

Patients' Rights and Citizens' Empowerment: through Visions to Reality

Joint consultation between the
WHO Regional Office for Europe, the
Nordic Council of Ministers and the
Nordic School of Public Health

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MANAGING FOR QUALITY OF CARE

By the year 2010, Member States should ensure that the management of the health sector, from population-based health programmes to individual patient care at the clinical level, is oriented towards health outcomes

(Adopted by the WHO Regional Committee for Europe at its forty-eighth session, Copenhagen, September 1998)

ABSTRACT

Many countries, including central and eastern European states, are following with great interest the outcomes and impact of the Nordic experience with patients' rights and citizens' empowerment: what are the benefits and possible side-effects, how is patient and professional satisfaction influenced, what are the possible links to the current debate on priority-setting and cost-containment, are just a few of the interesting questions raised throughout Europe.

This meeting's objective was to bring an update of the development of patients' rights in Europe and draw a plan of action for future activities of the network. It also aimed at identifying new areas for collaboration and new methodologies for promoting patients' rights, based on the principles of the *Declaration on the Promotion of Patients' Rights* (1994) and the *Ljubljana Charter on Reforming Health Care* (1996).

Keywords

PATIENT ADVOCACY LEGISLATION
PATIENTS LEGISLATION
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Introduction: scope and purpose

The Nordic countries (Denmark, Finland, Iceland and Norway) have been in the forefront line of patients' rights development in Europe. Their role was paramount at a European consultation on patients' rights (Amsterdam 1994) which endorsed the **Declaration on the Promotion of Patients' Rights in Europe**, laying down the principles for giving effect to patients' rights. Taking that message forward, the WHO Conference on European Health Care Reforms (Ljubljana 1996) endorsed the **Ljubljana Charter on Reforming Health Care**, further elaborating the principles of patients' rights and citizens' views by stating that health care reforms must address citizens' needs, taking into account, through the democratic process, their expectations about health and health care. Such reforms should ensure that the citizens' voice and choice decisively influence the way health services are designed and operate. The **Convention for the Protection of Human Rights and Dignity of the Human Being with regard to the Application of Biology and Medicine** was agreed by the Member States of the Council of Europe at Oviedo in 1997. The Convention addresses the issues of patients' rights to private life and information.

In the Nordic arena, Finland, Iceland and Denmark have recently approved separate legislation on patients' rights, in 1993, 1997 and 1998, respectively. In Norway a law will be in force in the year 2000 and in Sweden there is lively debate on patients' rights, although consensus on the way forward has not yet been reached. Many countries, including central and eastern European states, are following with great interest the outcomes and impact of Nordic experience with patients' rights and citizens' empowerment: what are the benefits and possible side-effects, how is patient and professional satisfaction influenced, what are the possible links to the current debate on priority-setting and cost-containment, are just a few of the interesting questions being raised.

Iceland is one of the leading countries with regard to patients' rights, and The Icelandic chairmanship of the Nordic Council of Ministers decided to place emphasis on issues of patients' rights and citizens' involvement. The expertise available would be more than sufficient to organize a timely consultation that would bring together various strands of information, offering an opportunity to learn from and reflect on experiences from other countries and to draw recommendations for the 21st century.

The Nordic Council of Ministers has had mutually satisfactory collaboration with the WHO network on patients' rights and citizens' was therefore organized jointly, as a continuation of this cooperation.

A) The consultation elaborated on the following pertinent issues:

- Patients' rights on the European scene: an overview
- The experience of the Nordic countries in promoting patients' rights in Europe
- Legislation or softer rules or both? Mechanisms to tip the balance
- Indicators for measuring the improvements of patients' rights – a quality aspect in the care of patients.

B) The consultation sought answers to the following timely questions:

1. How can legislation (and other legal means) for patients' rights be implemented and citizens empowered in real life?
 - Care providers at primary, secondary and tertiary levels
 - Complaints process
 - Administration
 - Role of associations of health care professionals
 - Role of patients' organizations
2. How do we know that patients' rights are improving and what does it mean to patients?

C) The expected outcomes of the consultation were to:

- Be a forum for discussion among participants and for media
- Identify new areas for collaboration and new ways to promote patients' rights
- Elaborate guidelines/recommendations for implementation of patients' rights and select a working group to take the work forward
- Prepare the network's newsletter that will include the meeting's report and proceedings

The consultation brought together countries from western, central and eastern Europe and national and international patients' organizations, consumers' organizations, medical associations and nursing associations, and other national and international bodies with influence in the area of patients' rights.

Addresses and keynote presentations

Patients' rights and citizens' empowerment: Through visions to reality

Mr David Gunnarson, Nordic Council of Ministers

Distinguished guests, ladies and gentlemen,

It gives me great pleasure to welcome you on behalf of the Nordic Council of Ministers to this consultation on patients' rights and citizens' empowerment.

This consultation is a result of fruitful cooperation between the World Health Organization, the Nordic School of Public Health and the Nordic Council of Ministers. It is my sincere hope and belief that this consultation will be of great benefit to our continuing efforts to reach our common goal – the promotion and implementation of patients' rights.

This is indeed a distinguished assembly. We have representatives of European governments, of international governmental and nongovernmental organizations, academic faculty members in the fields of law and medicine, representatives of patients' associations, health professionals' organizations, patients' ombudsmen and media representatives. Finally we have members of the WHO Network on Patients' Rights and members of the Nordic Senior Officials Committee on Health and Social Affairs.

The main purpose of this consultation is to provide a forum and a breeding ground for continuous reflections and debate for people who are engaged in – and devoted to – the promotion of patients' rights. The dialogue-form is also the reason why we call it a “consultation”. To my mind, this comprehensive assembly provides the best conditions for achieving our purpose.

The subtitle of this consultation, “Through Visions to Reality”, also indicates some very important questions which will be put to participants during the next two days: How do we ensure that legislation – or other legal instruments – are implemented in real life? How do we know – and how do we evaluate – whether patients' rights are improving? Several European countries have recently passed legislation on patients' rights. Several other countries are preparing such legislation and others have agreed upon and signed patients' rights charters. Conferences have been held and networks are being established. This raises various questions: Why do we need such legislation – where are its roots – what needs are we driven by? What happened to Hippocrates? What has become of the education of our physicians and nurses, if we really need to have legislation on various points regarding patients' rights? Are the discussion about, measures taken for, patients' rights a part of the international demand for respect for basic human rights, do they testify to a lack of respect for patients or a problem of our own, or do they reflect a growing tendency to regulate human behaviour by legal means?

We should remember that in the Gospel according to Luke it is the Lawyer who asks: "Master, what shall I do to inherit eternal life?" He gets the following answer from Jesus: "What is written in the law?" And the Lawyer answers: "Thou shalt love the Lord thy God with all thy soul, and with all thy strength, and with all thy mind, and thy neighbour as thyself." But the Lawyer was not fully confident with that answer and came back asking who his neighbour was. And Jesus told the story of the good Samaritan, which we all know. I want to stress that the Samaritans were not among the respected citizens. They were the outsiders. The story tells us that those of high social standing declined to help the poor man on the road between Jerusalem and Jericho. Is it possible that, when we modernize our health services, we have to spell out in the law all the rules on how to care for our neighbours?

During the Viking era, in the world of the Nordic Gods, the inhabitants went out every morning to do battle with each other. At the end of the day, the dead and the wounded were carried to the Great Hall of Valhalla to be cared for. And so effective were the cures that in the morning they all rose anew in complete health to resume the fighting. The moral was simple. If you were brave and were killed or wounded in a battle you had full patients' rights. This is in contrast to the biblical message that those in need can expect help, even from those least expected to offer help.

Are we faced with a development that is moving our societies away from wanting to help our neighbours in needs, towards society's demand where the young and the brave get high-technology treatment from highly trained health professionals in expensive tertiary health care institutions that only use the most expensive equipment and drugs? Is this our modern Valhalla?

The goal of this meeting is a dialogue to discuss, among other things, the issues I have mentioned across national borders, between groups of health professionals and patients' organizations. This is a consultation with a common goal, to ensure that the legal measures that are taken are not only solemn words but that they really improve conditions for the patient, not only for the brave but for all patients.

It is not only the law we must think of, but most importantly the patient. Who are the patients we are talking about? Most people think of patients now living and receiving care. But in the age of genetics and bio-engineering we must also think both of our deceased and of the future patients.

It may be worth remembering that the Hippocratic works and medieval texts were the core of medical knowledge until the Renaissance. Little progress was made during that time. The reasons for this are no doubt many. Some people believe that one of the more destructive ones was a ban on autopsies issued by Pope Bonifacio the Eighth in 1300. Autopsies were vital for development of the study of anatomy and training in surgery. The papal letter was misinterpreted, however. What Bonifacio was really dealing with was that the crusaders did not want to leave the bodies of their dead comrades in foreign soil. To facilitate the transporting of the bodies back to Europe, the flesh was cut from the bones. Then, after boiling, the bones were ready for transport and burial at home. The pope's decision was misinterpreted, and it halted medical and scientific development for a considerable time. Even though for some time autopsies were performed secretly.

Today we must bear in mind that knowledge changes very rapidly, and what we find evident and true today may be thought highly disputable even in the near future. The lesson we can learn from this experience is that we need to be careful when laws on patients' rights are enacted to ensure that they do what we expect them to do, also for patients in the future.

I will finish by citing Egill Skallagrimsson, one of the most famous characters in the Icelandic sagas. He was not only a valiant warrior and a poet but also a skilled healer. He was called to the bedside of a very sick young maiden. She was having difficult fits of anxiety and depression. After examining the patient and the bed, Egill found under the pillow a strange text written in runes. The runes had been cut in wood and put there by a young man who had fallen in love with the young maiden. He wanted to influence the girl and make things happen. Egill removed and destroyed the runes and put new ones under the pillow. The girl immediately recovered. What Egill said was: "Those carving runes must know precisely what they are doing."

We must have this in mind when we write our own modern "runes" in the form of legal texts or when we are treating patients.

Patients' rights network

Dr Sylvie Stachenko, WHO Regional Office for Europe

I am pleased to welcome you to this meeting on patients' rights and citizens' empowerment. Patients' rights are an important issue on our regional agenda, so we welcome our collaboration with the Nordic Council of Ministers and the Nordic School of Public Health in organizing this meeting, and we are certainly delighted to see the interest generated in both western and eastern Europe, as is evident from the impressive list of participants in this meeting today.

In the last decade, the issue of patients' rights and citizens' empowerment has received increasing attention at both national and international levels. In Europe, WHO's Regional Office played a significant role in preparing the 1994 Amsterdam Declaration on the Promotion of Patient's Rights, which now serves as a guiding framework for Member States as well as for patients' and consumers' organizations. Subsequently, in 1996 the ministerial conference on health care reform held in Ljubljana highlighted the need for health care systems to recognize the importance of the citizens' voice in the organization of health care systems.

These developments in Europe stimulated the establishment in 1997 of the WHO European network for patients' rights and citizens' empowerment, which now counts members from 27 countries. This network has already had considerable success in heightening awareness of patients' rights in the European Region, and the theme of this meeting today, "From visions to reality", is a very timely one as the network is now very well positioned to consider more specifically aspects of giving effect to patients' rights.

A recent WHO review of the 51 Member States in our European Region reveals that we are making progress. Seven Member States have now patients' rights legislation in force, six are preparing such laws and four others have national charters or codes. This certainly reflects a growing need to critically examine and develop the rights and responsibilities of patients at a time when governments are focusing their attention on issues of the accessibility, quality and funding of health care. Patients' rights are intimately linked with the quality of care, and in this regard I would like to make reference to the new Health for All policy framework for the European Region. This framework, entitled HEALTH21, 21 targets for the 21st century, emphasizes a people-centred and quality-oriented health sector.

Until recently, it was generally assumed that well trained physicians and other health care providers with access to systematic information about scientific innovations and working in well equipped health care institutions would automatically produce high quality health care. However, a growing body of evidence indicates that even with similar characteristics, there are still substantial differences, in terms of the outcomes of the care that patients receive, as between institutions and individual health care providers. And it may be argued that this situation can represent a breach of the right to health, since a patient entering the system can end up with vastly different results depending on the health care provider or institution where he or she is treated. In this regard, citizens can certainly help to improve the quality of care by participating in the planning, management and evaluation of health services. Besides governments, nongovernmental organizations (NGOs) have an important role to play in furthering the patients' rights and citizens' empowerment agenda. For many years, patients' rights organizations that have dealt with specific issues such as AIDS, cancer or mental health, have done an excellent job in highlighting the need to change our ways of working in order to better address the concerns of individuals and families, and there are now good models that we can learn from.

In closing, I would like to thank Dr Gunnarson for bringing the issue of patients' rights to the attention of the Nordic Council of Ministers and for their generous contribution that has made this gathering possible, and we certainly look forward to continued collaboration with them. Thanks also to Dr Magnusson from the Nordic School of Public Health, for his important input to the organization of this meeting and also for the significant support of the school in a number of joint WHO initiatives. And finally, I would like to wish all of you an enjoyable and productive meeting here in Copenhagen.

Why patients' rights?

Dr Mikko Vienonen, WHO Regional Office for Europe

It is a pleasure for me to welcome you all to this distinguished meeting. This is the first time that we have had this kind of joint venture between the Nordic Council of Ministers, the Nordic School of Public Health and the WHO Regional Office for Europe.

Why do we feel that this topic is so pertinent? I think the previous speakers' opening statements have already pointed to many reasons why we are here. The Amsterdam

Declaration from 1994 was of course not a starting point. A lot of work had been done before, but it brought those lines together and it has streamlined the work that we have been able to do since then. Another speaker also mentioned that in Ljubljana we had a conference on health care reforms, where we were also able to place the issue of patients and citizens high on the agenda of health care reform.

The important partner in the field of human rights is the Council of Europe, which in 1997 came with the Convention on the Protection of Human Rights and Dignity of the Human Being with regard to the Application of Biology and Medicine. One question arises: when will this really become everyday practice? When do we move from the ethics of ignorance to real consumer participation? There are two reasons to put forward these questions: 1) Patients are in the process of “taking their seat at the steering wheel”: they want to know about and be part of the process dealing with their own health and their health care systems; and 2) The spirit, the “djinn”, is out of the bottle and it will not go back.

Often, when WHO and many of the organizations you are working with deal with professional organizations and administrators, there comes (if not explicitly somehow implicitly) the feeling that everything would be so much simpler and easier if we didn't have to explain all these things to citizens and patients, because by definition we are doing a good thing. But this attitude doesn't work anymore – and maybe this is one of the issues that will still come up in our debates later in this meeting.

What have the European Member States done so far? In 1993, Finland passed a law on patients' rights, and the people who helped this process will be on our panel for this afternoon's discussions. In 1994, the Netherlands was the second country to do so, coming from a different setting for a health care system (an insurance-based one). And again has gained broad and but very interesting experiences in this field. In 1996, Israel passed its patients' rights legislation, and we also have representatives from Israel here today. In 1996, Lithuania passed a law which is not often remembered when we talk about patients' rights in Europe, but Lithuania was the first central European state which came onto the European scene after 1991. In 1997, Iceland joined the club, and it is sometimes forgotten that Greece also has patients' rights legislation. Norway is currently debating such legislation in parliament and will very likely pass the law during this year. Denmark passed its legislation in 1998, so the Nordic countries are very prominent on this issue.

Passing legislation is not the only way of promoting patients' rights. Other countries have promulgated charters of patients' rights: France was the first to do so in 1974 and renewed the charter in 1995, and the United Kingdom in 1991 adopted a very strong national charter of patients' rights which has markedly influenced its national health service. Ireland and Portugal also adopted charters, in 1991 and 1997 respectively.

Many countries have charters that operate at the institutional level, so when it comes to looking at patients' rights in Europe, it is sometimes difficult and debatable to categorize countries. We have come to the conclusion that this is not the most important thing, anyway. The most important is what is really happening in the

country. The “hot” issues everywhere are consumers’ protection, citizens’ empowerment and the whole development of civil society, a trend which is perhaps taken for granted in western European countries but which is getting stronger in central and eastern Europe.

What has WHO done so far? The network of patients’ rights and citizens’ empowerment was launched very soon after the Ljubljana Conference, and the first meeting was held in Gothenburg at the Nordic School of Public Health, which explains why that establishment has had such a strong input into developments in this area. The second meeting took place last year, in Canterbury, and the third one is now. We have also tried to map the scene in the European Region: there have been annual reviews of patients’ rights developments, assessments of citizens’ empowerment, assessment of prioritization and rationing, and we have established collaborating centres (Canterbury, Gothenburg and Warsaw) that are helping WHO in this area.

There have also been other meetings and conferences where we have taken and tried to bring the messages of patients’ rights and citizens’ empowerment to the fore. There was one in Rotterdam last year looking at the rights to health care, there was a meeting in Strasbourg on health and human rights organized by the Council of Europe, and we had a meeting in Bonn recently on citizens’ participation. At a European Union meeting last autumn, the Badgastein Forum, on “Creating a better future for health systems in Europe”, I was asked to present the views of the patients’ rights network. However, I re-formulated the title of the meeting, because in my view we should ask: “Is it our role to create better health systems in Europe?” We should be more concerned about creating a better future for the patient and consumer of health systems in Europe. And I am happy to say that when I saw the title of this year’s Badgastein forum meeting, it had been changed to “For better health in Europe”, a title which, without mentioning consumers or patients, is not so system-oriented.

We should now ask ourselves: Is this enough? My answer is no. We hope the movement is having an impact in our countries, but something more needs to be done. That is one of the reasons why, together with the Nordic Council of Ministers, we decided that this is a very important issue to bring up together with the countries in the north which have been so active in this area and those countries who have shown their interest at national or organizational levels or among scholars and individual people. Can we find out which are the best mechanisms to tip the balance towards better patients’ rights, as indicated in the Amsterdam Declaration? I must say that when I bring the Amsterdam Declaration up in other fora, it is amazing how little it is known among those people who are really drafting and planning health care systems. And when I have brought it up, they say it is a great help, and many countries are now using this document, when drafting their patients’ rights legislation.

Is patients’ rights legislation the right way? Should it be charters that are emphasized? Or both? Or should it be something totally different? How do we know if the situation is improving? This is the other question I would like to raise at this meeting. In fact, when we have been trying to assess the developments, we have

realized how very difficult it is to measure the improvements. How do we know which are the most pertinent problems? Again, the problems differ from one country to another, and we have learned that a blueprint method, trying to adopt somebody else's approaches, is not working. What are the indicators for measuring improvements in patients' rights in reality and in practice? Our open-space meeting will discuss this topic. As Dr Stachenko mentioned, patients' rights are a very important aspect of the quality of care and of satisfaction with care.

What do we expect from this meeting? We hope that you can act as a forum for discussion and the exchange of ideas. Hopefully you will go home enlightened and enthusiastic about promoting patients' rights in your respective countries, more than you would have done if you had not made these contacts. And, of course, these contacts should also be there also for you to use in your daily life, to call on your colleagues and to strengthen your ideas.

We hope that we have identified new areas for collaboration and innovative ways of promoting patients' rights and tackling the problem areas. We have laid a firm foundation for the future work of the patients' rights and citizens' empowerment network. Let's make this a worthwhile event, a starting point for a revitalized network which we hope you will all be part of. We will listen to country reviews and presentations, we will consider the practical implementation of ethics, we will have a panel debate on what really has happened, and we plan to have an open-space meeting which will focus on the move from theory to practice, a brainstorming session where you are expected to give your input and get the views of others, thus enriching your own ideas. And then we will have the business meeting on Saturday.

Patients rights in the Nordic countries

Mr Lars Fallberg, Nordic School of Public Health

Introduction

"Patients have needs, not rights" is a commonly heard response to increased patient rights. In fact, they have both. "Health" and "life" are primary values expressed by health care professionals, but the right to make one's own choice about treatment options, sometimes called "autonomy" or "self-determination" is even more important to most people. Recent research within the healthcare system opens up new opportunities in terms of care and treatment. However, in the wake of this rapid development come reports and alarm signals from hospitals and nursing homes bearing witness to violations of the rights of individuals. Therefore, the need to strengthen and safeguard patient's rights of self-determination is greater than ever before. The Nordic countries are among the world leaders when it comes to safeguarding patient rights (1). To date, seven European countries have introduced laws aimed at safeguarding patient autonomy. More than half of these are Nordic countries or countries close to these.

There are several factors behind increasing interest in patient rights in the Nordic countries as well as in the rest of Europe. The two dominating factors are medical technological advances and the fact that we now live longer than before.

As demands on the health care system are accelerating, the risk of people being “run over” in the process is greater than ever before. Concepts such as "drive-through deliveries" and "clinical treatment completed" give an indication of the situation. Another noticeable trend, perhaps primarily within public-financed health care, is that increasingly it is necessary to be active and seek the answers of your health problems yourself. "The decibel method" is an observed fact. It is in this situation that demands for increased legal security for patients are raised. In the health sector, legal security is principally related to:

1. physical and psychological integrity;
2. decisions and actions without delay;
3. equality;
4. just and fair treatment;
5. control against being declared “judicially incapable”;
6. qualitative minimum standards (2).

Patient rights legislation has several important functions (3). Besides safeguarding the patients' legal security, such legislation has an important pedagogical function. To the legally inexperienced, it may be difficult to get an overview of one's rights when it comes to placing demands on the health care system. Bringing together the relevant legislation makes it easier for both patients and health care personnel to do this. In addition, since rights are aimed among other things, at promoting equal treatment, they may reduce the scope of the doctor's discretion. However, striving towards this "McDonald's" effect (equally good quality all over the country) ought to be a matter for patients as well as for health care professionals.

The concept of patients' right

Application of the concept of a “right” varies in the different domains of legal terminology, and the general opinion seems to be that the concept is void of reference. It has, nevertheless, a practical function, namely to describe, in a concise and straightforward manner, an existing legal position, which would otherwise have to be described using a great variety of circumstances, something which would become cumbersome to grasp.

Patients' rights are divided into *negative* and *positive rights*, or expressed differently, as "the right emanating from something" and "the right to something" (4). Negative rights are by their nature not linked to costs but aim to safeguard the individual's legal power to make autonomous decisions without excessive involvement of the authorities. Positive rights include the legal power to take part of the good of society including, among other things, the right to health care. These rights entail an obligation on the authorities to ensure that society's resources are fairly and impartially distributed among its citizens. “Social rights” can be compared to a bag of money at society's disposal, which means that they are limited to the resources of the society.

Further divisions of patient rights can be made when we look at the power of the rights, as well as different periods of time in the patients' contacts with the health care system. The first refers to the broad interpretation given to the concept of patients' rights. Based on a recent investigation into patients' rights in the Nordic

countries and legal texts (1), it can be said that the strength of patient rights can be divided into at least three levels (5):

1. Legal rights. They contain well-defined areas and have no limitations related to resources. The patient has a right of appeal to a court or similar authority if they are not respected. If violation occurs, compensation and/or sanctions are imposed.
2. Quasi-rights. Obligations on the part of the health care principal, embodied in health services personnel. Well-defined provisions have been reformulated into patients' rights. This group also includes so-called targets or legal framework provisions which are conditional on available resources at a given point in time.
3. Non-legal policy documents as a patients' charter, policy documents and similar principles, where the "right" is mainly moral in character. These also include the waiting list "guarantees" and service "guarantees" frequently used in the Nordic countries.

Rights according to the first level are comparatively uncommon in the Nordic countries. To the extent that they exist, it is primarily within the social legal area. In **Sweden**, for example, there exists certain legislation in the area of disabilities especially directed towards vulnerable groups in society. The Norwegian Municipal Officers Act contains such elements of rights (6). These rights cannot be curtailed due to lack of resources and are an important tool for safeguarding the social rights of vulnerable individuals.

With the exception of the few existing provisions concerning so-called legal rights, Nordic health care is characterized by *legislation of obligations*, i.e. health care personnel's obligations towards their patients (7). This legislation pertains to public law, whereby health care principals have a "vertical" relation to individuals. This can be compared with, for example, the situation in the Netherlands, where private carers are more common within the health care system. There, citizens are regarded as having a civil law, or "horizontal", relation to their carers, even if complementary provisions of obligations exist.

At the third level, where so-called patient charters or non-binding policy documents are found, a non-legal strategy is applied. In the Nordic countries, different forms of treatment or waiting list "guarantees" are used, representing a kind of policy document. The individual is not in a position to make legal demands based on the waiting list "guarantee", which is usually an agreement between the carer and the State. Consequently, the existence of rights legislation at levels 1 or 2 does not exclude the application of a policy document according to level 3.

Distinctive Nordic characteristics

Due to their close cooperation and common frames of reference, health care legislation in the Nordic countries has acquired certain common characteristics. In the following, I will try to describe these as well as some national disparities. Health care legislation in the Nordic countries is characterized by a **legislation of obligations**, i.e. the health care principal and the staff have obligations in relation to the patients (7). However, it is not a question of a simple relationship between two

parties - between patient and doctor or nurse. Instead, relations can be described as a triangle. The staff have a relation to the health care principal (in the context of labour law) while the relationship between patients and the health care principal comes within the scope of administrative law.

Furthermore, patients' relations to health care personnel and the health care principal largely lack the general legal guarantees related to administrative law, which are otherwise important in the relationship between administrative authorities and citizens. The framing of the provisions concerning obligations is such that patients are not in a position to place legal demands on the health care system concerning, for example, a certain form of medical treatment or diagnosis. Instead, it is the task of supervisory authorities to ensure that patient safety is regarded and that the staff fulfil their obligations. Patients have the possibility to report any errors or shortcomings to the supervisory authorities, which may lead to investigation of the care unit(s) in question. A limited number of regulations, among others those providing for the right to medical care in emergency situations and the right for patients to read their own medical records, give patients the possibility to turn to court if the health care personnel have not fulfilled their obligations. Considering the extensive area of supervision of the supervisory authorities, it is important that patients react and report to the supervisory authority concerned. Few do so.

Another distinctive characteristic of Nordic health and medical care is the existence of so-called treatment “**guarantees**” (9). This is how the State handles the existing queues of patients waiting to receive care and treatment. The extent of the guarantee varies between the Nordic countries and includes, among other things, the right to be examined by a doctor and to receive care and treatment within certain time frames. In *Norway*, where the “guarantee” has been the most lively debated and analysed, a first variant of the waiting list guarantee was introduced in 1990. It was linked to the priority order, which was in the process of being implemented. This was followed by similar guarantees in *Sweden* (1992) and *Denmark* (1993). In *Finland*, a pilot scheme was initiated in some health care districts in 1995, but it was not completed. Of the Nordic countries, both *Finland* and *Iceland* lack some form of care guarantee. However, in the Icelandic Patient Rights Act of 1997, certain criteria are established for how to prioritize in the event of queues. In addition, health service staff have the obligation to be informed about and to inform the patients about waiting lists and possibilities of receiving treatment more quickly in another institution.

In practice, the care guarantee is an agreement between the State and the health care principal, a relation to which the patient is not a party. He or she has no legal rights. Nor does the *Norwegian* care guarantee, the only one in the Nordic countries to be framed as a legal obligation on the part of the health care principal, give the individual patient any rights. A *Norwegian* patient who did not receive treatment within the time stipulated demanded to be treated in another health care district. The patient's request was heard in a Norwegian court in 1998 but was dismissed on the grounds that the provision does not assure patients' legal rights. The *Norwegian* patients' rights bill, which is expected to come into force in 2000, is expected to contain a proposal that the provision regarding waiting time guarantee should be framed as a right enforceable by law.

An important legal possibility within the health care system is the possibility to complain and to receive compensation due to malpractice at hospitals and other health service institutions. As in most other European countries, patients who have suffered injury are entitled to demand damages under civil law regulations. However, the laws of damages in the Nordic countries are in most cases framed in such a way as to exempt staff from liability to damages. Instead, it is the health care principal, in the capacity of employer, who becomes responsible for damages with regard to error or neglect by the employees. Only if the error was made with intent can the employee be made personally responsible for damages. To sue for damages is always associated with great problems for the individual, who is required not only to show evidence of wrongdoings or neglect on the part of the opposite party but also to have the financial resources to carry through legal proceedings. All this takes place in a situation when the patient has been weakened by disease and perhaps still suffers from physical and/or mental problems.

Due to the difficulty of obtaining damages compensation in a civil court, a **no-fault patient insurance scheme** was introduced in Sweden in 1975 (10). Some years later, a similar insurance scheme was introduced for injuries related to pharmaceuticals, the so-called **pharmaceutical insurance scheme** (1978). The patient insurance scheme was originally constructed as a voluntary insurance, built on agreements between health care principals and insurance companies. The idea of the insurance scheme is not to point out any 'culprit'; instead, the aim is to compensate the injured patient and, hopefully, to accumulate knowledge to prevent injuries in future. Individual patients need not gather evidence or obtain reports from experts; they only have to report the injury, whereupon the patient insurance scheme takes over and investigates the case. Finland introduced a patient insurance scheme in 1987 patterned on the Swedish scheme. Norway followed with a temporary patient insurance scheme in 1988, which was later made law. Denmark introduced its patient insurance scheme by way of an act in 1992. Today, only Iceland lacks a comprehensive national patient insurance scheme. Here, institutions have assumed responsibility for paying damages in the case of malpractice. This system is applied at Rikshospitalet, as well as in some of the other hospitals. A bill proposing a comprehensive patient insurance scheme is expected to be passed in the year 2000.

Recent development in the Nordic countries

The Nordic region has undergone a faster development compared to any other part of the world when it comes to legislation to safeguard patients' rights. Of the Baltic States, Lithuania has introduced legislation concerning patients' rights. Considering Norway's advanced plans, this means that no less than five countries have strengthened, or are planning to strengthen, patients' rights. Other countries with this type of legislation are the Netherlands, Israel and Greece (11). In the following section, the developments in the Nordic countries and the differences between the countries are analysed.

Finland

The **Finnish law** of 1993 is called a law of rights. However, it is built on obligations of the staff and the health care principal in relation to the patient. The patients' right of care embraces all who live permanently in the country but is not an absolute right, being limited by the availability of resources. *"Every person who stays in Finland*

permanently, without discrimination, is entitled to the health and medical care required by his state of health within the limits of those resources which are available to the health care system at the time in question". When it comes to patients' consent to care and treatment, such regulations are lacking. From the legislative material, it can be seen that "silent" or "presumed consent" is sufficient, but that this varies with how pervasive the treatment is. A proposal for a legal requirement for consent was rejected, due to not having been sufficiently investigated. Regarding juveniles, there is an age limit of 18 years for consent to care and treatment. A proposal to set the limit at 12 years was discussed, but in the provision it is stated that *"The opinion of a minor patient on a given treatment has to be assessed if it is possible with regard to his/her age or level of development"*.

The provision dealing with patient autonomy is general in character and is designed to guarantee the patients' autonomy in situations of, for example, blood transfusions, involving patients who are members of Jehovah's Witnesses, as well as patients who make their will in the terminal stage of life. One of the more interesting provisions in the Finnish law deals with the obligation of every care unit to have a special patient ombudsman. Their task is, under the Act, to: a) inform patients about the content of the Patient Rights Act; b) help the patient to file a complaint or to apply for compensation; c) spread information generally about patients' rights; and d) devote themselves to informing about, and implementing, the present regulations. As a result of these provisions, hundreds of patient "ombudsmen" have been appointed and are employed part-time all over Finland, a task which they carry out parallel to their ordinary work as social workers or nurses. Thus, the built-in conflict is overt.

Even if the introduction of the Patient Rights Act has not meant very many new provisions, an evaluation made by the Ministry of Social Affairs and Health shows that the general public as well as health professionals feel that the law has influenced practical health care functions. However, some provisions, such as the right to informed consent, are criticized for the vagueness of their formulations (12).

Denmark

Besides the Norwegian bill, **Danish health and medical care legislation**, with its Patient Rights Act, is one of the most specific among the Nordic countries. The Danes are provided with free visits to doctors, both in primary care and in hospitals, free choice of local hospitals all over the country and specialist care without referral by a GP. This has attracted international attention. The aim of the new legislation (from 1998) regarding patients' legal position is primarily to protect patients' dignity, integrity and autonomy. The Act contains no provisions regarding material preconditions for when and how the right to treatment arises. However, the patient's right of autonomy is emphasized, as is the fact that no treatment may be started or continued without the patient's informed consent. This also applies to patients who are above 15 years of age and who are capable of foreseeing the consequences of their decision. The right of autonomy is valid irrespective of treatment. For patients under 15 years of age, the parents have to give consent, but the child should so far as possible be involved in the decision. The law states that consent should be in writing, oral or, depending on the circumstances, tacit.

The emphasis of the legislator on the individual's right of autonomy is also noticeable in ethically difficult situations. The law enumerates four situations where the health care personnel are obliged to respect the patient's wish, even if this may lead to the patient's death. These situations are: a) hungerstrike; b) refusal to receive blood transfusion; c) treatment of a dying patient; and d) where the patient's living will states that life-supporting measures may not be taken in a situation where the patient is unable to exercise his or her right of autonomy. Normally, special emergency provisions are applied to justify interventions in situations such as the above. In this case, however, the legislator has chosen, as far as possible, to avoid the law being invoked by clearly and distinctly describing how the provisions are to be applied.

The complaint function in Denmark is, with the exception of the no-fault patient insurance scheme, gathered in one organization, the Health Services Complaint Board (HSCB). The Board deals with complaints directed towards, for example, professional activities of staff, lack of information to patients or violation of professional secrecy. It is also the supervisory body for the local psychiatric patient complaints committees. HSCB regularly publishes a newsletter, where statistics is presented and issues of interest in principle are highlighted.

Iceland

The **Icelandic** health care legislation largely builds on the Danish one, a result of Iceland's strong ties to Denmark. Some of the distinctive features otherwise characterizing Nordic patients' rights are missing here. Among other things, the system of waiting list guarantees is not applied, despite the fact that health care is publicly financed. Nor has the country had any comprehensive patient insurance scheme; however, such a scheme is expected to be introduced during 2000. This is, among other things, due to the relatively small size of the country (approximately 250 000 inhabitants). The size of the country enables greater social control to be exercised as well as offering increased possibilities, at an early stage, to react when someone is starting to have problems. However, calls for the strengthening of patients' rights by law were made which, after discussions in the Icelandic parliament, led to the introduction of such a law in 1997.

The Icelandic Patients' Rights Act is aimed to strengthen patients' legal security in their contacts with the health care system. In the introduction to the Act, it is stated that patients are entitled to receive the best health care available. No limitations are given, nor any sanctions if the right to medical care is not respected. The Act describes in detail the information that patients are entitled to receive. It includes:

1. the patient's state of health, including medical information and prognosis;
2. proposed treatment and expected outcome, as well as risks and possibilities;
3. the possibility to seek a second opinion by another doctor.

A note is to be made in the patient's medical record that the above information has been given to the patient. Care and treatment presupposes the patient's consent; the latter may, at any time, discontinue the treatment. When this occurs, it should be noted in the patient's medical record and the patient informed about possible consequences of the decision. The patient is also to be informed about, and must give

his or her consent to, the presence of medical students during care and treatment. The Patients' Rights Act includes special provisions concerning children under the age of 16. Children between 12 and 16 years of age should, however, be allowed to have an influence as far as this is possible.

Doctors have an obligation, with some exceptions, to let patients take part of their medical record, and, at their request, to give them a copy of sections thereof. If a patient or his or her representative considers that the content of the medical record is misleading or erroneous, the patient's comments should be noted down in the medical record.

A special provision sets out the patient's obligations. It is, among other things, stated that patients are responsible for their own health, to the extent that they are able to. They also have a responsibility, if their health condition allows, to take an active part in the care and treatment they have agreed to.

The Act does not include any provisions concerning how health care personnel are to handle questions related to living wills and blood transfusions to patients who are members of Jehovah's Witnesses, but these issues are dealt with instead through documents and guidelines on ethics. However, it is stated that, in the case of a dying patient who expresses the wish not to be subject to life-supporting measures, health care personnel have an obligation to respect this wish.

Norway

Among the Nordic countries, as well as compared with other European countries, Norway is the most developed one when it comes to patients' rights. Researchers and health care personnel have, since the mid-1970s, been actively engaged in issues related to patient rights (8). Since the 1980s, there have been plans to introduce a law on patient rights. New regulations and changes in practice, which have successively been introduced, indicate that something is going on - but what is the value of a patients' rights law if it is not matched by corresponding legislation concerning obligations on the part of health care personnel? In the complex of laws expected to take effect in the year 2000, the legislator has taken this into consideration. In addition, there is a law concerning psychiatric care and specialist care. In the following, I use the future patients' rights legislation as the point of departure, as it is presently known (7).

The fact that Norway has paid a great deal of attention to the problem of waiting lists can be seen in the expected proposals on patients' rights. These include rights for those who have been referred by their general practitioner to a hospital or specialist for a medical examination within 30 days. The patient has the right to choose which hospital in the country is to carry out care and treatment. There was previously fear on the part of health care administrators that a free choice of hospital would make planning and organizing the service more difficult. However, investigations performed in some counties within one so-called health region show that it has resulted in few patients seeking help across county borders. The right to undergo a health examination is complemented with provisions, already in force, regarding a waiting time "guarantee". According to this, patients with one of a specified list of diagnoses or diseases are to be given treatment within three months.

Patient autonomy and participation are two important themes in the new legislation. To be valid, the patient's consent is required by law to be based on sufficient information having been provided to the patient. The consent can be given orally or tacitly except in special situations, where special consent is required depending on the degree of seriousness of the intervention. The law also includes a provision which is directed towards the patient's family members. If the patient agrees, these have a right to receive information about the patient's state of health, as well as about the care and treatment given. Besides patients' express rights with regard to information and consent, the law states that patients have the right to participate in the choice between available treatment methods. In cases when the patient is below the age of consent in this respect, senile or similar, the patient's next-of-kin have a right to take part in the choice together with the patient.

The new legislation also includes a provision regarding the right to obtain a second opinion. The provision is motivated by the fact that the patient-doctor relationship sometimes gives rise to situations where the basis for continued cooperation is lost due to the patient losing confidence. This may be due to, for example, either errors or violations on the part of the doctor, or misunderstandings and unreasonable demands and expectations on the part of the patient. The right of a second opinion is only valid once for the same condition and presupposes that the general practitioner and the patient both agree on the need for a second opinion by an independent doctor.

Sweden

In Sweden, there have also been discussions regarding the need to introduce an act with respect to patients' rights. In 1997, the official report "The patient is right" (13) was published, concluding that patients' rights in Sweden are well protected and that the aim is to gather all relevant patients' rights provisions into a special law. In the meantime, a number of complementary provisions were proposed, which came into force in 1999. In Sweden, too, the Health and Medical Services Act does not state in what situation patients have the right to health and medical care. What it does state is that the health care principal has an obligation to offer good care to all residents in the county. It does not, however, mention anything about what waiting times can be regarded as consistent with the requirement of good care, even if a public priority-setting committee presented a proposal for guidelines some years ago.

In Sweden, health care personnel have an obligation to obtain consent from the patient prior to every form of physical or mental intervention. There are no special formal requirements for the consent, except in the case of pervasive interventions such as sterilization. However, even if the rules of consent are found both in the Health and Medical Services Act and in the Constitution, the provisions are not linked to other rules of sanction than those existing in the Criminal Code. This means that, apart from purely public law sanctions, health care personnel who violate patients' right of autonomy can in practice be prosecuted only on grounds of varying degrees of crimes against life and health. Furthermore, patients have no other means of remedy, in the case of infringement of the rules of consent, than those obtained by applying the criteria stated in the Tort Liability Act, as well as obviously groundless deprivation of freedom at the hands of the public authorities.

There is no provision governing the rights of children in the Health and Medical Services Act. Instead, reference is made to the Code on Parents and Children, where an 18-year limit is stipulated for children's right of self-determination. Even if supervisory bodies and preparatory work underline the importance of also involving individuals under 18 years of age in the decision-making process, the fact remains that consent to care or treatment by under-age individuals has no support in law.

Among new provisions introduced in January 1999 is a strengthening of the health care personnel's obligation to provide information. The provision states that the information should be adapted to the ability of the patient to understand and assimilate it. When there is a choice between two or more equal treatment alternatives, the patient has the final decision; however, the effect of an alternative has to be related to the costs, a calculation which is made by the doctor. The information given and the patient's decision must be documented in the patient's medical record. The new provisions are aimed at improving and individualizing the information, as well as at increasing patients' influence in the doctor-patient relationship.

Another provision, which did not exist previously in Swedish health legislation, is the right to a second opinion. This possibility existed earlier in practice, in that a patient can turn to another doctor than the one who first gave his or her opinion. However, the new provision is restricted to patients with a life-threatening or particularly serious disease and where the medical decision is of great importance to the patient or may involve special risks.

As in Finland, patients' possibilities of putting forward their views and complaints are spread across several different authorities and organizations. Besides the No Fault Patient Insurance Scheme and the Pharmaceuticals Insurance Scheme, which are relevant in issues regarding injuries, the patient can turn to the Medical Responsibility Board (MRB), which takes decisions on sanctions or restrictions on the right to prescribe medicaments. In addition, the National Board of Health and Welfare is responsible for patient safety at the country's health care establishments, private as well as public. For problems of a relational character, each hospital has an obligation to appoint a doctor or nurse responsible for patients, if the patient so demands. This person then coordinates the patient's hospital stay with visits to different departments and health care personnel. Moreover, all county councils have an obligation to have a County Complaints Board (CCB). The CCB has no power, nor is it allowed to "take sides" on behalf of the patient. Instead, the CCB is to act as mediator in conflicts between patients and health care personnel and to inform patients about their rights. In the marketing of their activities, CCB is portrayed as independent and as a patient representative; however, its work is in fact part of the county council's activities, and indeed it also has responsibility in its capacity of an employer.

The legislator's reluctance to introduce enforceable rights through the introduction of a patients' rights law in Sweden is due, among other things, to the county councils' relatively strong position. For instance, together with the State, they have the right to tax their citizens. To strengthen patients' rights would not only require more money but also reduce the scope of county council politicians' decision-making and

prioritizing, in pace with the introduction of compulsory rights. Partly with a view to counteracting the effects of the absence of legislation, the Federation of County Councils presented, in connection with the official report "The patient is right", guidelines for the county councils which are linked to the present legislation. These guidelines are intended more as recommendations than as mandatory obligations.

Discussion

An analysis of patients' rights in the Nordic countries and other European countries shows that it is not impossible to legislate in situations where ethics and law conflict. It also shows that the Nordic countries have made such progress when it comes to safeguarding patients' legal rights. Perhaps one of the most important provisions, in order for patients to be able to defend their legal security, is the possibility to make a complaint. The range of complaint procedures is impressive, meeting an important need among patients who for some reason are dissatisfied with their care and treatment. The differences between, for example, the complaints procedure in Finland (where dissatisfied patients have no less than 10 different bodies and authorities to turn to) and that in Denmark, with only one national complaint body, create interesting possibilities for comparisons between the countries.

The next step in the Nordic countries' development is no longer a matter of creating new regulations in situations not previously anticipated, but of implementing the present regulations in practice. There are still gaps in the public's knowledge about the existence of laws concerning patients' rights. There are also gaps in the knowledge of those who have a duty to apply the legislation. It is therefore important that health care professionals, in partnership with users and their representatives, create opportunities for providing information about and for applying the existing regulations in practice. One-sided competence on the part of consumers of care creates scope for conflicts and disagreement. It ought to be the obligation of every care unit and user organisation to develop a strategy for how to apply existing legislation in practice.

Another problem is the conflict between ambitions and resources. Health care politicians in the Nordic countries have a common tradition of using legal or quasi-legal concepts for describing parts of the services offered by the health system, for example patient ombudsman, treatment contract, treatment agreement, care guarantee, and rights. However, the application of legally loaded concepts creates high expectations in patients. When it proves to be impossible to satisfy these expectations due to lack of resources or insufficient organization, patients feel frustrated and disappointed. It is therefore important that ambitions within the health system do not diverge too much from what will one day become reality, and that rights, contracts and ombudsmen are given correct names.

A not too far-fetched scenario for the Nordic countries is that ageing populations and rapid technological development in the field of medicine, accompanied by a progressively growing need for health and medical care among the general public, will lead to calls for more robust prioritization. These prioritizations will no doubt pose a threat to the development of patient rights, and this in turn increases the need for the public to participate actively in the prioritization debate and to try to influence the distribution of resources to the health system as well as within it. Patients'

associations in the Nordic countries are important representatives of users but have, in an international comparison, close links with the producers of welfare services. An active and creative dialogue between user organizations and health care officials assumes the independence of the former from the State and the municipality. However, the role of county councils and the State as the principal financier in many of the user organizations gives, no support for the concept of independent organizations.

One important consequence of Nordic work and experience, when it comes to legislation regarding patients' rights, is the role these countries can play as carriers of knowledge and as an information bank. At a time when an increasing number of European countries are striving to strengthen patients' legal security and position within health system, it is important to have both the models and the tools required. By exporting their competence and experience in patients' rights, the Nordic countries can take part in the development of the rights of patients in the rest of Europe.

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The philosophy and practical implementation of ethics

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Thank you for inviting me to speak at this meeting. However, don't expect a "missionary" statement, with a central message saying "Do as we do in Denmark or in the Nordic countries and go back home and do it". We share fundamental values in Europe and outside Europe, to some extent at least, and we have found some of the solutions; we can exchange information on them, but we have also experienced the shortcomings and mistakes we have made in this country and the other Nordic countries.

The re-entry of ethics as a term and as a concept took place 30-40 years ago. Before that only philosophers and a few theologians used this term among themselves, but then came a time for re-entry because the history of the world, what had happened, the atrocities during the second World War had shown that we needed something more than to discuss technicalities and economics; we needed some overall expression for what is a very important constituent of human life: love, respect, duties, rights, things that are not always transferred to the legal part of our societal lives. In a strange way, the health sciences and health services have acted as a kind of "epicentre", to the extent that thinkers, philosophers, theologians and other sociologists have observed this sector for its ethical problems and meanings just like a family watching a strange animal in the zoo. The situation has changed now, but we had to take upon ourselves the responsibility of being a sort of "eye-opener" for ethics in society as a whole. But the sudden reappearance of a term often leads to the fact that the term, as a linguistic sound, runs ahead of its precise meaning. You know that there are a few seconds after we hear a new term before we react in a grown-up way and ask "What does that mean?" I had the same experience with "subsidiarity" in the language of the European Union – if you don't ask very soon, then you pretend that it's a term everyone knows, and that means we all leave such a term behind us, we use it, but it's a kind of tower of Babel: it forms the basis for a widespread misunderstanding which blocks the real understanding.

Ethics does not belong to the prehistoric words of our languages like "bread", "man", "woman", "knife", "day", even "church" and others that appeared very long ago. It's a later societal concept and it's related to a person's life with his or her fellow citizens; it reflects existential and even religious principles through our daily behaviour, our non-verbal language, what we do to other people, how we deal with the tax authorities and whatever is known that I read of in books. And even our practical actions. Consequently, ethics varies with time and history – that is a truism, but sometimes we have to use truism as a platform.

Therefore, etymology, the art of knowing the origin of words, is of historic but little contemporary interest for the definition of ethics. We have to go to semantics, the art of knowing and describing what a words means in a contemporary cultural context. This is central for ethics and it has led to many definitions. I will save time by not going into some of them, because I don't think they are applicable today. I dare to use my personal definition, that ethics express the fundamental principles under lying the complex of values, norms and attitudes held by the majority of a national

population or global region such as Europe. They are essential for our personal life, for which we have some responsibility. Essential for our life with our fellow human beings and essential for citizens' life with societies and institutions – and by institutions I mean not only the public institution where you deposit your children during the day or where you send them to school, but also the commercial institutions, transport institutions, and everything where we have created a sort of ordered network in our societies. Even this definition is not easy to deal with, because it creates what the famous Norwegian play writer Ibsen described as the “onion-peeling phenomenon”: by defining ethics in the way I have just done, we use words such as norms, values and attitudes, and this is really a problem, which I will return to in a moment. But this onion-peeling phenomenon in a definition should not lead to a “laissez-faire” approach, where we say “It’s too complicated, we’d better each have our own language”. It should make us realize we have a duty to define the constituents of the definition, even if we peel another layer from the onion and probably even then don’t find the centre, and it should make it necessary (which is central to me) that, when we use the word “ethics” in a political context dealing with patients’ rights and duties, we declare the values involved.

Values are, as I define them, measures and targets of the non-material quality of life. But then, as you can hear, I’ve just peeled the onion a little more, because what is quality of life? But at least we get a little closer to the probably non-existing centre of the onion. Values are important in the context of European health systems; some of them are outlined below:

- equity in dealing with ethnicity, with sex and age, with social class. I have been a medical clinician long enough to have seen that even Nordic societies used to rely very much on a kind of “staircase”, where some citizens were more important than others – probably it was not said, but it was reflected in many of the decisions taken. That state of affairs fortunately passed away long ago, even if there are small residual “lumps of ice” still to be seen.
- The samaritan duty to serve your fellow citizen despite his anonymity – you haven’t met him before, you cannot expect anything in return, but you do it all the same. Many of our societal constructions especially, within the health sector, are actually based on this fundamental value of our duty to help our fellow citizens in accordance with their needs, and not merely in the expectation that he or she will do the same. That’s one of the very basic aspects of European culture. I think we should do much in these very tragic days to preserve and apply this value in our health sector.
- Truth as a value appeared late in health services and health sciences. Paternalistic lies were very common when I was a young doctor. We have learned now that patients have a right to expect us to tell the truth, unless they signal that they would like to stop a little before, because under serious conditions they prefer to have a little uncertainty left over for their personal hope and their relatives’ hope. And we should learn to respect this value.
- And then there is responsibility, a value that I define as being a visible and responsible part of a process. There’s not much discussion about responsibility for the positive aspects of our system. But when things go wrong, it’s necessary to find who has the responsibility. In such cases, it’s easier to make them visible if you create (no-fault) legislation where any

health professional could be held responsible not only for malpractice but also for other sorts of accidents or side-effects, but where society would still compensate people for these damages if they were not trivial and at a low level.

- I would also mention freedom, which I define as the sum of personal options, under the presupposition that in a democratic society the individual citizens' sum does not decrease other citizens' sums of options. We have introduced this concept late in health sciences in Europe.
- The patient's right to be informed, to say no thank you or just no to a suggested treatment or diagnosed procedure – that has been very important, and it is easier to apply if a nation creates a national health system and not just a system where everyone has to deal with his or her own security and pay for it in one or another.
- The last thing I would mention is humour. It's a value that is not much discussed in serious groups dealing with health systems and ethics, but it is very important in meeting with patients. They appreciate more the use of humour, because good humour (not irony or other skewed ways of meeting your fellow citizens) involves the health professional and the patient, or relative in a commonwealth of human frailty. This signal is very well understood by patients so we should allow this and not bring doctors or nurses to court if they use humour, even in rather serious situations, because it's often very much esteemed by patients.
- Norms are cut-off points on value spectra. For instance, freedom is not an absolute value – sometimes you can push decision-making on to patients and thereby place a burden on them even, when they signal that they would like you to take something over in a kind of caring paternalism or maternalism.
- Attitudes are fundamental principles applied when society's values are not applicable. Jehova's Witnesses are one example: they do not regard blood transfusion as a gift from one citizen to another, but in their reading of the Bible they find other sorts of interpretations. This is their right, and we have learned rather late in the health sciences to respect this.
- The word majority was mentioned, too, in my definition. It presupposes an open democratic society, otherwise a country is fascistic. There are still some countries in the world that have a majority in favour of non-equity, cruelty, no freedom. So you cannot just use a numerical measure.

The practical implementation of ethical principles needs a fertilized soil, a national culture. It changes over time, it changes in Europe and around the world, but very much in Europe. Through our international debates we learn very much from each other, and there is no such thing as a clear-cut road for learning, south to north or the opposite, east to west or the opposite. It's a very important sort of fertilized soil that we share together.

The day-to-day implementation of these values in the health services and sciences in contemporary democratic societies takes place via national official means. These include laws, notifications, circulars, internationally binding directives, conventions such as the Council of Europe's Oviedo Convention on Bioethics (1997) on one of whose protocol committees I am a member, national or international declarations,

guidelines, recommendations, etc. They have proliferated to such an extent, in Europe today, that researchers and clinicians find there is a thicket of different regulations, and therefore they have to consider in which order to follow them. But this creates problem, it gives a signal-to-noise ratio that is sometimes low. So we have to coordinate better and not say that each society and each group of interested people should start by creating their own set of guidelines with seeing what others have done.

Are framework regulations or detailed regulations most appropriate? I would say, dealing with research, certainly framework regulation based on principles, and even when dealing with the practical parts of the working health service, regulations should not be too detailed either, because things are changing so fast that such detailed legislation may be outdated in a few months after having been passed by the Ministry or Parliament.

In Denmark at least, so I won't offend other people, there is often a discordance between sets of principles and the means chosen to give effect to them. Here I can see a hierarchy stretching from detailed regulations through group regulations and general principles to prohibitions. These means are often supplied independent of the underlying sets of principles, that this leads to inappropriate shifts between the political or administrative macro, meso and micro levels. You can also use the terms "strategic", "tactical" and "operational" levels, although some people find them rather military.

Where are the limits and what happens between them? The macro limit in our European democratic societies is the parliament, the meso level is the ministries and central administrations, and the micro level is health institutions, local administrators and those of us working with patients there. The ideal is that parliament issues relatively few laws of principle, they reach the ministries who then bring them from the tactical or meso level to those of us working out there. But this is not always the case. We see rather often that parliament, through stories in the media, "jumps" from this level down to the micro level and leaves the ministries or central administration in a kind of vacuum, thereby generating a great deal of disturbance down at the working level. This is particularly the case if it is done in a hurry because of "harsh" presentation, especially in the electronic media.

Fast-changing sectors such as the health sciences and health services point to the use of such means as principles and frameworks, rather than detailed regulations, as I have already said. We saw this in the Danish legislation of the 1970s dealing with new techniques for retrieval of data in computers or data files – it was all too detailed. I have read the two laws in question many times, and I have difficulty understanding them. I have asked people representing the Ministry concerned and they have admitted that they, too, had the same problem because the laws were all too detailed.

Of major importance for day-to-day compliance with protective regulations are:

- The extent to which society as a whole accepts ethical values and national or international sets of principles and means. If it's not well timed, if you have

regulations, international bio-conventions or directives from Brussels affecting some of our nations, and the soil is not fertilized, you have a problem. On the other hand, it is not enough to have local definitions of what is important for me and my group, which values do we rely upon; no society can live and work as a conglomerate of a very wide range of personal attitudes and values.

- One should avoid relying on either isolated “polaroid” solutions of spontaneously existing values or on central control measures. As an example, German Democratic Republic made it very easy from the central point of view deal with the ethics of transplantation, because they issued the statement that all organs of all citizens in the country belonged to the state. That’s rather easy, but I don’t think it is acceptable for any of us.

So, in conclusion, I would say that we should rely on an interaction between what’s going on in public debates and what’s going on in parliaments and ministries, and we should not rely on ourselves as citizens of one country.

Technology assessment in health care

Dr Sten Thelander, Swedish Council for Technology Assessment in Health Care (SBU)

I am a specialist neither in ethics nor in legal regulations governing patients’ rights. However, I am an expert on systematic reviews and evidence-based evaluation of medical treatment and other forms of interventions, and as part of this work we have recently finished making a systematic review of the basis for the doctor/patient relationship. One aspect I will focus on is an important part of patients’ rights, that doctors should inform patients about what alternative treatments are available and what benefits and risks they can expect. To do that, the doctor must know what he or she can do, and that is not always the case, since the pace of medical development is extremely quick. It has been estimated that an internist, if he or she is to keep up with practical relevant developments in the field, must read about 20 medical articles every day of the year, and that is obviously impossible. Different approaches are therefore adopted to filter this information, so that clinicians and decision-makers within the health care system get the best available evidence on what to do and what not to do. SBU is one of many agencies in this area. We focus on efficacy, what works in clinical experimental trials, on efficiency, how does it work in European practice, on safety aspects and also on cost-effectiveness. We have also been charged with looking into the ethical and social aspects of different treatment alternatives, but, this is not always done, since it is very complicated.

Why do we need scientific evidence and what is scientific evidence? There are lots of examples of important discoveries by clinicians who make a connection between two co-occurring events and then find that they are causally related. Most important medical findings have been made in this way. But they must be confirmed in some sort of controlled fashion, since most treatments and other interventions in health care have only minor or moderate effects. Most of what doctors do is not that effective, and it is rare for doctors to cure a disease – most commonly, they limit the consequences of a chronic disorder. And in such cases there have been many fatal or

at least costly misjudgements. That is one reason why you need more systematic and controlled evidence for many of the decisions you must make in medicine.

Who should be responsible for this? This is a question of values and, in part, a conflict of interest: you can never reduce every important decision in medicine to a scientific question, and Professor Riis underlined this very well when he said that ethics and values are integrated in health care. You should not allow or force doctors to make hard decisions, since many decisions are not scientific; you should make values and conflicts of interest open and they should be openly discussed, since whatever level of wealth of country's health system has it still has limited resources in comparison to what could be asked for; and you always have to make a choice between one treatment or one group of patients getting one sort of treatment, in comparison with another. This sort of prioritizing and dividing different funds into different "pots" within the health care system is only to some extent scientifically based – and to the extent that it is, we try to get the background material for politicians, health care administrators and clinicians to make those decisions as part of an open discussion, also of course with patients and patients' representatives. The point here is that patients may be experts in the disease but they are also buyers of services in exactly the same way as other decision-makers in health care, since if you have a disease or represent a group of patients with the disease, when you want everything that's possible for this disease. This may be in competition with another group of patients who also have a legitimate demand for a treatment, and someone has to make this sort of conflict of interest open. You cannot just say that patients' organizations must decide what to do – it should be an open democratic decision.

As I mentioned initially, the patient/doctor relationship has been studied by us and when we do a systematic review, we search all the available medical and psychosocial databases so that we can be sure to find most of what is published, although of course, we can never find what is not published. In this case, our comprehensive search yielded about 2 000 studies, of which we found 800 to be of reasonably good scientific quality (we have special rating systems for quality aspects which are quiet) standardized and agreed on with the evaluation community throughout the world

What did we find? We found vast areas of ignorance, which is a pity, but we also found some aspects which for some of you might be rather trivial, but in a way they are evidence for what you already thought was obvious. Most patients expect their physician to be open and to collaborate, to agree on what is their health problem and what are the ways to solve it or at least to reduce the problem. In reality, however, many physicians actively avoid questions related to psychosocial problems, although most patients want them to discuss these issues. This is a problem, because it has been shown that a lot of consultations within the health care system are in fact related to psychosocial problems, yet these are actively ignored. If the patient tries to discuss the problem at work or at home, the doctor returns to the traditional biomedical questions. This may be the right thing to do if a doctor is dealing with an emergency, but in many cases when you go to your family doctor you do not have any urgent severe disease. It has also been shown, at least in the western world (where old people are less valued and their experience and knowledge are less appreciated), that they are often treated in a patronizing way, and even if their mental abilities are

intact. When old people visit a doctor and have a son or a caring relative with them, it is very common for the doctor to direct the questioning and communication more to the caring relative and not to the patient. What has also been shown is that most patients with a life-threatening disease want to be fully informed, but that a significant minority do not want to be fully informed – this is what Professor Riis said, they want to keep some hope for themselves, for their relatives, and this should also be respected. Even if the law says that the patient has the right to get all the information, he or she does not always want to use this right, and this must be respected. When this serious and alarming information is given, it should be given in private and not during a “grand round” with plenty of other staff and maybe other patients present. It should also be given in a personal face-to-face communication, not in writing or just in a letter or a phone call. This has been shown in many studies to be the best way to do it. When you come to the question of life-sustaining interventions, if you have a terminal illness and you may have a cardiac arrest or get some pulmonary or breathing dysfunction, the question may arise whether you should be put on a respirator. In many cases, these questions should be discussed with the patient in advance but again, as a physician, you have to be open to the possibility that the patient does not want this discussion and respect this, although in North America there have been many studies showing that a majority of patients with terminal illness want this sort of discussion.

Unfortunately no firm conclusions can be drawn regarding the quality of the doctor/patient relationship in terms of compliance or medical outcome. I know that “compliance” is not a modern term, since it implies that the doctor has authority while the patient should do what the doctor says, but I could not find a better term. What we really want to know is whether a good relationship between patient and doctor leads to the patient being more willing to follow the recommendations and treatments than if he/she does not trust the doctor. That is very probable, but it has not been shown. What has been shown in a few short-term studies on long-term disorders is that blood pressure tends to be lower when the relationship is good and that control of blood sugar levels and other aspects of the metabolism is better when the relationship is good, but these were only 3-month studies and we are talking about life-long disease. What has been shown over and over again is that patients are much more satisfied with doctors who give as much information as the patient wants and include them in the medical decision-making. Another good thing is that medical students and experienced clinicians can be taught communication skills: it has been shown in quite a large number of controlled trials that this can be done in a rather simple and inexpensive way. Those who are least professional in communicating with patients are often men; they gain the most, but they will not gain any skills from lecturing like I am doing now. They have to practice, they have to be filmed, and then on the basis of the film they can discuss what is good and what is bad in their communication with the patient. The patient can also be a professional actor and they have been shown to be good surrogates for real patients. In the area of sexuality, too, many disorders and many treatments of diseases can cause sexual dysfunction, and doctors are rather bad at discussing these aspects, although patients expect them to initiate these sorts of discussions, but those skills can also be learned.

Most studies have been performed in north America, the United Kingdom and the Netherlands, as well as in some areas of the Scandinavian countries but very few

have been done in other countries. Again most studies focused on outpatients with chronic diseases, while patients in emergency wards or with life-threatening acute disorders were very rarely included. Obviously, it is much more difficult to organize a study in those settings, but it is important to do studies of that kind. To some extent it limits the generalizability of the result, but we nonetheless believe that they can be generalized to the European scene.

There have been different experiments in Canada where students with top grade levels from their schools could be admitted by medical schools by writing a personal description or stating why they thought they would be a good doctor and then being given a sort of interview (this has been tried in many settings), and what can be said today is that they do at least as well as those who have a really high level of academic skill. In Sweden, fewer of them who leave medical school without graduating and they do better at the final test, before they get their licence to practice than those who were recruited only on school records. Whether they also proved to be better at communicating, a better “patient-doctor”, has not been studied, or at least we have found no studies on this, but of course it would be a very interesting question to look into. We also had a problem with recruiting medical students, since doctors can be most found working both as physicians and as educators, researchers, basic scientists or administrators. We do not know, for example, if we lose the best research potential by not using at least a quota of really high academic degrees or school degrees that way since it is not automatic that because you are a good “patient doctor” you are also a good researcher – it could be so, but it has not been demonstrated to my knowledge.

Since this conference is about legal aspects, I have taken the liberty of formulating a few conclusions. When U.S. police officers arrest someone, and they say “You have the right to remain silent,” but here I would say to patients “You have the right not to remain silent”. Patients are often not allowed to say what they want before the doctor interrupts them, and that should not be so. You have the right to call an attorney, but I would not in general recommend it. You have the right to know the basis for your doctor’s recommendations and to get a second opinion. How this should be organized must be decided nationally and locally. If you have rights, you might also be considered to have obligations, but what they should be, I do not know. Costs may and do limit the availability of effective treatments. Politicians and administrators try to push these difficult decisions back onto clinicians, and clinicians back again onto politicians, but this is not only a scientific question, it is also to a large extent a question of values. Treatments without documented efficacy should not be offered with tax funding, at least unless they are part of a clinical trial. Many health care practices throughout the world have not been tested in formal trials, but most people would agree they probably work; however, there are also a lot of interventions or treatments where we do not know at all if they work, and these should be tested in trials, if possible.

Panel debate: Mechanisms for giving effect to patients' rights

Finland

Ms Paula Kokkonen, Member of the Finnish Parliament

Ladies and Gentlemen. The term “Europe” has been used here frequently, and I find that people mean different things when they use this term. For some people it means that European Union, for others it means the Council of Europe, while for yet others it means WHO Europe, and that includes different countries from any of these other Europes. When we speak about Europe, we should always be very precise about what we speak of, and when you look at the flags you see that they are very colourful, different colours for different countries. I am just pointing out that Europe is not one entity, it has many cultures.

So when you start to legislate on patients' rights or any other subject, you have to draft your charter taking into consideration each country's history, cultural traditions, existing legislation and administrative systems. Legislation can be regarded as a safety net. You have to know where the holes are when you start your net. I am not saying that our solution would be a model one for everyone and, as most speakers have rightly pointed out here earlier this morning, there may be different solutions – I would hate to say that we are trying to make an uniform solution for the whole of Europe for the coming few years, because we are all at different stages.

Why did we draft the kind of document which we did? The reason was that had in 1973 or a little later I had started to give lectures in one of our major Finnish hospitals about patients' rights and the doctors would always ask me “Patients' rights, what on earth do we need them for? We are taking care of their rights, there is no need to talk about such a topic. Yet many patients felt, like in the picture that Mikko Vienonen was showing, here that they were tiny little creatures caught between the doctors who knew everything, who had all the power, and who would use that power and manipulate their patients in the way they wanted. We thought that, because we have patients' rights spread all over in different texts (from the Constitution to hospital rules and every other kind of document in between), we wanted to have a very compact text, which you could show like this and, go around and teach to patients and health care personnel as well, instead of having long books and long legal texts. We wrote on the most essential rights, answering the questions which had created constant uncertainty, varying interpretations and non-uniform practice. The questions which were usually asked when I used to lecture about patients' rights concerning their right to self-determination, the right to information, medical secrecy and rights of access to treatments, as well as the issue of who makes the decision that the patient has been wrongly referred cannot be admitted to hospital (this was sometimes made by the doorman, etc). This non-uniform practice, etc. was against the interest of patients and also against the interest of the personnel. I will not go into the law, because it has been discussed here, and you have an overview of it in your booklet; there are also references in the literature, which we can give you if you want to go into more details.

A report was drafted by the Ministry of Health after three years of practical experience, and only two things were really new: the patients' ombudsman and the

local complaints procedure. There is nothing that would have hindered patients from making local complaints earlier, but it was not the custom and people did not know how to deal with them, and that is why we drafted a local complaints procedure, because we thought we could reduce the number of complaints coming to the central government and all the different officials involved (ten, as our Swedish colleague counted them earlier). The patients' ombudsman was thought of being a kind of person who would "flag" patients' rights, who would go around and when health care personnel would see that there was an ombudsman, they would always remember that they had to take patients' rights into consideration. He or she would be a kind of "selling agent".

What are the major complaints of patients' ombudsmen? One is the lack of time: not all of them are working on a full-time basis. Another point is that, while the law we were proposing implied that we would like ombudsmen to come quite outside the government machinery, we could not afford it at that the same time when we were drafting this law, so we had to create or invent a system where personnel would be appointed from the hospital or the hospital would fund the activity; but even I could never imagine that they would be so creative that they might in some units appoint a head nurse or even in the worst case a doctor who was in charge of the hospitals as a patients' ombudsman. This is one question which I think we have to tackle. We did not want to set up special specifications, like saying they would all have to be lawyers, because honestly, having had a very long experience of taking care of complaints and although I am a lawyer myself, I realised that what is much more important is the personality of the individual, who is a kind of mediator between health care personnel and the patient. I still think that it is much more important to have a person who is building bridges rather than breaking them drawn. They should also play a preventive role, which I don't think they have really adopted. They should focus more on quality assurance in hospital – this has not been the case according to my observations and according to the reports drawn up. Then if you are going to have a patients' ombudsman system, they need support, if they do not get any support from anyone, they are lost, you can imagine one person who gets complaints from both sides, and everybody is kicking the patients' ombudsman. They have to have support, they have to have job supervision and also, where they are not lawyers themselves, they need some legal advice. The Ministry of Social Affairs and Health was supposed to introduce this system in the field, but I don't think enough has been done so far to really make this everyday knowledge of all health care personnel and not all patients do not know their rights very well, either. But I know that in hospitals, for instance, they have files in every relevant unit and they have information about the patients' ombudsman, etc.

One other point I would like to make is that the most difficult thing is that attitudes change very, very slowly. This is probably a question of generations, because the younger generation is rather willing to accept that the patient has the right to self-determination and is more willing to interact truly with patients. I think this is a question that one should focus much more attention on. The last point is that in Finland the Minister of Social Affairs and Health presented to parliament last year a bill on the status and rights of social welfare clients, and it was lacking two things: the proposal did not have this kind of ombudsman, and it did not have a local complaints procedures. So we, in the Social Affairs Committee of the Parliament,

rejected the proposal for those reasons, because our experience with these two quite new things has been rather good.

Norway

Mr Eric Hersdal, Ministry of Health of Norway

As I am from the Ministry of Health, I am working on giving effect to a new Act relating to patients' rights after it has most likely been approved by Parliament this spring. So I would like to say a few words about the ideas that form the basis of the new Act.

Firstly, as some of you probably know, this new Act on patients' rights is one of four new acts that together make up a reform of the health sector in Norway. The other acts relate to health personnel, hospitals and psychiatry. Taken together, they should create an almost complete picture, and of course these three others are part of the picture for patients as well.

The scope of the new Act on patients' rights was to focus on patients, giving effect to the following principles:

- Moving from the patient as an object in the health system to the patient as a subject;
- Safeguarding the trust between patient and health personnel.

The goal was to secure, for the whole population, equal accessibility to health care services and to secure their respect of human worth and integrity. This is part of what we were talking about earlier. I will try to show you how it is supposed to be or how this is thought to be.

Firstly, we felt that putting all the provisions concerning patients' rights into one act would make it easier for patients to find out about their rights and how to enforce them. I think that this point was also stressed by our Swedish colleague earlier today, referring to the subject of transparency, and also by our Finnish colleague who said it is important to have something on one paper that you can show to patients and also to the people working with them. So this more easily understandable paper, would be an act, but in a way I think it also has some other arguments behind it.

The patient is given the right to be assisted within 30 days after being at the hospital, he is given the right to have a second opinion from another doctor, he is given a free choice of hospital. I think that last point is quite important, and here I would like to describe what we are trying to do, at a lower level, to make things easier and ensure that the reality really happens. At this lower level, we also have a reference group on this subject, and the Ministry will (from that group) prepare guidelines and routines for handling the question of a free choice of hospital. The reference group does not have any representatives from patients' organisations, but they had their views incorporated in the work since we had the whole bill out for a big public hearing and I guess they will still keep on telling us how they think this should be done. The free choice of hospital has another side, too, which is that hospital financing is achieved partly on the strength of the hospital's own stimulus for hospitals to make their best

efforts, because in that way they will see more patients but they will also receive more money, so I think they will work together and create a better system both for hospitals and for patients and the people working there. This will also create competition between hospitals.

We already talked about the provision for securing the patients' rights to participate in the treatment and to be given information. The patient is given the opportunity to participate in the choice of treatments. It is also the duty of health personnel to give the patient the right information. Patients should also be given the choice to undergo treatments or not, and they should have the right to see their medical records.

What comes next is maybe the most important, that it is possible to make complaints to the county doctor, and that a patients' ombudsman system will also be set up in each county. I think these two aspects make it easier for patients to ensure that their rights are properly enforced. Health personnel will also be sanctioned if they do not act according to the Act on patients' rights.

In conclusion, I will just reiterate the most important points: the ombudsman system, and the fact that there is a complaints procedure. These are crucial if we are to the level of reality, and not just visions. The obligations of health care personnel are also very important in this context. One topic that has been discussed in depth is, of course, how many material rights the patient really can get.

Iceland

Dr Gudmundur Sigurdsson, Iceland

I would like to review what has been done and what is planned, in order to implement the Act on the Rights of Patients in Iceland. I will then go on to present some of the core issues that I would like us to address today.

When the Act on the Rights of Patients was adopted in Iceland in 1997, most of its components already existed in other laws. What was new in the Act were the activities related to a system of research ethics committees, the right to have interpreters for those not fluent in the Icelandic language, and the obligation of patients to be responsible for their own health and to take an active part in the treatment they had agreed to, if appropriate.

An article in the Act on how to rationalize or rank priorities for treatments was new but did not have much content, other than to say that if it was necessary to rationalize services it should be done first and foremost on "medical grounds". What this means remains to be dealt with, but there are proposals on the matter from a special working group. These proposals have been accepted by the Minister of Health but not yet implemented. One of the main purposes of the Act was to bring together in one place the components that were previously contained in several other acts. This was to make them more accessible and easier to know for the public and health workers.

The obligation to inform the public and health workers about patients' rights was placed on the Ministry of Health and Social Security and the Director-General of Public Health.

A special committee was appointed to make proposals about how to introduce the new law effectively. Thus the committee sent its proposals to the Minister of Health in February 1998. As described in the document on the development of Patients' rights, the proposals are being worked on in the Ministry. I will not go into them in detail but will be very selective.

First, with regard to the Research Ethics Committee, regulations about ethics committees have been issued. A Central Ethics Committee has been established and has been operational since April 1998. I can add that the Central Committee has been very busy there is an extensive programme of genetic and genealogical research, and the Committee had to deal with close to 30 proposals or protocols in one year.

The new article about interpreters is effective: people are working on specific instructions about when the right to interpreters applies. With regard to the new article about the ranking of priorities for treatments, the proposals are there, but they must now be put into effect. There are several other things which have been planned – I would like to say that a special committee which was set up to see how people should introduce this Act has worked very well, and it has put forward these proposals more than a year ago. It has to be admitted that in a small country or a country with a small population like Iceland, I do not think it is just a question of money, it is more a question of manpower resources: we simply do not have the people to do all the work that needs to be done. Even if the work is done, it seems that, although we are talking about this very small percentage of we spend on health services, it is always more difficult to find the money for things like this. However, I would respect that, this is not just a question of money, it is a question of manpower and resources.

What has been the outcome of these efforts? It is really too early to tell, two years is not a long time. Apart from a generally positive reaction to the Act, it has to be said that no evaluation has yet taken place. There has been a lot of discussion and debate among health professionals, especially physicians by the general public and in parliament about patients' rights in connection with the Act on a Health Sector Database, which was adopted in Iceland in December 1998.

This discussion has focused on how to respect self-determination and ensure confidentiality with regard to information in health care records. This discussion has not dealt with patients' rights except in this narrow sphere, but it has undoubtedly increased awareness of the issues concerning patients' rights in general.

The core issues that I would like us to focus on today are the following:

1. How do you evaluate?
2. In the documentation compiled for this meeting, patients' rights are divided into two categories: social rights, such as the right to receive and have equal access to care; and individual rights inherent in the individual as a human being. How do

we handle possible conflicts between individual and social rights and between social rights and social obligations?

3. The concept of informed consent: Is it a goal in itself or a mechanism to ensure autonomy or self-determination? It is very difficult to say in different circumstances what amount and type of information is reasonable. What is reasonable for patients in different circumstances to be informed about? I think we should look at the criticism that has been made about this concept, a couple of months ago there was a series of articles in the *British Medical Journal* entitled "Theories in health care" and one of the articles set out the criticism, from different philosophical viewpoints of the concept of informed concept. In Iceland, we consulted all patients' associations before the bill was introduced in Parliament, and they are again being consulted about the implementation now. There are close to 50 patients' associations in Iceland. They are organized around patients with specific diseases or problems, and I find it a little problematic to imagine what happens if they compete with each other for scarce resources? How does this effect equity?
4. How do we foster better communication skills among health professionals? How do we achieve a patient-oriented clinical method? I think there is scope for different research orientations, we have in Iceland two university departments of nursing, and one of them is very much involved in phenomenological and hermeneutical research. I think and hope that this kind of research will increase respect for the clinical skills that seem to be undervalued in the professional hierarchy.

United Kingdom

Mr Barrie Taylor - CHINA – Citizen's Health Information Network & Alliance

A project partnership, established by the United Kingdom's Community Health Councils Development Association, between the WHO Regional Office for Europe, the National Health Service Executive, the Association of Community Health Councils for England and Wales, the University of Kent, the Kings' Fund Centre and UNISON (the public services trade union).

A short history of community health councils

Set up the government, 25 years ago, to represent lay interests in the national health service (NHS) – on the premise that it was appropriate to divorce the executive from lay interests.

The remit of each Community Health Council (CHC) is to "keep under review health services within its own district" (a given geographical area with around 250 000 people)

Membership of 24 (a mixture of local authority councillors/representatives of voluntary organizations and Secretary of State nominees)

Three members of staff

Budget of approximately £23 million for the whole of England & Wales) = 33p / head of population

Over 200 city / town centre outlets

Role and function - interpreted at the local level, but all CHCs perform a mixture of the following:

- Monitoring
- Consultation
- Advice & information giving
- Networking and empowerment
- ▶▶▶▶▶ Leading to Representation

Rights and duties of CHCs

UK citizens do not have a Constitution to rely upon to protect their interests. A large proportion of UK state functions are centrally driven (although significant devolution is now in progress – Scottish Parliament / Welsh Assembly). As a consequence, tensions exist between central and local state institutions.

The introduction of local state mechanisms in the UK is often linked to ‘enabling’ legislation, in order to allow for local interpretation – evolutionary approach, not central dictate. CHCs were established within this framework.

The rights and duties of CHCs all focus on how to use information. CHCs have a democratic right to:

- ◆ Be provided with the NHS information required to carry out its public duties (accessing relevant sources, but not patients’ personal records);
- ◆ Access, in order to monitor services paid for by the NHS;
- ◆ Pose questions, obtain answers and express opinions on behalf of local people.

CHCs have a public duty to:

- ◆ Hold meetings in public and make CHC papers open to public scrutiny
- ◆ Meet their respective Health Authority at least yearly
- ◆ Publish an annual workplan and an annual report

Analysis of strengths and weaknesses

Issue	Strength / Weakness
Autonomy / independence – individual CHCs are funded by and held accountable to the National Health Service Executive (NHSE)	<i>Weakness</i> – can produce ‘democratic deficit’ – direct funding by NHSE of individual CHCs may undermine public credibility

Issue	Strength / Weakness
Membership	<p><i>Weakness</i> – due to voluntary status of CHC membership – not even protected by Employment Protection Act – has led to age profile of members being mainly older / semi retired</p> <p><i>Strength</i> – voluntary membership less likely to be influenced by external pressures</p> <p><i>Weakness</i> – mixed nomination process creates problems for urban / city CHCs</p>
The right to access information	<p><i>Strength</i> - a democratic right for all citizens</p> <p><i>Strength</i> – allows for CHCs to become informed, and to educate / empower local people and groups with an interest in health</p> <p><i>Strength</i> – offers training arena for potential members of Health Boards and CHC staff moving into mainstream NHS</p>
The right to speak on behalf of a community	<p><i>Strength</i> - a democratic right for all citizens</p> <p><i>Strength</i> – opinion based on a given constituency of local people</p>
The ability to set own priorities	<p><i>Weakness</i> – creates variability in performance of CHCs</p> <p><i>Strength</i> – permits focus on local need – “keeps NHS firmly grounded in reality”</p>

Why access to information enables CHCs to empower citizens

The use of information stretches across the organization – a separate chart is available giving more details of what underpins the outcome of advice and complaints processes and lay involvement in NHS decision-making processes.

On a practical note, the overall value of CHCs and their performances is shown in the paper *CHCs making a difference*¹, issued by the Association of Community Health Councils for England and Wales (ACHCEW).

CHCs statutory access to information is critical to their value in empowering local communities.

The national association – ACHCEW - also provides briefings on national issues – copies of CHC briefing papers on “Rationing”, “Health Improvement Programmes” and “Quality in the NHS” are available for further information.

The patients' perspective on the UK Patients' Charter²

CHCs proposed a patients' charter in 1986 – to include 17 standards. The government issued the first national charter in 1991 – with ten rights (no legal standing) and nine standards (guarantees as targets).

Ten rights (making explicit existing rights)

1. Care to be based on medical need, not ability to pay
2. To register with a GP
3. To receive immediate emergency care
4. To be referred for a second opinion – with GP's agreement
5. To receive an explanation of treatment
6. To have access to health records
7. To choose not to take part in medical training / research
8. To obtain detailed information on local services
9. A guarantee to reduce all waiting lists for treatment to under two years
10. To receive a full response to personal complaints

Nine national standards

1. Respect for privacy and dignity
2. Equity of access to health care
3. Information for relatives and carers
4. Target times for waiting
5. Ambulance call out
6. Assessment at Accident and Emergency departments
7. Outpatients appointments
8. Cancelled operations – time for rescheduling
9. A 'named nurse' while in hospital

The ACHCEW subsequently proposed 12 new standards, and five were introduced in 1996.

¹ *CHCs making a difference*. London, ACHCEW, 1997

² *The Patients Charter – the patients' perspective*. London, ACHCEW, 1997

Comment

Initially, the Patients' Charter was focused on NHS efficiency (not clinical issues) and on making explicit inherent rights. The current debate is about exposing more of the clinical standards (developed by local action) about clinical governance and about national bodies such as the National Institute for Clinical Excellence (NICE).

The experience of patients is also now to be included within a regular national survey, undertaken by a new Commission for Health Improvement (CHI).

Summary

Community health councils have intrinsic value in the development of 'informed citizens' and in empowering individuals and organisations with an interest in health.

CHCs represent a citizen's democratic right to a voice in health – underpinned by the statutory right to information and the right to self-determination.

CHCs have contributed positively to the agenda of setting standards as expressed in the Patients' Charter and contribute towards the process of keeping the NHS grounded in reality.

Germany

Dr Robert Francke, Professor, Institut für Gesundheits- und Medizinrecht, Universität Bremen, Germany

First of all, I would like to give a very short overview of the current situation with regard to the individual rights of patients. In Germany, the strategy that we have is part of a legal framework – we do not have patients' rights, but we do have different laws.

Today we have achieved a satisfactory level in the area of individual patients' rights and this satisfactory level was achieved not by Parliament, not by legislation, but by court decision. In the past 20 years, there have been many different court decisions and very concrete and special instances of patients' rights. We have today a very well developed right of information of patients, to ensure the autonomy of patients' decisions. We have doctors' duties of providing practical information, to ensure the quality and safety of medical practice, and a functioning system of damage compensation. Although these individual rights concern information and advice, there are specific areas where these court decisions leave a lack of information and advice. There are special problems with the extent of information, the different treatments that can be offered. There is also a deficit concerning the extent of the patients' rights to inspect his or her medical records and especially in cases of chronic disease, there are questions about the doctor's duty to communicate to the patient information about the condition, the treatment and the prospects of the illness. What should he do? Last but not least, there have been recent developments concerning patients' rights to negative information.

What I have just said about individual rights is separate from the social security system as it currently operates. We have a very well developed system of individual

rights, but these rights cannot all be realised in the social security system. You have by civil law the rights of free choice of doctor and hospitals, but in the social security system these rights are restricted.

We also currently have some deficits at the practical level. There is a high degree acknowledgement of the existing rights of patients in legal science, but their realisation in the medical system brings a lot of problems. It is interesting that these deficits concern not good practice but good information. In Germany a discussion is under way about formulating a charter on patients' rights. This is a very complicated process, politically. Bringing forward this charter was initiated by the Government, but this charter on patients' rights is not yet finished. We suppose that this will come probably at the end of 1999 or at the beginning of next year.

Another deficit concerns the collective rights of patients to participate in the medical and social security systems. For instance, we see that patients' organizations in Germany and in other countries do not participate in the discussions on the development of guidelines.

In the process of developing the charter of patients' rights, I would say that our position in Germany is that we are organizing a cooperative public process of learning about patients' rights and their implementation. This is a very complicated thing. And of course the role of the different parties, their contributions to this process are different – the role of the care providers, the political role of the government, and especially we have some problems with the professional board. The professional board of course claims that it knows best what is good for the patients.

The last question concerns the implementation of patients' rights in real life. In short, we assume here that the cooperative public process of learning about patients' rights will affect their implementation.

Open-space meeting: how can we support each other in promoting patients' rights? - conclusions

The concept of the open-space meeting was developed in Canada and the United States of America by Harrison Owen, who is a consultant to large organizations and community systems. Having organized many conventional academic meetings and large conferences, he noticed that much of the so-called real work took place outside formal meeting sessions, and he wondered how the dynamics of that work could be incorporated and made publicly available, and how less effort could be put into what he believed to be less productive formal meeting sessions.

This approach to harnessing the dynamics of the real work developed into a methodology for holding meetings, which was triggered by observing how various societies manage their affairs and deal with complex decision-making through a participatory and democratic approach. The open-space meeting has been used in many and varied settings for over ten years in developed and developing countries. It has helped organizations, systems and communities to address and work together on complex, often contentious and intractable issues, where there seem to be no obvious

straightforward solutions, but many diverse interested parties. The format can work well with groups ranging from ten to many hundreds of people. From its earliest days, it has been used with mixed groups of varying social and cultural backgrounds, and has been shown to work where more than one language is spoken among the participants.

Experience in WHO and that of Canadian and American colleagues suggests that the open-space meeting is best seen as part of an organizational or systemic development process. The work that goes into the preparation and the follow-up are just as important as the meeting itself; indeed, the entire process is about gaining commitment from the widest range of stakeholders (the involved parties) not only to what needs changing but also to how change may be achieved in real situations. In general, it illuminates and alters everyone's perceptions about the way the world works and can rapidly shift prior prejudices, often in surprising and very creative ways.

The open-space meeting is distinct from conventional meetings and conferences in that each participant has a key role and responsibility for ensuring that the important and relevant issues are brought to light and addressed. In its formal structure, a facilitator opens the meeting in a plenary session by explaining the process and methodology of the open-space meeting and why the group has been brought together on that occasion. Having determined the purpose and main issue(s) of the meeting, the participants are then invited to form their own groups to discuss topics concerned with the main issue(s). The structure of the open-space meeting does not allow for presentations or the delivery of technical papers. The participants, both individually and collectively, contribute their expertise, experiences, visions and values to take the agenda forward throughout the meeting.

The participants do most of their real work in the group (topic) meetings. They are convened by individual participants who feel strongly about a topic that relates and contributes to the main issue(s) and overall aim of the open-space meeting. Each group meeting lasts 45 minutes and several groups could be meeting at any one time. A set of meetings would be arranged at the start, but these could multiply as time passes in the light of events during the groups' discussions.

The participants who convene group meetings are responsible for introducing their topics and then briefly recording (on prepared sheets of paper): the names of those taking part, the key topics, concerns and recommendations that emerged from their groups. When the group work is finished, these brief reports are immediately posted on a notice board for all participants to see. At this stage, any other participant may write additional comments on the report(s).

Striking features of the open-space meeting format are: the opportunity it presents for informal networking among the participants, the discussions this generates and the initiatives taken by the participants, who often find themselves working with people to whom they may not have normally related in everyday organizational life. This dynamic is strongly encouraged, to complement the formal side of the open-space meeting.

Participants take part and contribute in a number of ways. As described, they convene their own group meetings and/or attend those convened by others. They may move from one meeting to another whenever they please, or reflect and network outside the formal meetings. This open, flexible approach allows and generates diverse involvement from everyone. There is only one rule if a participant is neither contributing to nor learning from a group, he or she should move on to another.

The final plenary session offers an opportunity for everyone to share conclusions, clarify collective and individual responsibility and plot the next steps to continue their work in real situations.

The following gives highlights from the discussions during the open-space meeting and some of the conclusions of the working groups. It is based on the reports that were prepared by the group convenors.

How to increase patient participation in clinical decision-making?

Discussions focused on the prerequisites for and levels of patients' involvement, the definition of clinical involvement and the methods to increase this involvement.

Since understanding is the fundamental basis of decision-making, information and knowledge become the two pillars of patients' involvement. A well informed patient, given time and a trustful relation to the health provider, is capable of taking sound decisions concerning his/her health or treatment. Some problems emerge, though: these include the emotional state of the patient, and assessment of the patients' understanding.

Clinical decisions include nearly every choice that has an influence on the patient's health. This includes:

- Care
- Cure (diagnostic and therapeutic procedures)
- Hospital environment
- Nature of the disease
- Status of the patient: consumer (subject) or victim (object)

There are various levels of decision making where patients can be involved: the "daily" level and the medical level. The daily level concerns the health facility and its schedule and procedures, while the medical level focuses on therapy choices and various levels of treatment (care and cure).

In order to increase patients' involvement in the process of decision-making, they have to be viewed as knowledgeable persons with fears and (dis-) abilities and as the best experts with regard to their disease. Patients should be involved in the running of health care facilities (as members of an executive board), thus providing a patient insight when decisions are made.

Finally, regular surveys on guidelines and practices should be conducted with patients who have received treatment at a given facility.

How to involve national patients' organizations in international work?

When international organizations, including WHO, are promoting the concepts and adoption of patients' rights in different countries, everybody agrees with the basic principle that patients and organizations themselves should be closely involved. In practice, however, it has turned out to be difficult to do this, for reasons that have seldom been fully explored or analysed. Therefore, the group tried to elaborate on those reasons and also to find ways of overcoming them and creating a true consultative process with those people (patients) who themselves should become subjects and not objects.

The group first elaborated an image where in the clouds there is the academia, experts and national and international administrators, while way below are consumers and patients' organizations. These organizations all consist of people, but they are very heterogeneous. Some, such as handicap associations or diabetes federations, are large whereas others depending on the size of the patient group are quite small, only few "umbrella" organizations exist at national level, and sometimes it feels as if the big "single course" organizations are not really interested in having those, due to their self-interest which they feel is threatened by other patients' organizations.

The group analyzed the reasons why it is difficult to involve patients' organizations in international discussions and found the following reasons for it:

- Culture and organizations differ
- There are too many small units and it is difficult to hand-pick only a few without creating resentment in the others
- Lack of money
- Different organizations have different goals
- Language problems (even using English is sometimes difficult for people working in national patients' organizations)
- Different interests

The group found the following reasons why international collaboration should be possible:

- There is genuine interest in learning from others in other countries
- Patients' rights is a "sexy" subject, meaning that the building of more civil societies interests many politicians and international foundations
- International involvement provides opportunities to influence the administrative and political system
- Uniting forces is power, and organizations understand this

The group developed the following individual suggestions and ideas:

- Need to include in the patients' rights legislation/charters the provisions whereby patients' organizations must be consulted in issues which involve their real interest/ mandate.
- WHO still has prestige in countries among patients' organizations, and WHO therefore can also act as an arbitrator and facilitator.

The group also elaborated two main proposals for involving national patients' organizations more closely in international work. Firstly, we suggest that an annual WHO bulletin for patients' organizations would be provided in standard format including guidelines and arguments for patients' rights. This could also be made available on a web site. Due to language problems, the idea was even brought up that one side of the bulletin could be English, and the other side could if possible be in the national language(s). This kind of bulletin would provide good feedback from countries, if it appears regularly. Secondly, we realised how important it would be to have a European directory of patients' organizations. Some countries such as Denmark already have such a directory. The items included should be the address, staff resources, main interests, number of members, interest in WHO/international level, goals, actions and achievements. The directory should be provided country by country and by interest/disease groups.

Finally, it was suggested that once every five years a convention or meeting on patients' rights and related issues should be organized for patients' organizations throughout Europe.

Media involvement in patients' rights

Media involvement in informing the public about their rights/patients' rights is paramount but in practice problematic. It seems that the media have an inborn ability to distort the news and are mainly interested in bad news. Nevertheless, in order to promote patients' rights it is important to reach all people. Therefore there is a tremendous challenge in how to make good news interesting. We must be aware that the media have their own "credo" and logic because they must make and sell news. We would need to identify allies and "enemies", which in our view is the "yellow press" and in some cases indiscriminate advertisers of pharmaceuticals and other health industry products. As an important group of allies we could identify women's magazines, since it is often the women who are the "health care managers" in a family.

Our messages are not necessarily very appealing to the press and media because too often we try to reflect the decision-makers' points of view and promote new legislation as news, which it is not as such. As said above, the media attempt to distort the relatively clear and simple message of patients' rights through scandals which lead to great confusion by making it appear as if everybody in the health sector is only trying to harm and exploit the patients. In the same ways, feedback from the public is often distorted. Nevertheless, the media also play an important role in informing decision-makers about that the feelings of the public through consumer satisfaction polls, interviews and hotlines. We created an image where the message of patients' rights is like a raw potato, staple food but not appealing as such. We

would need to make it into a lucrative product like the French fries which everybody wants to have. This means that patients' rights advocates would need to become "five-star cooks" or chefs.

The group tried to transform news items that we would not like to see into the type of news which we would gladly read:

- "Another poor patient was damaged/killed..." => "An unfortunate incident happened yesterday, for which the patient has been properly compensated and the following measures have been taken in order to prevent such unfortunate things happening again in the health system..."
- "This doctor/hospital is terrible..." => "We present the following positive examples of good service/practice in our town..."
- "What stupid idiots patients are," said Doctor So-and-so...=> "This is how you become a clever/wise health service consumer..."
- Any change is news => Not all this is bad, not all that is new is necessarily good, use your common sense.
- A new alternative therapy is now available 99% of patients will be cured of any disease.... => These kinds of alternative treatment do not exist, use your common sense, they are also business for someone, if people promise you a certain cure for all diseases they are quacks.
- Single item interest => Understanding of the whole

It is important to convey the messages that ideal systems and ideal remedies do not exist and that not everything which is foreign is better than what you have at home.

The group was able to identify two ideas/recommendations which could help ensure appropriate involvement of the media in patients' rights. First, it is important to make journalists your allies/partners. Never try to make them your servants or subordinates, because you only create resentment. They have a right to make their own decisions and make up their minds, but it is your duty to provide them with all the relevant information in a form that can be fully understood by people. Journalists want to make a good story and very few of them deliberately want to tell lies, in fact if they do they are not professional journalists. Some countries have developed a "club" for health sector journalists with whom they organise regular meetings and even training. The medical and the nursing associations can be very important and good partners in this work. One could think of creating a club for journalists on patients' rights by inviting them to (national or international) conferences.

The second proposal is that we need to understand better the logic followed by journalists and the media. Therefore, organizing courses, writing articles, creating collaboration and developing guidelines would be useful.

Finally the group concluded that we are facing a new era where health care is becoming a service and where the public and patients need to be "king" consumers. Therefore, people need to know their rights, because in most European countries health care is publicly funded and the public has already pay for it. As one member of the group, humoristically said, "SOH!, if you cannot save our souls, at least Save

Our Health.” Other concepts from the group were: “KYRS” (Know Your Rights, Stupid) and “YHPIS” (You Have Paid for It, Stupid). It is of paramount importance that patients become wiser consumers. At the same time, national administrators must create better consumer protection and control, although we concluded that control and smooth laws cannot “do the trick” unless the public understand their own rights. In this work, the media are our indispensable partner.

Role of the courts in enforcing patients' rights - legislation or soft rules?

Since two people in the working group came from countries in transition, the discussion was mainly focused on patients' rights in the perspective of central and eastern Europe. The main question was: given the newly emerged interest in patients' rights, how can these rights be strengthened?

Two options were discussed, namely by means of legislation (i.e. a separate act of parliament or by amending current legislation or a charter (i.e. including legally non-enforceable rights and freedoms, “soft rules” or quasi-legislation). Such soft rules could be found in the (ethical) codes of professional associations. It was not easy to answer this question. According to the participants, relevant aspects include the national tradition and culture, the stage of reform, political consensus, and international commitments. Several aspects were discussed in more detail.

Soft rules

Some of the participants seemed to opt for an ethical code, since this could be relatively easily realised given the current documents (ethical codes) of the various medical associations. Modernization should be focused on including both basic and derived patients' rights in these ethical codes.

One major objection, however, is the non-binding character of such a code. Since the ethical code has no statutory base, it only binds members of the association. In case of voluntary membership, the ethical code (including provisions concerning patients' rights) does not bind non-members. Furthermore, even those norms which are binding are not legally enforceable, which substantially weakens their effect.

The absence of a legal framework of patients' rights characterizes an approach that opts for a non-legislative strategy, i.e. apart from some basic rights, patients' rights are promoted at institutional level. This means that medical associations or health care establishments, for instance elaborate their own code/charter based on the provisions of legislation and documents prepared by professional bodies. In this case, developments follow court rulings and are vulnerable to the hazards inherent in each individual situation dealt with. Countries opting for this alternative rely on case law.³

The voluntary and non-enforceable basis of non-statutory codes may entail certain drawbacks, which could be avoided if a legislative approach is opted for. For instance, the Code of Patients' Rights in Health Institutions in the Czech Republic reveals prominent shortcomings in the current situation. Although most countries

³ Wijnberg B. Patients rights and legislative strategies. *Medical law*, 12: 137-140 (1993).

suffer from implementation gaps to some extent, and errors in implementation occur in even the most developed systems, here the gap seem so systematic and serious that it unacceptably undermines the realisation of patients' rights. In view of the internationalization of patients' rights and the emergence of international mechanisms for their protection, the Czech Republic can be exposed to legal and political risk, as patients would hold the government accountable for violations.

Consequently, in the near future, the non-legislative approach will be difficult to maintain, particularly since most countries in central and eastern Europe have ratified or will ratify the European Convention for the Protection of Human Rights and Fundamental Freedoms⁴. When national legislation is largely lacking, patients' rights offences can be directly based on the European Convention. It can provide a judicial foundation for contesting the infringement of patients' rights, for instance in case of unlawful detention (Right to liberty, Article 5), requests for hearing within a reasonable time by an independent and impartial tribunal (Right to a fair trial, Article 6), or claiming respect for individual's privacy (Right to respect for private life, Article 8)⁵.

Furthermore, the prospect of the Bioethics Convention may prompt legal changes by regulating 'the protection of human rights and dignity of the human being in biology and medicine'⁶. Although the Convention does not provide for an individual right to complain to the European Court of Human Rights. Despite the lack of the possibility to lodge a complaint based at the Bioethics Convention, it is not unlikely that the European Court may include the Bioethics Convention in arising European Convention cases.

Towards a legal framework of patients' rights?

In view of some countries' (future) membership of the Council of Europe and subsequent relevance of international treaties and other (non-legal) documents, it remains to be seen whether continuation of a non-legislative strategy is appropriate. Both the European Convention and the Bioethics Convention require adequate legislation stipulating the nature and scope patients' rights, and curtailments "necessary in a democratic society...". The phrase '[e]ach Party shall take in its internal law the necessary measures to give effect to the provisions of this Convention' as stipulated in the Bioethics Convention (Article 1), imposes on legislators the requirement to provide an adequate legal framework to effectuate

⁴ For an overview of signatures and ratifications of Council of Europe treaties, see the website www.coe.fr/tablconv/5t.htm (accessed 13 October 1999)..

⁵ According to most national constitutions, the European Convention is generally considered as a directly binding treaty on human rights and fundamental freedoms, duly ratified and promulgated and therefore taking precedence over national statutes.

⁶ Officially, the Convention on Human Rights and Biomedicine, 1997. This treaty has not entered into force yet. The impact of this Convention in the national legal setting is not quite clear. Since the Convention includes various fundamental human rights and freedoms it can be considered as a directly binding treaty when ratified. Nonetheless, Member States can make (specific) reservations in respect of any particular provision of the Convention in case of non-conformity of the Convention with national law (Article 36 section 1 Convention). According to the Explanatory Report, the concept of "law" must be interpreted extensively, including secondary regulation. Until this moment it is not clear if and to what extent national government have made or will make such a reservation and therefore restrict the applicability of the Convention in their legal setting.

patients' rights. As such, ethical codes can be considered a preliminary stage to the framing of a specific law on patients' rights, including effective enforcement mechanisms according to European standards.

Patients' rights legislation

Role of the Constitutional Court

At the moment, several central and eastern European countries (e.g. Hungary, Lithuania, Poland) have opted for introducing legally binding norms, i.e. legal norms which have been enshrined in the Constitution and elaborated whether or not by separate statutory act.

In this respect, an interesting development was discussed. On various occasions it appears that national governments have tried to limit patients' rights, for instance of access to health care services, by means of ministerial regulation⁷. In several countries constitutional courts have considered this practice to be unconstitutional. In the case of introducing patient's own payments (co-payments) this would restrict patients' access to health care, thus restricting a patient's constitutional right to health care. Since these limitations require an explicit statutory base, restrictions based on derived regulations are considered insufficient, therefore unconstitutional⁸. As a consequence, governments were forced to repair the unconstitutional situation created. This has resulted in a statutory list of detailed health care services whether or not fully reimbursed by the compulsory health insurance fund, and hence the introduction of patients' co-payments by law. From a legislative and technical perspective, this is a laborious and time-consuming procedure, particularly since the type of services and scope of contributions may alter over time.

Judicial failure to comply with constitutional rights

At the ordinary court level, difficulties with 'internationalisation and the changing perception of health care rights give reason for concern. In several countries of central and eastern Europe, the unwillingness of ordinary courts to comply with constitutional rights has been mentioned as a major problem in securing patients' rights.

With regard to the applicability of international treaty rights, it appears that some courts do not feel bound by decisions of the constitutional court⁹. Consequently, the *de facto* primacy of domestic law above international law is still asserted and may cause legal problems. Related to health care, for instance the antagonistic behaviour of ordinary courts may give rise to concern. Particularly in view of the ratification of the European Convention on Human Rights, including additional protocols, violations of *individual* human rights and freedoms can be directly based on the

⁷ Den Exter and Hermans. Constitutional rights to health care: The consequences of placing limits on the right to health care in several western and eastern European countries. *Eur. J. of Health Law*, 5, December 1998.

⁸ Court ruling Pl US 35/93 (Czech Republic); 43/1995 DZ 1991 (Poland).

⁹ Holländer P. The role of the constitutional Court for the application of the Constitution in case decisions of ordinary courts. In: The Czech legal system in European contexts. Gillis M, ed. Prague, Charles University 1998. Similar problems have been observed in other countries of central and eastern Europe.

Convention. Incorporating individual rights and freedoms, recent European Court of Human Rights case law includes a *rapprochement* of individual and social and socially related rights. Enhancement of these rights within the framework of the Convention is thus also of relevance to other Member States. The *López Ostra* and *Tavares* cases, in particular, explain the role of national (health) authorities in ensuring applicant's rights¹⁰. In these cases, by denying the convention's self-executing effect, ordinary courts seem to deprive its citizens from appealing to legal causes, which potentially could strengthen claimants' right to health care.

Subsequent inconsistencies in reasoning and outcomes between the Constitutional Court and ordinary courts also give rise to concern. Improving the judiciary's level of expertise, in order to remove its negative perception of constitutionally enshrined rights, should be a priority in the near future. Furthermore, the need for domestic legal norms matching "supra-domestic law" is evident. This is primarily a task for the legislature, entailing the modernization of the statutory framework.

Protection of children's' rights and psychiatric patients - patients' right to information

The group discussed the problems that occur in large psychiatric institutions. The shortage of staff may lead to violence between patients and against patients by staff, and vice versa, and may also cause unnecessary restrictions on patients' rights. The expertise required in the psychiatric care of children is often inadequate and there are not enough care units for children.

The importance of international conventions and clear national legislation and effective follow-up of these were emphasized.

Development of information technology and its impact on confidentiality

The group discussing this topic was inspired by the new Icelandic Act on a Health Sector Database¹¹

The group tried to consider the possible advantages and threats of electronic health care records and health cards. One possible advantage is that the patient can gain more control over his/her personal data. By holding a health card a patient can withhold all information about him/herself.

Access to the data can be limited as much as is seen necessary. New technologies can also serve as tools to provide more accurate information for physicians, if the data are well organized.

¹⁰ European Court of Human Rights. *López Ostra v. Spain*, 9 December 1994 no. A 303-C. In this context, a more recent case, *Guerra and others v. Italy*, 19 February 1998 (116/1996/735/932) is also worth mentioning.

¹¹ English version of the Action available on the Internet at <http://brunnur.stjr.is/interpro/htr/htr.nsf/pages/gagngr-log-ensk>, consulted 14 October 1999.

The technical security problems and possible leaks of information were regarded by the group as possible threats. It may also be difficult to limit access only to certain parts of the database. Electronic databases make it possible to combine data from different sources unnecessarily and make it difficult to administer information about patients' relatives for example.

It is therefore vitally important to investigate measures to reduce these threats. These might include for example the setting of clear rules, ensuring an informed public and limiting access by e.g. encryption of electronic correspondence. It was agreed that it would be difficult to have just one record for each patient and that emphasis should be placed on privacy issues.

The role of health care providers with regard to patients' rights

The best way to improve and enrich the relationship between the health care provider/doctor and the patient is simple, but also difficult: education and information on both parts. Therefore, medical studies and training should include additional education on ethics and patients' rights and how to bond psychologically with patients. Some aspects are already included but would gain impetus if they were further elaborated:

- Ethics: covering subjects such as the rights and obligations of patients, just as patients but also as human beings;
- Management: practical issues such as methodologies for correctly completing a clinical report. This is the best defence against improper legal actions. A clinical report is a proof that every judge accepts.
- Psychology: how to treat a patient as a patient and as a person with needs and fears. Sometimes it is only when doctors have to be treated as patients that they realize how hard it is to be a patient.

In Spain, the average patient does not know exactly what kind of services the national health system offers. Patients are not aware of their rights and entitlements, or of the limits to their expectations.

Patients do not know how the system works. In other words, citizens do not have the minimum level of knowledge and information they need when becoming a patient. All potential users of the national health system must know the services offered by the system and how to access them.

Giving adequate information to patients should help to markedly improve the relationship between the national health system and its users. Every actor in the health area must have information about the rights they enjoy. They must also keep in mind the fact that resources are limited.

In the Spanish system, the Charter of patients' rights is informative and does not have any binding forces. On the other hand the law is binding and it establishes citizens' subjective rights. If patients know that a subjective right has been infringed, then they know that the law is protecting them and they can go to court to obtain redress.