IRELAND

COMHAIRLE NA nDOCHTÚIRI LEIGHIS

THE MEDICAL COUNCIL

CONSTITUTION AND FUNCTIONS

A GUIDE TO ETHICAL CONDUCT AND BEHAVIOUR AND TO FITNESS TO PRACTISE

1981

Medical Council
Lynn House
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1981

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and published in Dublin, May 1981.

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Contents

Introduction

This guide to the Council's constitution and functions is primarily intended for doctors who have recently qualified in Ireland. It will be useful to doctors from other European Economic Community countries who wish to be registered with the Council in order to practise medicine in Ireland. It will also help doctors from countries outside the Community who have obtained temporary registration in order to practise for a limited period in Irish hospitals approved by the Council.

The Medical Council has been created and its constitution determined by the Medical Practitioners Act, 1978, and has thus been granted statutory powers and functions.

The Council sees its overall responsibility to be in the interest of the public by maintaining a Register of properly qualified medical practitioners who are bound to the traditional standards of ethical conduct and behaviour. To achieve this, the Council has been given statutory powers to control medical education and training, thus establishing standards for admission to the Register, and also to control professional conduct and fitness to practise, thus ensuring standards of behaviour and competence necessary for the retention of doctors on the Register.

The Council is funded solely by the doctors on its Register. It receives no support from Government or other public funds. It is not an organisation for protecting the interests of the medical profession. Such organisations exist but the Council has no connection with them. The members of the Council, both nominated and elected give their services on a voluntary basis.

The Council is affiliated to the International Conference of Medical Councils (Conférence Internationale des Ordres et des Organismes d'Attributions Similaires) which meets regularly in Paris. The Conference is preparing a European Guide to Ethics and Professional Conduct, and a copy of the Preamble to this Guide is included as an appendix to this handbook.

David Mitchell
President

Membership

The Medical Council consists of twenty-five members appointed as follows:—

One by each of the five Medical Schools in the State.

Two by the Royal College of Surgeons in Ireland, one representing the surgical specialties and the other jointly the specialties of anaesthetics and radiology.

Two by the Royal College of Physicians of Ireland, one representing the medical specialties and the other jointly the specialties of pathology and obstetrics and gynaecology.

One appointed by the Minister for Health after consultation to represent psychiatry.

One appointed by the Minister for Health after consultation to represent general medical practice.

Ten who are in medical practice in the State, elected by registered medical practitioners, of whom at least:—

Two are hospital consultants other than psychiatrists
One is a consultant psychiatrist
One is a community physician
One is in hospital practice, but not a consultant
Two are general practitioners

Four persons appointed by the Minister, at least three of whom are not registered medical practitioners, to represent the interests of the general public.

The Council which normally meets four times each year, is re-elected every five years and no member may serve more than two consecutive terms. The Council elects its President and Vice-President. The Registrar is the Chief Officer of the Council.

Functions

THE REGISTER

The General Register of Medical Practitioners is published by the Council every five years, with annual supplements in the intervening years. It gives the name, address and qualifications of each doctor with the date of registration, indicating whether this is Full, Provisional or Temporary. Official Certificates of Registration are issued. There is a statutory obligation on the doctor to display the certificate at the place where the practice of medicine is conducted.

REGISTRATION

Full Registration is normally preceded by Provisional Registration which follows on primary qualification and limits practice to residence in one or more approved hospitals for such period as the Council decides. After this period of training with clinical responsibility a Certificate of Experience is obtained allowing the doctor to proceed from Provisional to Full Registration. Doctors who are nationals of European Economic Community Member States and who hold formal medical qualifications awarded in Member States are entitled to apply for Full Registration by making application in the prescribed form and manner. Information is available from the Registrar at the Council's Office. Doctors from countries with which this country has reciprocity of registerable medical qualifications may apply for full registration.

Temporary Registration, which is limited to doctors who are not otherwise entitled to registration, enables doctors from countries outside the Community to gain experience by being employed in hospitals approved of by the Council. Their medical qualifications and experience must be of a standard acceptable to the Council before temporary registration is granted. Temporary registration is for an aggregate period of five years which cannot be extended.

The retention of any name on the Register is contingent on payment of the prescribed fee. Registered doctors may apply to the Council to have their names removed from the Register at any time provided that no disciplinary proceedings are pending.

It is an offence for any person falsely to represent himself or herself to be a registered medical practitioner, or to make any false representation for the purpose of obtaining registration.

Any certificate, prescription or other document which is required to be signed by a medical practitioner is invalid and ineffective if signed by a person who is not duly registered.

EDUCATION AND TRAINING

The Council has the statutory responsibility of satisfying itself as to the suitability of undergraduate medical education and training provided by recognised medical schools and as to the standard of theoretical and practical knowledge required at the examinations for primary qualification. It must also satisfy itself as to the clinical training and experience required for the granting of a certificate of experience, and the adequacy and suitability of postgraduate education and training. In all cases the Council must see that the minimum standards specified in the relevant EEC Directives are satisfied.

FITNESS TO PRACTISE

The Council is empowered through its Fitness to Practise Committee, to enquire into the conduct of a registered medical practitioner on the grounds of alleged professional misconduct or alleged unfitness to practise by reason of physical or mental disability. For further details see Section 5.

Ethical Conduct and Behaviour

"It shall be a function of the Council to give guidance to the medical profession generally on all matters relating to ethical conduct and behaviour."
Medical Practitioners Act, 1978. Section 69, (2).

In giving guidance to the medical profession on questions of ethical conduct it is not the intention of the Council to issue a code of medical ethics. Some Member States of the European Community have legal codes which specify ethical conduct for doctors in great detail. The Council does not consider it feasible to compile such a catalogue of behaviour where non-observance would be regarded as "professional misconduct." Even the most carefully constructed codes are capable of different interpretations and the rapid advance of medical science and social evolution would make constant revision necessary.

Professional misconduct has been defined as conduct in the course of professional activity which doctors of experience, competence and good repute consider disgraceful or dishonourable.

The Council considers that the circumstances of any case may be so complex and variable that the question of a doctor's fitness to practise must be considered on its merits. Traditionally cases of professional misconduct are examined by the peers of the practitioner concerned, with due regard to the practitioner's constitutional rights, and within a legal framework. The Fitness to Practise Committee of the Council operates in this way under the Medical Practitioners' Act, 1978, with the inclusion of a non-medical member of the Council who represents the interests of the general public.

Medicine is a form of service to man combining scientific knowledge and professional experience to meet human needs. It has come to be entrusted to a group of individuals who have devoted themselves to a working lifetime acquiring this knowledge and experience. Medicine in all its branches is basically social in attitude. Medicine is for society — not for society as an organisation but for each and every individual composing it. Thus, medical care must not be used as a tool of the State to be granted or withheld or altered in character under political pressure. Regardless of the framework of their practice the task of all doctors is to help the sick and injured. Doctors must practise without consideration of religion, nationality, race, politics or social standing. Doctors should not allow their professional actions to be influenced by any personal financial interest.

Doctors must be allowed an independence of thought, judgment and action if they are to carry out their essential functions. This independence can be threatened by economic and political pressures, against which the profession must be on its guard.

Society allows the doctor many privileges and with each of these goes responsibility. If these privileges are used without a due sense of responsibility, there can be little surprise if a climate of public opinion develops in favour of limiting professional freedom.

RESPONSIBILITY TO PATIENTS

The rapid advance of scientific knowledge and medical technology has brought with it many new areas of ethical concern in addition to the traditional problems considered by our predecessors. Doctors must do their best to preserve life and promote the health of the sick person. This implies the further obligation to keep abreast of progress. A doctor must give emergency help unless he or she is satisfied that alternative care is available. Once doctors undertake care of ill patients ordinarily they must give continuity of care for the duration of the illness. If they wish to withdraw their services they must inform the patient and allow sufficient time for alternative medical care to be sought.

Confidentiality

"Whatever . . . I see or hear . . . which ought not be spoken abroad, I will not divulge." So says the Hippocratic oath.

Confidentiality is a time honoured principle of medical ethics. There are three circumstances when exceptions may be made:

- when required by a Judge in a Court of Law;
- when necessary to protect the interests of the patient;
- and when necessary to protect the welfare of society.

Medical records, both clinical and technical, must be safeguarded. The Council considers it appropriate to draw attention to the dangers to confidentiality of computers and electronic processing in the field of health service administration. The Council supports the resolutions of the 27th World Medical Assembly — see Appendix B.

Doctors belonging to the following disciplines may experience problems in relation to the conducting of medical examinations and the reporting thereof to a third party:— community physicians, occupational physicians, doctors reporting to insurance companies, military medical officers, police surgeons, prison medical officers. Special care must be taken where a statutory or other authority requires a medical report.

The following points should be borne in mind:—

(i) The doctor-patient relationship should be respected at all times.

(ii) Where circumstances permit, the examinee's own personal physician should be informed.

(iii) The significance rather than the precise details of the medical findings should be conveyed to the third party.

(iv) Documents containing medical details should always be transmitted under confidential cover.

(v) The doctor has the right to refuse to examine a person against the will of that person.

In order to fulfil statutory requirements, it may be necessary for a clinician to provide a community physician with medical information which may be used for the benefit of a patient. For example, clinical details may be provided so that the payment of a financial allowance may be recommended. In such instances the community physician is not obliged to release the specific details, but may interpret them to the administrative authority concerned.

Similarly, an occupational physician may present to an employer the significant aspects of a medical condition which he may discover as the result of an examination. Only with the consent of the person examined may the employer have access to that person's medical records and then only in specifically agreed circumstances. All consultations with an occupational physician or a community physician must always be regarded as confidential.

An employer has not got the power, as of right, to be informed of the clinical details of illness or injury. The doctor he employs may, when assessing the nature of the particular disability, interpret the medical findings in terms of the patient's likelihood of continuing to work.

Special problems will arise when a doctor finds that an employee is suffering from a communicable disease. Here the real or potential risk to public health must be carefully assessed and the doctor must have strict regard to the statutory obligations in the matter of reporting such a case.

Consent

Medical intervention normally requires consent. Whether or not a person is sufficiently informed and sufficiently free to consent to medical investigation and treatment may be difficult to resolve. Every effort should be made to ensure that a patient understands the nature and purpose of the medical procedures involved. The Council urges special caution whenever children, prisoners, mentally ill, mentally handicapped, or unconscious persons are involved.

Information

A request for information by a patient always requires a positive response. A request by a third party for information about a patient should be refused unless the patient has given consent. In general, medical practitioners should ensure that patients and, with their consent, members of the family concerned, are as fully informed as possible about matters relating to the illness.

The Council considers it essential that doctors should keep accurate records of patient care both in their own interest and in the interest of the patient.

RESPONSIBILITY TO COLLEAGUES

The practice of medicine is sometimes difficult and often demanding. Doctors should give moral support to each other. Doctors should be careful to ensure that public statements concerning the conduct of colleagues can be fully substantiated. They should not hestiate to consult with colleagues but should not associate professionally with or refer patients to unregistered medical practitioners. Doctors should where necessary co-operate with recognised paramedical professionals.

Setting Up Practice

Medical practitioners' premises should be adequate for the purpose. Nameplates should be unostentatious and notices in the press should be strictly limited. Canvassing for medical practice in any form is regarded by the Council as professional misconduct. Practitioners are obliged to take every reasonable precaution to avoid damaging the practice of colleagues. This obligation is particularly compelling when there has been a recent professional association. The attention of doctors is drawn to the need to set up and maintain a proper record system.

Fee Splitting

This practice is against the patient's interest and is professional misconduct.

Advertising

The reputation of a medical practitioner is firmly founded on professional integrity, knowledge, and skill. Advertising to enhance a professional reputation is professional misconduct.

Attendance on Doctors and their Families

The Council strongly supports the traditional practice that doctors should cherish their colleagues and their families as if they were their own relatives.

Relationship with Junior Colleagues

The Council is of the opinion that doctors have a personal and continuing responsibility to junior colleagues and medical students. They are obliged to transmit acquired knowledge and skills and, by word and example, to attempt to foster correct professional attitudes and behaviour. Doctors must take care not to delegate to junior colleagues tasks and responsibilities beyond their skill and experience.

Deputising Arrangements

Doctors have a special responsibility to ensure, as far as lies in their control, that patients will receive adequate professional care from another doctor when alternative arrangements have to be made during their absence.

RESPONSIBILITY TO THE COMMUNITY

Relationship with the Media

The media are legitimate and valuable vehicles for communication with the community. Doctors have a responsibility to influence the quality and accuracy of the health information disseminated. Doctors must avoid giving any impression that they, or the institutions to which they may be attached, have unique or special solutions to health problems. The Council, recognising the increasing anxiety within the profession concerning possible abuses, has decided that the following procedure should be observed by doctors:—

As a general principle doctors in clinical practice should not be identified on television or radio, or in the non-medical press.

If they believe that their identification is essential on any particular occasion, they should inform the Council in advance giving the date and time of the programme or publication. This does not imply the approval of the Council.

Doctors should never discuss individual case histories or answer enquiries about personal health problems, especially on phone-in programmes.

Certification

The Council takes a serious view of the important matter of the issue of certificates, reports and other formal documents bearing a doctor's signature. Great care is necessary to see that strict accuracy and truth are observed. Any statement that cannot be verified should be omitted. Pressure from any source to deviate from this standard must be resisted.

Human Research

Many factors are involved in this difficult area. One is the possible benefit of the proposed procedure to the patient. Another relates to the adequacy of the patient's consent. Another concerns the limits on the potential risks concerned with the research procedure involved, and the competence of the patient to assess these and give well-informed consent to the proposed procedure. The Council strongly supports the formation of ethical committees in all institutions where human research is undertaken. Individual practitioners are advised to seek approval of an appropriate supervisory organisation before undertaking any research project involving risks to human subjects. The Council supports the resolutions of the 18th World Medical Assembly and as revised by the 29th World Medical Assembly — see Appendix C.

Reproductive Medicine

In an age of changing social, economic, political and philosophical attitudes the implications of scientific discoveries in the field of reproductive medicine present many new problems.

It is important for doctors to keep abreast of these developments which may have an important bearing on many aspects of patient care. These include — family planning, infertility, sterilisation, artificial insemination and the prevention of congenital handicap. In this whole area of conflicting attitudes, doctors while obeying the laws of the State, must always be guided by their own informed consciences.

Abortion in any circumstances is professional misconduct and it is illegal in the Republic of Ireland. Doctors must be prepared to resist requests by patients and their relatives to advise termination where pregnancy is unwanted.

There is evidence that a growing number of Irish women seek abortion from medical services outside the State. There is, thus, a special need for the profession to adopt a sympathetic and supportive role in caring for women presenting with unwanted pregnancies or pregnant women with disabling physical or psychological problems or where there is reason to believe that their baby will suffer from a congenital anomaly. The profession should encourage services for the support and care of mother and child. Doctors must maintain the time-honoured medical principle that every effort should be made to preserve human life, both born and unborn.

Donor Organ Procurement

Aside from the complex problem of definition of death the ethical issues are comparatively minor and arise only where the competency to give consent of the person from whom the organ would be obtained is in question or absent. Critical consideration should be given to the case of a child, a mentally handicapped or mentally ill person or a competent adult subject to coercion.

Euthanasia

Where death is imminent it is the doctor's responsibility to take care that a patient dies with dignity and as little suffering as possible. Euthanasia involves actively causing the death of a person and is illegal.

Relationship to Prisoners

The Council supports and draws attention to the 1975 Declaration of Tokyo by the World Medical Association concerning torture and other cruel, inhuman and degrading punishment. See Appendix D.

Community Resources

Community funds for health care are limited. A decision to spend money in one area often involves a parallel decision not to spend money in another.

The Council considers that individual doctors have a responsibility to conserve resources and give considered advice, when appropriate, on their allocation. Their responsibility to the community should not transcend their responsibility to an individual patient in their care.

PROFESSIONAL STANDARDS

The reputation of the profession demands a high standard of behaviour from its members. Experience suggests that abuses are most frequent in the following areas:—

(a) Irresponsible use of alcohol or other drugs.

(b) Irresponsible prescribing.

(c) Abusive or insensitive behaviour towards patients.

(d) Advertising, canvassing, deprecation of colleagues and improper practice arrangements.

Doctors are reminded that any form of sexual advance to a patient with whom there exists a professional relationship is professional misconduct. In this connection doctors are urged that they should exert special care and prudence in circumstances which would leave them open to an allegation of such misconduct.

Alleged professional misconduct will be evaluated in the light of the definition given earlier in page 10.

This brief review of ethics must not be considered as the Council's last word on the matter. Indeed the Council anticipates, in response to demand from the profession or the public, that it may need to produce further guidelines on specific issues. In doing this the Council would hope to achieve an ethical standpoint by consensus.

Fitness to Practise

The Medical Practitioners Act, 1978 introduced major changes into the disciplinary procedures governing the profession. These encompass not only the alleged offences but also the methods of adjudication.

The Act provides that if any registered medical practitioner is convicted in the State of an offence triable on indictment (or convicted elsewhere of a similar offence) the Council may decide that his name should be erased. The long established phrase "infamous conduct in a professional respect" now becomes "professional misconduct" and two new reasons for possible erasure are laid down. The first involves fitness to engage in the practice of medicine by reason of physical or mental disability. The other arises from the fact that an annual retention fee is now payable and that failure to pay this will result in erasure.

The new procedures are administered by the Fitness to Practise Committee (hereinafter called the Committee), set up under Part V of the Act. No set number of members is specified but the majority must be elected members of the Council. All must be members of the Council, at least one of them shall be a lay person appointed by the Minister and its Chairman may not be either the President or Vice-President. It is this Committee which considers applications for an inquiry into the professional conduct of a registered practitioner, or into his fitness to practise for health reasons, and which actually carries out the inquiry. The application for an inquiry may be made by the Council itself or by "any person." In practice, all complaints about practitioners are fully considered. Should the Committee decide that there is not sufficient cause to warrant an inquiry it so informs the Council. The latter may, having considered the matter, agree and decide that no further action should be taken. However, it has also the power to over-rule the Committee and to direct it to hold an inquiry notwithstanding.

There are therefore two situations in which an inquiry may be instituted — either by direction of the Council, or if the Committee has itself decided that the facts alleged constitute a *prima facie* case for holding one.

In the conduct of the inquiry the Committee has very wide powers — those of the High Court — in compelling the attendance of witnesses, examining them under oath and compelling the production of documents. The Registrar or some other person presents the evidence and the practitioner has the right to know the evidence which it is proposed to consider, to be present and to be represented. On completion of the inquiry the Committee reports to the Council.

If the Committee has found the practitioner to have been guilty of professional misconduct or to be unfit to practise because of physical or mental incapacity, the Council may decide that the name should be erased from the Register or from the Register of Medical Specialists or

that registration may not have effect for a specified period. Effectively, this means suspension for a given length of time.

The Council does not, however, proceed directly to erasure or suspension. The practitioner must be informed of the Council's decision and may apply to the High Court within twenty-one days for its cancellation. There are procedures set out to ensure that there will be no undue delay in such an application. Alternatively, if no application has been made to the High Court by the practitioner the Council may itself apply for confirmation of the decision. The Court may cancel the decision or confirm it. If it is confirmed the Court may order the Council to erase the name of the practitioner or to suspend effective registration.

These are considerable safeguards for the practitioner, but the Council has also been given greatly expanded disciplinary powers. After an inquiry has been held and the Committee has reported the Council may, instead of erasure or suspension, retain the practitioner's name on the Register but may attach "such conditions as it thinks fit" to its remaining there. An application to the High Court is also available in this instance. Finally, following an inquiry and report from the Committee the Council may advise, admonish or censure the practitioner.

The Council has the further power to apply to the High Court, if it considers it as a matter of urgency in the public interest to do so, for an immediate order suspending the registration of any practitioner for a specified period. Such an application is made in private.

It is important to know that in all instances involving erasure or suspension the matter is considered by the High Court on the application either of the practitioner or of the Council, and that the Council does not erase or suspend the name until directed to do so by the High Court. If professional misconduct is under consideration at the hearing the Court may also admit evidence from "any person of standing in the medical profession as to what is professional misconduct" — a further safeguard for the practitioner. On the other hand the Council (and only the Council) may at any time restore the name of any person which has been erased or suspended and may attach such conditions as it sees fit to restoring the name.

The findings of the Committee and the decision of the Council on its report will not be made public without the consent of the practitioner concerned unless the practitioner has been found guilty of professional misconduct or unfit to practise medicine because of physical and mental disability.

Appendix A

PREAMBLE TO A EUROPEAN GUIDE TO ETHICS AND THE PROFESSIONAL CONDUCT OF DOCTORS

The purpose of this Guide is two-fold: to remind doctors of the ethics of their profession wherever they may practise medicine and of the special rules which may apply in any one country of the European Community; and to reassure the public that any doctor in the Community, whatever his country of origin, can be relied upon to provide competent and devoted service.

The European Medical Community, which arose from the Treaty of Rome, wishes to preserve those ethical traditions which are common to the practice of medicine in every European country. The basic principles of medical conduct are generally regarded as having their origin in a Hippocratic Oath, but the changing laws and regulations of present-day societies call also for an understanding by the doctor of the ethical code or guide of the particular country within which he chooses to practise. Whilst these guides and codes are in overwhelming agreement on major issues, they differ in detail.

The various codes and guides* listed in this booklet all set out the duties of doctors towards patients, society, and colleagues. Nevertheless, the International Conference of Medical Councils and Similar Organisations wishes to take advantage of these introductory paragraphs to this Guide to reaffirm some of the essential obligations of all doctors within the European Community.

The practice of medicine, the purpose of which is to maintain and restore physical and mental health and to relieve suffering, is founded upon the knowledge and conscience of the individual doctor. All human life is to be respected regardless of race, nationality, religion, social status or political opinions, in peace and war.

Whatever the pressures to which a doctor may be subjected in a modern society, he needs at all times to bear in mind the responsibilities of his profession. His concern is with the quality and continuity of care, and he should not allow himself to be diverted from the exercise of his personal and professional conscience.

Respect for human life calls for particular firmness and diligence in areas such as professional confidence, the health of people held in prison or detention, medical experimentation, and clinical trials.

No form of treatment, examination, or investigation, may be undertaken without the consent of the patient where this is obtainable, and never against the patient's interests. Departure from these principles may expose the doctor and his patients to arbitrary political measures and

compromise the doctor's professional independence and power of making decisions.

The strictest regard for the truth is required of every doctor in relation to documentation and certification.

Every doctor is a guardian for his generation of a centuries-old tradition of ethical medical conduct. A profession has a duty to set and maintain its own standards. In medicine, this is the guarantee to the public of the high level of care and competence which people are entitled to expect from their medical attendants.

*CODES AND GUIDES TO MEDICAL ETHICS AND PROFESSIONAL CONDUCT OF THE MEMBER STATES OF THE EUROPEAN COMMUNITY

Belgium: Code de Déontologie Médicale (Brussels, 1975).

Denmark: Order Concerning the Practice of Medicine Act (Copenhagen, 1976).

France: Code de Déontologie Médicale (Paris, 1979).

Germany Berüfsordnung fur die Deutschen Ärzte (Cologne, 1976).

Italy: Codice di Deontologica Medica (Rome, 1978).

Luxembourg: Le Collège Médicale (Luxembourg, 1968).

Netherlands: Gedragsregels Voor Artsen (Utrecht, 1978).

United Kingdom: Professional Conduct and Discipline (London, 1979).

Appendix B

RESOLUTION ADOPTED BY THE 27th WORLD MEDICAL ASSEMBLY — MUNICH, GERMANY 1973

MEDICAL DATA BANKS

Medical Secrecy

"*Whereas:* The privacy of the individual is highly prized in most societies and widely accepted as a civil right; and

Whereas: The confidential nature of the patient-doctor relationship is regarded by most doctors as extremely important and is taken for granted by the patient; and

Whereas: There is an increasing tendency towards an intrusion of medical secrecy;

Therefore be it resolved that the 27th World Medical Assembly reaffirm the vital importance of maintaining medical secrecy not as a privilege for the doctor, but to protect the privacy of the individual as the basis for the confidential relation between the patient and his doctor; and ask the United Nations, representing the people of the world, to give to the medical profession the needed help and to show ways for securing his fundamental right for the individual human being."

Computers in Medicine

"*Be it resolved* that the 27th World Medical Assembly —

(1) draw the attention of the peoples of the world to the great advances and advantages resulting from the use of computers and electronic data processing in the field of health, especially in patient care and epidemiology;

(2) request all national medical associations to take all possible steps in their countries to assure that medical secrecy, for the sake of the patient, will be guaranteed to the same degree in the future as in the past;

(3) request member countries of WMA to reject all attempts having as a goal legislation authorising any procedures to electronic data processing which could endanger or undermine the right of the patient for medical secrecy;

(4) express the strong opinion that medical data banks should be available only to the medical profession and should not, therefore, be linked to other central data banks; and

(5) request Council to prepare documents about the existing possibilities of safeguarding legally and technically the confidential nature of stored medical data."

Appendix C

DECLARATION OF HELSINKI

Recommendations guiding medical doctors in biomedical research involing human subjects.

Adopted by the 18th World Medical Assembly, Helsinki, Finland, 1964, and as revised by the 29th World Medical Assembly, Tokyo, Japan, 1975.

Introduction

It is the mission of the medical doctor to safeguard the health of the people. His or her knowledge and conscience are dedicated to the fulfillment of this mission.

The Declaration of Geneva of the World Medical Association binds the doctor with the words, "The health of my patient will be my first consideration," and the International Code of Medical Ethics declares that, "Any act or advice which could weaken physical or mental resistance of a human being may be used only in his interest."

The purpose of biomedical research involving human subjects must be to improve diagnostic, therapeutic and prophylactic procedures and the understanding of the aetiology and pathogenesis of disease.

In current medical practice most diagnostic, therapeutic or prophylactic procedures involve hazards. This applies *a fortiori* to biomedical research.

Medical progress is based on research which ultimately must rest in part on experimentation involving human subjects.

In the field of biomedical research a fundamental distinction must be recognised between medical research in which the aim is essentially diagnostic or therapeutic for a patient, and medical research, the essential object of which is purely scientific and without direct diagnostic or therapeutic value to the person subjected to the research.

Special caution must be exercised in the conduct of research which may affect the environment, and the welfare of animals used for research must be respected.

Because it is essential that the results of laboratory experiments be applied to human beings to further scientific knowledge and to help suffering humanity, The World Medical Association has prepared the following recommendations as a guide to every doctor in biomedical research involving human subjects. They should be kept under review in the future. It must be stressed that the standards as drafted are only a

guide to physicians all over the world. Doctors are not relieved from criminal, civil and ethical responsibilities under the laws of their own countries.

1. Basic principles

1. Biomedical research involving human subjects must conform to generally accepted scientific principles and should be based on adequately performed laboratory and animal experimentation and on a thorough knowledge of the scientific literature.

2. The design and performance of each experimental procedure involving human subjects should be clearly formulated in an experimental protocol which should be transmitted to a specially appointed independent committee for consideration, comment and guidance.

3. Biomedical research involving human subjects should be conducted only by scientifically qualified persons and under the supervision of a clinically competent medical person. The responsibility for the human subject must always rest with a medically qualified person and never rest on the subject of the research, even though the subject has given his or her consent.

4. Biomedical research involving human subjects cannot legitimately be carried out unless the importance of the objective is in proportion to the inherent risk to the subject.

5. Every biomedical research project involving human subjects should be preceded by careful assessment of predictable risks in comparison with foreseeable benefits to the subject or to others. Concern for the interests of the subject must always prevail over the interests of science and society.

6. The right of the research subject to safeguard his or her integrity must always be respected. Every precaution should be taken to respect the privacy of the subject and to minimize the impact of the study on the subject's physical and mental integrity and on the personality of the subject.

7. Doctors should abstain from engaging in research projects involving human subjects unless they are satisfied that the hazards involved are believed to be predictable. Doctors should cease any investigation if the hazards are found to outweigh the potential benefits.

8. In publication of the results of his or her research, the doctor is obliged to preserve the accuracy of the results. Reports of experimentation not in accordance with the principles laid down in this Declaration should not be accepted for publication.

9. In any research on human beings, each potential subject must be adequately informed of the aims, methods, anticipated benefits and potential hazards of the study and the discomfort it may entail. He or she

should be informed that he or she is at liberty to abstain from participation in the study and that he or she is free to withdraw his or her consent to participation at any time. The doctor should then obtain the subject's freely-given informed consent, preferably in writing.

10. When obtaining informed consent for the research project the doctor should be particularly cautious if the subject is in a dependent relationship to him or her or may consent under duress. In that case the informed consent should be obtained by a doctor who is not engaged in the investigation and who is completely independent of this official relationship.

11. In case of legal incompetence, informed consent should be obtained from the legal guardian in accordance with national legislation. Where physical or mental incapacity makes it impossible to obtain informed consent, or when the subject is a minor, permission from the responsible relative replaces that of the subject in accordance with national legislation.

12. The research protocol should always contain a statement of the ethical considerations involved and should indicate that the principles enunciated in the present Declaration are complied with.

II. Medical research combined with professional care (clinical research)

1. In the treatment of the sick person, the doctor must be free to use a new diagnostic and therapeutic measure, if in his or her judgement it offers hope of saving life, reestablishing, health or alleviating suffering.

2. The potential benefits, hazards and discomfort of a new method should be weighed against the advantages of the best current diagnostic and therapeutic methods.

3. In any medical study, every patient — including those of a control group, if any — should be assured of the best proven diagnostic and therapeutic method.

4. The refusal of the patient to participate in a study must never interfere with the doctor-patient relationship.

5. If the doctor considers it essential not to obtain informed consent, the specific reasons for this proposal should be stated in the experimental protocol for transmission to the independent committee (1, 2).

6. The doctor can combine medical research with professional care, the objective being the acquisition of new medical knowledge, only to the extent that medical research is justified by its potential diagnostic or therapeutic value for the patient.

III. Non-therapeutic biomedical research involving human subjects (Non-clinical biomedical research)

1. In the purely scientific application of medical research carried out on a human being, it is the duty of the doctor to remain the protector of the life and health of that person on whom biomedical research is being carried out.

2. The subjects should be volunteers — either healthy persons or patients for whom the experimental design is not related to the patient's illness.

3. The investigator or the investigating team should discontinue the research if in his/her or their judgement it may, if continued, be harmful to the individual.

4. In research on man, the interest of science and society should never take precedence over considerations related to the wellbeing of the subject.

Appendix D

THE WORLD MEDICAL ASSOCIATION, INC.
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DECLARATION OF TOKYO

Guidelines for Medical Doctors concerning Torture and Other Cruel, Inhuman or Degrading Treatment or Punishment in relation to Detention and Imprisonment.

As adopted by the 29th World Medical Assembly, Tokyo, Japan, October, 1975.

PREAMBLE

It is the privilege of the medical doctor to practise medicine in the service of humanity, to preserve and restore bodily and mental health without distinction as to persons, to comfort and to ease the suffering of his or her patients. The utmost respect for human life is to be maintained even under threat, and no use made of any medical knowledge contrary to the laws of humanity.

For the purpose of this Declaration, torture is defined as the deliberate, systematic or wanton infliction of physical or mental suffering by one or more persons acting alone or on the orders of any authority, to force another person to yield information, to make a confession, or for any other reason.

DECLARATION

1. The doctor shall not countenance, condone or participate in the practice of torture or other forms of cruel, inhuman or degrading procedures, whatever the offence of which the victim of such procedures is suspected, accused or guilty, and whatever the victim's beliefs or motives, and in all situations, including armed conflict and civil strife.

2. The doctor shall not provide any premises, instruments, substances or knowledge to facilitate the practice of torture or other forms of cruel, inhuman or degrading treatment or to diminish the ability of the victim to resist such treatment.

3. The doctor shall not be present during any procedure during which torture or other forms of cruel, inhuman or degrading treatment is used or threatened.

4. A doctor must have complete clinical independence in deciding upon the care of a person for whom he or she is medically responsible. The doctor's fundamental role is to alleviate the distress of his or her fellow men, and no motive whether personal, collective or political shall prevail against this higher purpose.

5. Where a prisoner refuses nourishment and is considered by the doctor as capable of forming an unimpaired and rational judgement concerning the consequences of such a voluntary refusal of nourishment, he or she shall not be fed artifically. The decision as to the capacity of the prisoner to form such a judgement should be confirmed by at least one other independent doctor. The consequences of the refusal of nourishment shall be explained by the doctor to the prisoner.

6. The World Medical Association will support, and should encourage the international community, the national medical associations and fellow doctors to support the doctor and his or her family in the face of threats or reprisals resulting from a refusal to condone the use of torture or other forms of cruel, inhuman or degrading treatment.