroad and the treating doctor in Finland, Iceland and in the UK respectively.

Relevant EU regulations

According to the EC Treaties the EU does not have the competence to govern health care systems and social security systems of the Member States as they are matters of subsidiarity.

However, citizens have the right to get services from another country than their own. This also applies to medical services. Recent European Court of Justice rulings indicate that in some cases, national countries are obliged to reimburse a medical treatment abroad. What are the rights of the patients when the service provider is abroad and a harmful effect occurs ? In telemedicine the place of establishment is the place where the service is given, i.e., where the patient is. Nationally,the doctor has to be insured in the country he/she practices.

CPME policy

(1) Liability/patient insurance should cover telemedical practice as any other form of practice of medicine.
(2) Doctors should ensure that they have adequate insurance coverage when they practice telemedicine within a country and/or to abroad.

8. Reimbursement of telemedicine

Description of the topic

Most citizens in the EU member countries are covered by public health care insurance or they have access to publicly arranged health care. Private health care insurance can be taken to cover the gap between total expenses and reimbursed costs or additional services which are not covered by public health care.

Reimbursement and health care systems differ from one country to another in Europe as well as the services they offer.

We studied:

- Whether telemedical services are reimbursed by public insurance systems.
- Whether telemedical services are reimbursed by private insurance.

Results of the study

Public sickness insurance

Telemedicine is reimbursed by neither public nor private sickness insurance in 8 respective 7 countries. National sickness insurance reimburses telemedical service in 4 (5) countries: Germany (in appropriate cases), Greece, Norway (limited by a special tariff) and Finland, which stated that telemedicine is reimbursed in some cases such as in a case of medical imaging.

Private health care insurance

Private insurance reimbursed telemedical service only in Germany and Greece.

Relevant EU regulations

EU does not have the competence to govern health care systems and social security systems of the Member States; instead, they are matters of subsidiarity. The European Court of Justice has however ruled that pointed health care services belong to commercial services, which can be freely sold and bought in the internal market. In the cases of Kohl and Decker and the recent cases of Peerbooms and Geraets it rules that in priciple, with some limitations, a patient can seek out-patient care as well as hospital care from another EU-country and be reimbursed without prior permission by his/her sickness fund. Specific cases concerning telemedicine are not available.

CPME policy

(1) Telemedical service should be reimbursed by the national social security system in the same way as any other form of medical service.
(2) Reimbursement of telemedical services across national borders should be made possible with agreements between national social security systems and/or private insurance companies.




9.
Advertising of health care services

Description of the topic

Rational regulations for advertising medical services are divergent in Europe, Scandinavia perhaps leading the most liberal policy. Advertising in on the Internet brings new dimensions for the promotion of medical services.

We studied:

- Whether advertising of medical services, conventional/telemedical, is possible by conventional means/via internet.
- Whether advertising of medical services is regulated by legislative or non-legislative measures.

Results of the study

Advertising of health care services

Advertising of conventional health care services is possible by conventional means in 11 countries (Denmark, Finland, Germany, Greece, Iceland, Italy, Norway, Slovenia, Spain, Sweden and the UK; not possible in Belgium, France, Netherlands and Portugal)) and via internet in 10 countries (all of the previously mentioned expect for Spain). Advertising is often strictly restricted.

Advertising of telemedical services is possible by conventional means in 7 countries (Denmark, Finland, Greece, Italy, Norway, Sweden and the UK) and on the Internet in the same 7 countries.

Legislative/Non-legislative measures for advertising

Advertising of health care services was regulated by legislative measures in 11 countries (Austria, Belgium, Finland, Germany, Iceland, Norway, Portugal, Slovenia, Spain, Sweden and the UK) and by (recommendations) in 6 countries (Belgium, Finland, Germany, Italy, Norway and Sweden).

Advertising telemedical services were regulated by legislative measures in 4 countries (Denmark, Norway and Portugal. In Sweden general legislation applied also to telemedical advertising) and by non-legislative measures (recommendations) in 4 countries (Belgium, Finland, Italy and Sweden).

Relevant EU regulations

Directive 2000/31/EC on certain legal aspects of information society services, in particular electronic commerce, in the internal markets promotes the regulated profession associations and bodies, thus also the doctors, to establish Community level codes of conduct for commercial communication (as a part of information society service) and to determine what type of information can be given to such communication.

CPME policy

CPME should adopt guidelines for internet advertising of medical services, which then should be adopted by the national medical associations in compliance to their national regulations.




10. E-mail in doctor-patient relationship

Definitions

E-mail is mail in electronic form; the sender composes a message on his/her computer and transmits it via a communications network to the receiver's computer (European Commission: Telemedical Glossary 2001).

E-mail correspondence between a doctor and a patient means in this context professional communication to assist the doctor to fulfil his/her professional obligations and to assist the patient to communicate with the doctor in the treatment or a follow-up of his/her condition.. (CPME Guidelines for e-mail correspondence in health care, **CPME 2001/112 Final**)

A. Volume of e-mail correspondence in doctor-patient relationship

We studied :

- volume of e-mail correspondence between a doctor and a patient (less than 10%/10-50%/more than 50%/No information)

Results of the study

Volume of e-mail correspondence

The results of the study could not give accurate estimates of the volume of the use of e-mail correspondence between a doctor and a patient. Seven of the countries that answered to e-mail part of the study did not give any estimates. Seven of the countries estimated that e-mail was used by doctors to correspond with their patients less than 10 %. These countries

were: Belgium, Denmark, France, Italy, Netherlands, Norway and Spain. Sweden seemed to use most e-mail in doctor-patient relationship by estimating that 10-50 % of the doctors used e-mail for this purpose.

B. Statutory framework for e-mail correspondence between a doctor and a patient

We studied:

- whether legislation exists on e-mail correspondence between a doctor and a patient (general/specific)
- whether there are guidelines on e-mail correspondence between a doctor and a patient
- whether there is a need for such guidelines and what these guidelines should contain (time scale for answering time/documentation of the e-mail/privacy matters/style of e-mail/definition for suitable topics/liability issues/other)

Results of the study

Legislation

Most countries (13/15) stated that they do not have legislation on e-mail correspondence between a doctor and a patient. Finland and Iceland stated that general legislation applies to e-mail correspondence in doctor-patient relationship. Germany and Italy stated that there was legislation on this issue; which was general for health care. This would probably also be the case in those countries that stated e-mail was not regulated by legislation.

Guidelines

Six countries out of 15 stated that there are recommendations concerning e-mail correspondence between a doctor and a patient. They were introduced by health authorities or professionals organisations. These countries were: Belgium, Finland, France, Italy, Norway and the UK. In Finland there was the reference to the CPME/WMA guidelines on telemedicine, but at least in the UK there exists a guideline also concerning the exact e-mail correspondence between a doctor and a patient, introduced by the General Medical Council. Iceland stated that a committee was preparing guidelines.

Special guidelines for e-mail correspondence

Most of the countries considered that a guideline for e-mail correspondence between a doctor and a patient should be provided. It should cover issues such as definitions for suitable topics, liability of e-correspondence, privacy matters, documentation of e-mail and turnaround time.

C. Charging and reimbursing of e-mail correspondence

We studied :

- Whether charging of e-mail correspondence is possible.
- Whether reimbursement of e-mail correspondence is granted.

Results of the study

Charging

Charging for email correspondence is possible in 3 countries

(out of 13): Netherlands and Norway, where also recommendations on the email consultation fee were set). The Social Insurance Institution of Finland assumed that email correspondence is charged, but no tariffs for reimbursement were given. However, reference to telephone consultation was made. In Norway law based tariffs for charges of e-mail correspondence are used.

Reimbursement

Email consultations are reimbursed in all the three countries where the services were charged, Finland, Norway and Netherlands.

Relevant EU regulations

EU does not have the competence to govern health care systems and social security systems of the Member States; instead, they are matters of subsidiarity.

CPME policy

Adopted guidelines on e-correspondence between a doctor and his/her patient (CPME 2001/112 Final). These guidelines state that doctors should be able to charge for professional e-correspondence in the same way they do for any other professional services and that the patients should likewise be entitled to reimbursement.




11. Electronic prescriptions

Description of the topic

Some EU-countries, such as Denmark, already use electronic prescriptions of drugs. Many other countries are currently developing and testing systems for electronic prescribing. So far, electronic prescribing is aimed to happen within one country, but in principle, electronic networks offer possibilities for cross-border prescribing, an action which is not legally clear.

A. Identification of the doctor

We studied :

- Identification of doctors by a prescription (number/code issued by health insurance/other).

Results of the study

Identification

Generally, doctor's signature and in most case, accompanied by a code was the main means to certify a prescription. The code number is issued either by a ministry of health, medical association, sickness fund or other relevant authority or body. Eight countries had an approved system for electronic signature: Austria, Denmark, France, Germany, Iceland, Portugal, Spain and Sweden. Four other countries stated that legislation on e-electronic signature was being developed: Belgium, Finland, Netherlands, the UK.

Finland stated that one possibility to check an e-prescriptions, at least used with telephone and -fax was to make a check call to the doctor.

Relevant EU regulations

Directive 1999/93/EC on a Community framework for electronic signature defines advances e-signature as: 'uniquely linked to the signatory, capable of identifying the signatory, created using means that the signatory can maintain under his sole control and linked to the data to which it relates in such a manner that any subsequent change of the data is detectable' (Art.2 2). The directive offers electronic signature the same legal position as a hand-written signature has: 'the Member States shall ensure that electronic signatures satisfy the legal requirements of a signature in relation to data in electronic form in the same manner as a hand-written signature satisfies those requirements in relation to paper-based data and that they are admissible as evidence in legal proceedings '(Art. 5.1.) The Directive gives the Member Sates states the possibility to require additional accreditation in the public sector: 'Member States may make the use of electronic signatures in the public sector subject to possible additional requirements. Such requirements shall be objective, transparent, proportionate and non-discriminatory and shall relate only to the specific characteristics of the application concerned. Such requirements may not constitute an obstacle to cross-border services for citizens' (Art 3.7.)

Directive 1999/93 has become into force in the Member States by July 19, 2001.

B. Accepted forms of e-prescriptions

We studied :

- which are the used means for e-prescriptions (telephone/fax/e-mail/other).
- whether any legislation/guidelines for e-prescriptions exist.

Results of the study

Used means

Some form of e-prescriptions is practiced in 9 countries. Different forms are:

- Telephone prescriptions: Finland, Greece, Iceland, Norway, Portugal and Sweden
- Telefax prescriptions: Finland, Iceland, Norway, Sweden and Netherlands
- E-mail prescriptions: Norway, Sweden and Spain
- Other forms of e-prescriptions: Denmark (closed networks), Finland (Internet server between the pharmacy and the prescribing doctor in a hospital or health centre; e-mail prescriptions are under development), Iceland (a communication set up by an EDI programme), Sweden (no specification) and the UK (no specification).

Legislation/Guidelines

Of those countries where electronic prescriptions were possible, either general legislation and guidelines apply to electronic prescriptions or special ones are applicable (Finland: Order issued by the National Agency for Medicines; Iceland: General legislation; UK: Guidelines by General Medical Council).

E-prescribing is not allowed in Austria, Belgium, France, Greece, Italy and Slovenia.

CPME policy

Electronic prescriptions should be made possible as soon as a reliable system for the identification of the doctor and for the assessment of his/her prescription right has been established

C. acceptance if not licensed in the country of delivery.

We studied :

- Whether an ordinary/electronic prescription issued by a foreign doctor was accepted if not licensed in the country of delivery.

Results of the study

Acceptance

A prescription issued by a foreign doctor who had no licence in the country in concern, is accepted only in Greece and in the Nordic countries, which accept a prescription issued by a Nordic doctor (though some limitations regarding the prescriptions exist). Iceland stated that it accepts prescriptions from any EEA country beside the Nordic ones. Denmark stated that it also a prescription issued by a doctor who has a licence in any other EU-country. Respectively, a telemedical non-national prescription is accepted in Norway (and France?)

Relevant EU regulations

Directive 93/16/EEC to facilitate the free movement of doctors

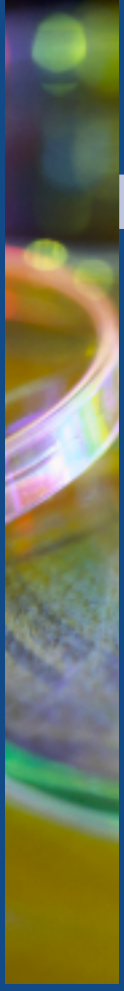
and the mutual recognition of their diplomas, certificates and other evidence of formal qualifications in principle refers the certificate of basic medical studies equal in every Member State. License to practice within a country has to be applied from the competent authority in order to practice in that country.

Council Resolution 95/C 350/04 on mutual recognition of the validity of medical prescriptions in the Member States calls the Commission in co-operation with member states to study the present situation of mutual recognition of medical prescriptions within the European Internal Market area. The Resolution marks that discrimination based on nationality of establishment and provision of (doctor's) services is prohibited in medical practice. The resolution does not apply to financing and reimbursement of medical products nor the prescriptions classified narcotic or psychotrophic drugs in the UN conventions.

The Commissioner of DG Industry, Mr. Bangemann, and the Commissioner of DG Internal Market, Mr. Monti have in their replies to written questions of the Members of European Parliament supported mutual recognition of prescriptions within the Internal market area.

CPME policy

A prescription of a doctor who is authorised to prescribe in one EU country, should be valid in all EU countries. Possible problems related to the recognition of the doctor and to the recognition and the proper use of medical product purchased from a foreign country, and to the reimbursement of the drug shall first be solved

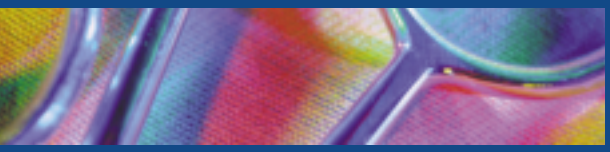


CPME COMITÉ PERMANENT DES MÉDECINS EUROPÉENS
STANDING COMMITTEE OF EUROPEAN DOCTORS

Telemedicine : use of information and telecommunication technologies to exchange information at a distance, with the aim to facilitate healthcare.

In order to give guidance to doctors in the use of this new technology, the Standing Committee of European Doctors (CPME) has developed guidelines for telemedicine. The CPME has also made a study in its member countries in order to evaluate in which way telemedicine is practiced and which problems are encountered.

CPME would like to thank Dr Äärimaa (CPME president 2000-2002) and Dr Mäkinen for their work on this document.



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