

**A DECLARATION ON THE
PROMOTION OF PATIENTS' RIGHTS IN EUROPE**

**EUROPEAN CONSULTATION ON THE RIGHTS OF PATIENTS
AMSTERDAM 28 - 30 MARCH 1994**

World Health Organization



ABOUT THE DECLARATION

The European Consultation on the Rights of Patients, held in Amsterdam on 28-30 March 1994 under the auspices of the WHO Regional Office for Europe (WHO/EURO), and hosted by the Government of the Netherlands, was attended by some 60 persons from 36 Member States. The purpose was to define principles and strategies for promoting the rights of patients, within the context of the health care reform process under way in most countries.

The Consultation came at the end of a long preparatory process, during which WHO/EURO encouraged the emerging movement in favour of patients' rights by, *inter alia*, carrying out studies and surveys on the development of patients' rights throughout Europe. These studies showed a common interest and a number of policy trends and normative initiatives in the European countries, indicating that additional support to policy development in many of those countries would be appropriate. The study results were published in the book: *The Rights of Patients in Europe* (WHO 1993). With the support of the Government of the Netherlands, and in broad consultation with governments and other institutions in European countries, technical experts in the field drafted *The Principles of Patients' Rights*, a comprehensive text which could be meaningful and helpful in the development of country policies on patients' rights.

The Declaration on the Promotion of Patients' Rights in Europe constitutes a common European framework for action and includes those principles, as endorsed by the Amsterdam Consultation. This declaration should be interpreted as an enhanced entitlement for citizens and patients in improving partnership in the process of care with health care providers and health services managers. The Principles of Patients' Rights endorsed at the Amsterdam Consultation will hopefully be a solid reference and a dynamic tool capable of improving new thinking in the health care process.

The complete proceedings of the consultation will be published as a separate publication during the current year.

Copenhagen, April 1994

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A DECLARATION ON THE PROMOTION OF PATIENTS' RIGHTS IN EUROPE

A WHO European Consultation on the Rights of Patients, meeting in Amsterdam, from 28 to 30 March 1994, endorsed the annexed document (*Principles of the Rights of Patients in Europe: A Common Framework*) as a set of principles for the promotion and implementation of patients' rights in WHO's European Member States.

The meeting gave detailed consideration to a wide range of possible strategies based on the principles presented in the document and on the recent and current experiences of participants. The essence of these strategies is presented below.

STRATEGIES FOR THE PROMOTION OF PATIENTS' RIGHTS

The development of a strategy to promote patients' rights and responsibilities has to be carefully prepared, in order to ensure that the intention is translated into practical action which commands the support of all parties involved. Such action does not follow automatically, but takes time to become fully effective.

National situations vary in respect of legal frameworks, health care systems, economic conditions, and social, cultural and ethical values, but there are certain common approaches which can be appropriately adapted to the circumstances of each country. We encourage all interested parties in our countries to initiate or renew multiple strategies of implementation, which will likely need most or all of the following components:

- legislation or regulations, specifying the rights, entitlements and responsibilities of patients, health professionals and health care institutions;
- medical and other professional codes, patients' charters and similar instruments, drawn up in the light of agreed common understandings between the representatives of citizens, patients, health professionals and policy-makers, and periodically revised in response to changing circumstances;
- networking between and among patient and health care provider groups, recognizing the distinction between citizen and user participation;
- government support for the establishment and effective running of nongovernmental organizations (NGOs) in the field of patients' rights;
- national colloquia and conferences to bring the parties together to create and promote a shared sense of understanding;
- involvement of the media in *informing the public*, stimulating constructive debate and sustaining awareness of the rights and responsibilities of patients and users and their representative organs;

-better training in communication and advocacy skills for health professionals as well as for patient and other user groups, in order to further the development of a proper understanding of the perspective and role of all parties;

-promotion of research to evaluate and document the effectiveness of legal and other provisions and the various initiatives taken in the diverse contexts of the different countries.

INTERNATIONAL ACTION

Cooperation between WHO, the Council of Europe and the European Union in support of patients' rights would be further enhanced by action taken as a result of this Consultation. Consistency of policy positions, coordinated strategies of implementation and an understanding of how their respective resources and competences can best be used are essential components of a sustained European movement to promote and protect the rights of patients and their professional providers and advisers. International NGOs also have a critical role to play in promoting the rights of patients.

The forthcoming WHO Regional Conference on Health Policy (Copenhagen, 5-9 December 1994) will provide an important opportunity for further promoting patients' rights in Europe. The proposed WHO Regional Conference on Health Care Systems in Transition in Europe, to be held in Vienna on 25-28 March 1996, will also explore issues concerning the rights, roles and responsibilities of both patients and providers. We propose to WHO that the Regional Office should establish an appropriate mechanism to monitor developments in countries and to present the findings to the Vienna Conference.

PRINCIPLES OF THE RIGHTS OF PATIENTS IN EUROPE:A COMMON FRAMEWORK

INTRODUCTION

1. BACKGROUND

Social, economic, cultural, ethical and political developments have given rise to a movement in Europe towards the fuller elaboration and fulfilment of the rights of patients. New and more positive concepts of patients' rights have been advocated. In part, this has been a reflection of the central place given both to full implementation of the concept of respect for persons and to equity in health as a policy objective in Member States. As a consequence there is now greater emphasis on the encouragement of individual choice and the opportunity to exercise it freely, and the commitment to build mechanisms for ensuring quality of care.

Developments within health care systems such as their increasing complexity, the fact that medical practice has become more hazardous and in many cases more impersonal and dehumanized, often involving bureaucracy, and no less the progress made in medical and health science and technology have all placed new emphasis on the importance of recognizing the individual's right to self-determination and often on the need to reformulate guarantees of other rights of patients.

Simultaneously, the human rights movement has gathered importance in the world since 1945 **when, in the Charter** of the United Nations, Member States reaffirmed their faith in fundamental human rights. This was followed, on 10 December 1948, by the adoption of the Universal Declaration of Human Rights and, on 4 November 1950, by the signature of the European Convention of Human Rights. Governments are more and more giving their active consideration to such issues. The World Health Organization's study of patients' rights in Europe shows that increasingly there are shared principles that are being adopted in a number of countries and which seem to be independent of the characteristics of a given country's health system. It seems timely to give this policy trend further momentum. The present document is an attempt to formulate a set of patients' rights which reflects the evolving concepts and is relevant to the context in which health care will be provided in future.

These Principles of the rights of patients in Europe have been drafted in full awareness of the work of others who have already been engaged in drawing up instruments specific to patients' rights. For the most part though, such earlier efforts were directed at particular groups or concerned with specific activities in health care or approached patients' rights from the perspective of the duties and responsibilities of health care providers and establishments. The present text is the result of an attempt to refocus these concerns from the patient's point of view as the user of and partner in health care in all its various forms. It has been deliberately couched in general terms, so far as possible avoiding reference to the circumstances of particular groups or illustrative examples. It is felt however, that this exposition of general considerations embraces the basic principles and concepts to be adopted when promoting and guaranteeing patients' rights in a particular country or other situation. The text does not directly cover questions of implementation, since these are necessarily specific to a country or situation; it has nevertheless been drafted in the belief that these guidelines can be further elaborated within countries to suit their particular needs and circumstances.

GUIDING PRINCIPLES

In this text, the concept of health care is derived from the principles of the World Health Assembly resolution on health for all (HFA) WHA 30.43, 19 May 1977) and the related model of health care set out in the Declaration of Alma-Ata (12 September 1978). Health care thus embraces a full range of services covering health promotion and protection, disease prevention, diagnosis, treatment, care and rehabilitation. Accordingly, the patient encounters a wide variety of health care providers and fulfills a variety of roles, from sick and dependent person to client receiving advice to consumer or customer obtaining health products for self-administration. Furthermore, this variety of patient roles implies a continuum of health states from high-level wellness to permanent disability and terminal illness.

In the treatment of patients' rights, a distinction should be made between social and individual rights. Social rights in health care relate to the societal obligation undertaken or otherwise enforced by government and other public or private bodies to make reasonable provision of health care for the whole population. What is reasonable in terms of the volume and range of services available and the degree of sophistication of technology and specialization will be dependent on political, social, cultural and economic factors. Social rights also relate to equal access to health care for all those living in a country or other geopolitical area and the elimination of unjustified discriminatory barriers, whether financial, geographical, cultural or social and psychological.

Social rights are enjoyed collectively and are relative to the level of development of the particular society; they are also in some measure subject to political judgment regarding priorities for development in a society.

In contrast individual rights in patient care are more readily expressed in absolute terms and when made operational can be made enforceable on behalf of an individual patient. These rights cover such areas as the integrity of the person, privacy and religious convictions. Although this text does address social rights, the main focus is on individual rights. The conceptual foundations for this treatment of patients' rights are for the most part laid on a number of intergovernmental declarations relating to human rights and freedoms. The intention is not to create new rights but to apply them in one coherent, comprehensive statement to the field of patients and health care. For similar reasons the text does not address general rights, obligations and liabilities, which are covered by the statutes and case law of each country.

A further issue arises concerning the place of exceptional limitations to particular rights of patients. For the most part these have been kept out of the text, in order to state the proposed rights as clearly and simply as possible. It is therefore pertinent to clarify here at the outset the nature of the principal forms of limitation. Exceptions to the rights of patients are usually anticipated in law. The guiding rule in such exceptions is always that patients can be subjected only to such limitations as are compatible with human rights instruments and in accordance with a procedure prescribed by law. In practice, this means limitations which apply for reasons of public order, public health and other persons' human rights.

In some situations, the reason for restricting the rights of the patient is an overriding interest of a third party (the so-called 'conflict of duties' doctrine), i.e. the unfettered application of the patient's right would cause serious harm to a third party, there is no other means to avoid the harm and there is a reasonable expectation that the restriction would prevent the harm. In other situations a similar justification applies when the purpose is to avoid serious harm to the patient (the so-called therapeutic exception). As this document addresses general principles, these exceptional limitations to the rights of patients have mostly not been included.

PURPOSE, OF THE DOCUMENT

The Principles of the Rights of Patients in Europe are offered as a contribution to support the growing interest in many Member States in the issues of patients' rights. In its scope and focus, this document seeks to reflect and express people's aspirations not only for improvements in their health care but, also for fuller recognition of their rights as patients. In so doing, it keeps in mind the perspectives of health care providers as well as of patients. This implies the complementary nature of rights and responsibilities: patients have responsibilities both to themselves for their own self-care and to health care providers, and health care providers enjoy the same protection of their human rights as all other people. There is a basic assumption in the text that the articulation of patients' rights will in turn make people more conscious of their responsibilities when seeking and receiving or providing health care, and that this will ensure that patient/provider relationships are marked by mutual support and respect.

Patients should be aware of the practical contributions they can make to the optimal functioning of the health system. Their active participation in the diagnosis and treatment process is often desirable and sometimes indispensable. It is always important that they provide the relevant health professionals with all the information required for the purposes of diagnosis and treatment. The patient has an essential role, the reciprocal of the provider's, in ensuring that the dialogue between them is carried out in good faith.

Indeed, the role patients play in the appropriate delivery of health care should be underlined, especially in today's complex health systems which are largely supported by collective financial mechanisms and where the economic and equitable use of resources allocated to health care is an objective which can be shared by health professionals and patients alike. Equally, while patients' participation in clinical teaching must be subject to their informed consent, they should also be aware that the competence of future professionals in part depends on patients agreeing to be involved in their training.

IMPLEMENTATION

It is a matter for decision by countries how they might make use of a document such as this when reviewing their present policies on, practices in and legislative support to, patients' rights.

Although for the purposes of clarity of presentation some proposals are made in a clear-cut way, the text is a set of guidelines which could be used in policy discussions within countries and in the formulation or reformulation, as the case may be, of national policies, laws or official statements on any or all of the issues covered. However, it is hoped that this document will be of direct value to all parties, including patient and consumer bodies involved in health care, professional associations of physicians and of other health care providers, and associations of hospitals and other health care establishments.

2. OBJECTIVES

Against this background, the Principles of the Rights of Patients in Europe can be seen, in terms of content, as a document which seeks:

- to reaffirm fundamental human rights in health care, and in particular to protect the dignity and integrity of the person and to promote respect of the patient as a person;
- to offer for the consideration of Member States a set of common basic principles underlying the rights of patients, which might be used when framing or reviewing patient care policies;
- to help patients obtain the fullest benefit from their use of the services of the health care system, and mitigate the effects of any problems which they may experience with that system;
- to promote and sustain beneficial relationships between patients and health care providers, and in particular to encourage a more active form of patient participation;
- to strengthen existing and afford new opportunities for dialogue between patients' organizations, health care providers, health administrations and wider societal interests;
- to focus national, regional and international attention on evolving needs in patients' rights and to foster closer international cooperation in this field;
- to ensure the protection of fundamental human rights and to promote the humanization of assistance to all patients, including the most vulnerable such as children, psychiatric patients, the elderly or the severely ill.

3. CONCEPTUAL FOUNDATIONS

In drafting these Principles of the Rights of Patients in Europe, the following intergovernmental instruments, which together offer a framework and a set of basic concepts which can be applied to the rights of patients, have been taken into account:

- *The Universal Declaration of Human Rights (1948)*
- *The International Covenant on Civil and Political Rights (1966)*
- *The International Covenant on Economic, Social and Cultural Rights (1966)*
- *The European Convention on Human Rights and Fundamental Freedoms (1950)*
- *The European Social Charter (1961)*

THE RIGHTS OF PATIENTS

1. HUMAN RIGHTS AND VALUES IN HEALTH CARE

The instruments cited in the Introduction should be understood as applying also specifically in the health care setting, and it should therefore be noted that the human values expressed in these instruments shall be reflected in the health care system. It should also be noted that where exceptional limitations are imposed on the rights of patients, these must be in accordance with human rights instruments and have a legal base in the law of the country. It may be further observed that the rights specified below carry a matching responsibility to act with due concern for the health of others and for their same rights.

- 1.1 Everyone has the right to respect of his or her person as a human being.
- 1.2 Everyone has the right to self-determination.
- 1.3 Everyone has the right to physical and mental integrity and to the security of his or her person.
- 1.4 Everyone has the right to respect for his or her privacy.
- 1.5 Everyone has the right to have his. or her moral and cultural values and religious and philosophical convictions respected.
- 1.6 Everyone has the right to such protection of health as is afforded by appropriate measures for disease prevention and health care, and to the opportunity to pursue his or her own highest attainable level of health.

2. INFORMATION

- 2.1 Information about health services and how best to use them is to be made available to the public in order to benefit all those concerned.
- 2.2 Patients have the right to be fully informed about their health status, including the medical facts about their condition; about the proposed medical procedures, together with the potential risks and benefits of each procedure; about alternatives to the proposed procedures, including the effect of non-treatment; and about the diagnosis, prognosis and progress of treatment.
- 2.3 Information may only be withheld from patients exceptionally when there is good reason to believe that this information would without any expectation of obvious positive effects cause them serious harm.
- 2.4 Information must be communicated to the patient in a way appropriate to the latter's capacity for understanding, minimizing the use of unfamiliar technical terminology. If the patient does not speak the common language, some form of interpreting should be available.
- 2.5 Patients have the right not to be informed, at their explicit request.
- 2.6 Patients have the right to choose who, if any one, should be informed on their behalf
- 2.7 Patients should have the possibility of obtaining a second opinion.
- 2.8 When admitted to a health care establishment, patients should be informed of the identity and professional status of the health care providers taking care of them and of any rules and routines which would bear on their stay and care.
- 2.9 Patients should be able to request and be given a written summary of their diagnosis, treatment and care on discharge from a health care establishment.

3. CONSENT

- 3.1 The informed consent of the patient is a prerequisite for any medical intervention.
- 3.2 A patient has the right to refuse or to halt a medical intervention. The implications of refusing or halting such an intervention must be carefully explained to the patient
- 3.3 When a patient is unable to express his or her will and a medical intervention is urgently needed, the consent of the patient may be presumed, unless it is obvious from a previous declared expression of will that consent would be refused in the situation.
- 3.4 When the consent of a legal representative is required and the proposed intervention is urgently needed, that intervention may be made if it is not possible to obtain, in time, the representative's consent.
- 3.5 When the consent of a legal representative is required, patients (whether minor or adult) must nevertheless be involved in the decision-making process to the fullest extent which their capacity allows.
- 3.6 If a legal representative refuses to give consent and the physician or other provider is of the opinion that the intervention is in the interest of the patient, then the decision must be referred to a court or some form of arbitration.
- 3.7 In all other situations where the patient is unable to give informed consent and where there is no legal representative or representative designated by the patient for this purpose, appropriate measures should be taken to provide for a substitute decision making process, taking into account what is known and, to the greatest extent possible, what may be presumed about the wishes of the patient
- 3.8 The consent of the patient is required for the preservation and use of all substances of the human body. Consent may be presumed when the substances are to be used in the current course of diagnosis, treatment and care of that patient.
- 3.9 The informed consent of the patient is needed for participation in clinical teaching.
- 3.10 The informed consent of the patient is a prerequisite for participation in scientific research. All protocols must be submitted to proper ethical review procedures. Such research should not be carried out on those who are unable to express their will, unless the consent of a legal representative has been obtained and the research would likely be in the interest of the patient.

As an exception to the requirement of involvement being in the interest of the patient, an incapacitated person may be involved in observational research which is not of direct benefit to his or her health provided that that person offers no objection, that the risk andfor burden is minimal, that the research is of significant value and that no alternative methods and other research subjects are available.

4. CONFIDENTIALITY AND PRIVACY

- 4.1 All information about a patient's health status, medical condition, diagnosis, prognosis and treatment and all other information of a personal kind must be kept confidential, even after death.
- 4.2 Confidential information can only be disclosed if the patient gives explicit consent or if the law expressly provides for this. Consent may be presumed where disclosure is to other health care providers involved in that patient's treatment.
- 4.3 All identifiable patient data must be protected. The protection of the data must be appropriate to the manner of their storage. Human substances from which identifiable data can be derived must be likewise protected.
- 4.4 Patients have the right of access to their medical files and technical records and to any other files and records pertaining to their diagnosis, treatment and care and to receive a copy of their own files and records or parts thereof. Such access excludes data concerning third parties.
- 4.5 Patients have the right to require the correction, completion, deletion, clarification and/or updating of personal and medical data concerning them which are inaccurate, incomplete, ambiguous or outdated, or which are not relevant to the purposes of diagnosis, treatment and care.
- 4.6 There can be no intrusion into a patient's private and family life unless and only if, in addition to the patient consenting to it, it can be justified as necessary to the patient's diagnosis, treatment and care.
- 4.7 Medical interventions may only be carried out when there is proper respect shown for the privacy of the individual. This means that a given intervention may be carried out only in the presence of those persons who are necessary for the intervention unless the patient consents or requests otherwise.
- 4.8 Patients admitted to health care establishments have the right to expect physical facilities which ensure privacy, particularly when health care providers are offering them personal care or carrying out examinations and treatment.

5. CARE AND TREATMENT

- 5.1 Everyone has the right to receive such health care as is appropriate to his or her health needs, including preventive care and activities aimed at health promotion. Services should be continuously available and accessible to all equitably, without discrimination and according to the financial, human and material resources which can be made available in a given society.
- 5.2 Patients have a collective right to some form of representation at each level of the health care system in matters pertaining to the planning and evaluation of services, including the range, quality and functioning of the care provided.
- 5.3 Patients have the right to a quality of care which is marked both by high technical standards and by a humane relationship between the patient and health care providers.
- 5.4 Patients have the right to continuity of care, including cooperation between all health care providers and/or establishments which may be involved in their diagnosis, treatment and care.
- 5.5 In circumstances where a choice must be made by providers between potential patients for a particular treatment which is in limited supply, all such patients are entitled to a fair selection procedure for that treatment. That choice must be based on medical criteria and made without discrimination.
- 5.6 Patients have the right to choose and change their own physician or other health care provider and health care establishment, provided that it is compatible with the functioning of the health care system.
- 5.7 Patients for whom there are no longer medical grounds for continued stay in a health care establishment are entitled to a full explanation before they can be transferred to another establishment or sent home. Transfer can only take place after another health care establishment has agreed to accept the patient. Where the patient is discharged to home and when his or her condition so requires, community and domiciliary services should be available.
- 5.8 Patients have the right to be treated with dignity in relation to their diagnosis, treatment and care, which should be rendered with respect for their culture and values.
- 5.9 Patients have the right to enjoy support from family, relatives and friends during the course of care and treatment and to receive spiritual support and guidance at all times.
- 5.10 Patients have the right to relief of their suffering according to the current state of knowledge.
- 5.11 Patients have the right to humane terminal care and to die in dignity.

6. APPLICATION

- 6.1 The exercise of the rights set forth in this document implies that appropriate means are established for this purpose.
- 6.2 The enjoyment of these rights shall be secured without discrimination.
- 6.3 In the exercise of these rights, patients shall be subjected only to such limitations as are compatible with human rights instruments and in accordance with a procedure prescribed by law.
- 6.4 If patients cannot avail themselves of the rights set forth in this document, these rights should be exercised by their legal representative or by a person designated by the patient for that purpose; where neither a legal representative nor a personal surrogate has been appointed, other measures for representation of those patients should be taken.
- 6.5 Patients must have access to such information and advice as will enable them to exercise the rights set forth in this document. Where patients feel that their rights have not been respected they should be enabled to lodge a complaint. In addition to recourse to the courts, there should be independent mechanisms at institutional and other levels to facilitate the processes of lodging, mediating and adjudicating complaints. These mechanisms would, inter alia, ensure that information relating to complaints procedures was available to patients and that an independent person was available and accessible to them for consultation regarding the most appropriate course of action to take. These mechanisms should further ensure that, where necessary, assistance and advocacy on behalf of the patient would be made available. Patients have the right to have their complaints examined and dealt with in a thorough, just, effective and prompt way and to be informed about their outcome.

7. DEFINITIONS

In these Principles of the Rights of Patients in Europe, the following terms have been used with the meanings given:

PATIENT(S)	User(s) of health care services, whether healthy or sick,
DISCRIMINATION	Distinction between persons in similar cases on the basis of race, sex, religion, political opinions, national or social origin, associations with a national minority or personal antipathy.
HEALTH CARE	Medical, nursing or allied services dispensed by health care providers and health care establishments.
HEALTH CARE PROVIDERS	Physicians, nurses, dentists or other health professionals.
MEDICAL INTERVENTION	Any examination, treatment or other act having preventive, diagnostic, therapeutic or rehabilitative aims and which is carried out by a physician or other health care provider.
HEALTH CARE ESTABLISHMENT	Any health care facility such as a hospital, nursing home or establishment for disabled persons.
TERMINAL CARE	Care given to a patient when it is no longer possible to improve the fatal prognosis of his or her illness/condition with available treatment methods; as well as care at the approach of death.