MEDICAL ETHICS AND MEDICAL EDUCATION

XIVth CIOMS Round Table Conference

Edited by: Z. Bankowski and J. Corvera Bernardelli

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The Council for International Organizations of Medical Sciences is an international non-governmental scientific organization established jointly by Unesco and WHO in 1949. It is essentially a federation of non-governmental international societies or unions representing specialized branches of medical sciences and practice. CIOMS has also national members, usually national medical or scientific academies or research councils, and associate members which include international, regional or national associations or societies representing various branches of biomedicine. In 1981 there were forty International Members, twenty-six National Members and twenty-four Associate Members, making a total of ninety member organizations of CIOMS.

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This conference was organized by the Council for International Organizations of Medical Sciences (CIOMS) within the framework of a joint WHO/CIOMS project for the Development of Guidelines for Ethical Review Procedures for Research Involving Human Subjects, with the collaboration of the International Congress and Convention Association (ICCA), and sponsored by the National Academy of Medicine, Mexico, the Mexican National Council of Tourism, the Pan American Health Organization/WHO Regional Office for the Americas, and the Sandoz Foundation.

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C O N T E N T S

Each paper is followed by a short summary in English or in Spanish, as appropriate.

INTRODUCTION

Alfred Gellhorn

On television and in the cinema, Western medicine is often shown as a brilliant network of tremendous scientific knowledge, technical skills and wonder drugs, all confidently directed by physicians in starched white coats or surgical green. The image and conception is that medicine is the implementation of scientific and technological advances and that the collective effort of scientific research and new technology will push death further and further away through mastery of disease.

But the television and movie pictures of medicine fail to depict the inequities in the distribution of the wonders and potentialities of medicine among the peoples of any country in our world, nor does the drama of scientific and technological research reflect the concerned interest of the medical profession and citizens in general in the ethical issues related to both bio-medical progress and the delivery of health services.

Ethics has been a fundamental part of the practice of medicine in all ages, but its rapid rise as a subject of interest to medicine and medical research, to the law, the social sciences, philosophy and religion is a phenomenon of the post-World War II period. In earlier ages medical ethics dealt with the obligations and responsibilities of the physician. The principal concern of the doctor for the welfare of his patient and the clear admonishment to do no harm were embodied in the Hippocratic Oath and all subsequent medical codes. All of these statements of ethics were professionally oriented.

The Nuremberg war criminal trials in 1947 judged the Nazi doctors, who carried out sadistic experiments on concentration camp prisoners, guilty of conduct contrary to the accepted values of humanity. This set the stage for a new phase of medical ethics in which the autonomy of the patient became the central focus. It is fascinating that the Nuremberg court was reinforcing a principle which had been enunciated by a prominent American jurist, Justice Cardozo, in 1914, 'Every human being of adult years and sound mind has a right to determine what shall be done with his own body.' (Schloendorff versus Society of New York Hospital, 105 N.E. 92,93 (N.T. 1914)).

The first session of this conference will examine the contemporary ethical issues in human experimentation. Are we to be guided by what Jacques Monod (Chance and Necessity, 1971)

called the 'ethic of knowledge', or, as he explains, the commitment to the scientific investigation of natural phenomena? Dr Philip Handler, President of the USA National Academy of Sciences, further emphasizes the high morality of scientific research, as he sees it, in his statement 'The search for truth is man's noblest enterprise'. Dr John Ladd, Professor of Philosophy at Brown University, Providence, Rhode Island, has examined this 'scientific imperative' in a number of stimulating papers and today he will focus on the ethical aspects of human experimentation.

The second presentation today will be by Dr Robert Levine, Professor of Medicine at Yale University, who has been a member of the National Commission for the Protection of Human Subjects of Biomedical and Behavioural Research. Dr Levine has had the opportunity to work extensively with one mechanism for the protection of human subjects in clinical research, the ethical review committees, and he will give us a critical insight on this process.

Dr John Dunne, who has many important responsibilities at the headquarters of WHO in Geneva and is the Secretary of the Secretariat Committee for Research Involving Human Subjects, will report on guidelines for the ethical conduct of human experimentation which have been developed in a joint study by CIOMS and WHO. It will be particularly important for this audience to react to these guidelines, for it is hoped that in meetings such as this a consensus will be formed to make these guidelines, with modifications which you may suggest, into an international agreement.

Following these three presentations, we will hear from representatives of many countries how the ethical review process in clinical research is carried out in their land.

Before calling on our first speaker, I wish to indicate how the ethical theme of today has continuity in tomorrow's programme. In the morning we will discuss medical ethics in medical education. Most of us at this conference had no course on this subject while we were in medical school, but a growing concern on the part of the public and of idealistic medical students regarding the impersonality of medical care together with the moral dilemmas arising from advances in biomedical knowledge and technology have led to a demand for discussion and instruction in medical ethics.

The final topic on the programme, Medical Education and Government, is also an ethical issue. What are the responsibilities and obligations of medical education to meet the needs of populations? How might governments and medical schools more effectively collaborate to meet societal needs? Or should there be complete separation between governmental and medical education functions?

All of the subjects before us are important and provocative. Your discussion will add to the rich fare which our speakers will provide.

INTRODUCCION

Alfred Gellhorn

En la televisión y en el cine se presenta con frecuencia la medicina occidental como una brillante red de impresionantes conocimientos científicos, capacidades técnicas y medicamentos maravillosos, dirigidos con gran seguridad por médicos ataviados con almidonadas batas blancas o con el verde atuendo del cirujano. La imagen responde a la idea de que la medicina es la aplicación de los adelantos científicos y tecnológicos y de que el esfuerzo colectivo de la investigación científica y de la nueva tecnología conseguirá alejar cada vez más la muerte gracias al dominio ejercido sobre la enfermedad.

Pero la televisión y la medicina olvidan describir las desigualdades que se registran en la distribución de las maravillas y de las posibilidades que ofrece la medicina entre las poblaciones de cualquier país de nuestro mundo; y, por otra parte, la manera espectacular en que se presentan las investigaciones científicas y tecnológicas no refleja el interés y la preocupación de la profesión médica y del público general por las cuestiones éticas que se plantean tanto en relación con el progreso biomédico como con la prestación de los servicios de salud.

La ética ha sido una parte fundamental del ejercicio de la medicina en todas las épocas, pero su rápida ascensión como objeto de interés para la medicina y la investigación médica, así como para la ley, las ciencias sociales, la filosofía y la religión, es un fenómeno propio del periodo que siguió a la Segunda Guerra Mundial. En otros tiempos, la ética médica trataba de las obligaciones y responsabilidades del médico. La principal preocupación del médico por el bienestar de su paciente y la admonición precisa de no causarle dano se incluían tanto en el Juramento Hipocrático como en todos los demás códigos médicos que le siguieron. Todas esas normas de ética estaban orientadas hacia la profesión.

En los juicios celebrados en 1947 contra los criminales de guerra, los médicos nazis que habían llevado a cabo sádicos experimentos en prisioneros de los campos de concentración fueron juzgados culpables de conducta contraria a los valores de humanitarismo reconocidos por todos. Este hecho sentó las bases de una nueva fase de la ética médica en la que la autonomía del

paciente pasó a ser el foco central. Es fascinador, ciertamente, comprobar que el tribunal de Nuremberg reinstauró un principio que un eminente jurista americano, el Juez Cardozo, había enunciado ya en 1914 en los siguientes términos: 'Todo ser humano de edad adulta y mente sana tiene derecho a determinar lo que debe hacerse con su propio cuerpo'. (Caso 'Schloendorff contra la Sociedad del Hospital de Nueva York, 105 N.E. 92,93 (N.Y. 1914).)

En la primera sesión de esta conferencia se examinarán las cuestiones de ética que se plantean en nuestros días en relación con la experimentación en el ser humano. ¿Deberemos guiarnos por lo que Jacques Monod, en su obra Chance et Nécessité, publicada en 1971, llamó la 'ética del conocimiento', o sea, como él mismo explica, el compromiso hacia la investigación científica de los fenómenos naturales? El Dr Philip Handler, Presidente de la Academia Nacional de Ciencias, de los Estados Unidos de América, insiste aún más en la alta moralidad de la investigación científica, tal como él la concibe, al decir: 'La búsqueda de la verdad es la más noble empresa del hombre'. El Dr John Ladd, Profesor de Filosofía de la Universidad Brown, de Providence, Rhode Island, ha examinado ese 'imperativo científico' en varios trabajos suyos del mayor interés, y se centrará hoy en los aspectos éticos de la experimentación en el hombre.

La segunda presentación de hoy correrá a cargo del Dr Robert Levine, Profesor de Medicina de la Universidad de Yale, que ha sido miembro de la Comisión Nacional para la Protección de los Sujetos Humanos de las Investigaciones Biomédicas y sobre el Comportamiento. El Dr Levine ha tenido ocasión de colaborar intensamente con un organismo establecido para la protección de los sujetos humanos en las investigaciones clínicas, a saber, los comités de examen ético, y nos ofrecerá una visión crítica de ese proceso.

El Dr John Dunne, que asume muchas e importantes responsabilidades en la sede de la OMS, en Ginebra, y es Secretario Ejecutivo del Comité Consultivo de Investigaciones Médicas, nos informará sobre las pautas de conducta ética en la experimentación en seres humanos que han sido establecidas en un estudio efectuado conjuntamente por el COICM y la OMS mediante subvenciones aportadas por varios países y fundaciones privadas. Importa en gran manera que los asistentes manifiesten su parecer acerca de esas pautas, porque se espera que, a través de reuniones como ésta, se llegue a un consenso que haga de esas pautas, con las modificaciones que ustedes estimen oportuno proponer, un

instrumento de acuerdo internacional.

Después de esas tres presentaciones, escucharemos a los representantes de muchos países que nos expondrán la forma en que se desarrolla el proceso de la revisión ética en sus respectivos países.

Antes de dar la palabra a nuestro primer orador, debo señalarles de qué manera el tema ético de hoy se prolongará en el programa de mañana. Por la mañana debatiremos el problema de la ética médica en la enseñanza de la medicina. La mayoría de los que participamos en esta conferencia no recibimos enseñanza alguna sobre esta materia en la Facultad de Medicina; pero la preocupación creciente del público y de los estudiantes de medicina más idealistas ante el carácter impersonal de la atención médica, juntamente con los dilemas morales que plantean los adelantos habidos en la tecnología y los conocimientos biomédicos han creado una demanda encaminada a conseguir que la ética médica sea objeto de debate y de instrucción.

El tema final del programa, la Enseñanza de la Medicina y el Gobierno, es también una cuestion ética. ¿Cuáles son las responsabilidades y las obligaciones de la enseñanza de la medicina con respecto a las necesidades de la población? ¿De qué manera pueden los gobiernos y las escuelas de medicina colaborar con más eficacia para atender las necesidades de la sociedad? ¿O debe existir una separación completa entre las funciones de gobierno y las de enseñanza de la medicina?

Todos los temas que se nos presentan son importantes y estimulantes. El debate entre ustedes será un excelente complemento del sustancioso material que nuestros oradores aportarán.

Keynote Address - MEDICAL ETHICS AND MEDICAL EDUCATION *

Hector R. Acuña

At this, the inauguration of the XIVth International Conference on Medical Ethics and Medical Education, sponsored by the Council for International Organizations of Medical Sciences (CIOMS), in cooperation with the National Academy of Medicine of Mexico, I should like to express the thanks of the World Health Organization and of the Pan American Health Organization for the high honor conferred on us by allowing us to participate in this distinguished international forum.

Recognizing that both clinical research and medical education play major roles in the health of the peoples of the world, I shall endeavour, in my presentation, to analyse the relations that exist between these disciplines and public health.

When the considerable responsibility and trust which is given to a physician is conferred on an individual, it is essential that he be worthy of that trust. Hence the concern that has weighed upon those who impart medical knowledge to their students to teach them, in addition to the art of curing, the duty to serve honestly and kindly. For its part, society has handed over the care and improvement of the health and the life of its members to physicians, who frequently practice without supervision or evaluation and act on the basis of their own moral and scientific judgement. Unfortunately, there are feelings or interests that may disturb those good intentions. In an attempt to transform those good intentions into a commitment, Hippocrates, five centuries before Christ, embodied them in his oath and later Maimonides wrote in a prayer: 'Let it be that I see no more in he who suffers than the human being'(1).

When the responsibility to preserve or restore health is not limited to the individual but extends to the community, the decisions taken call for even more judgement and moral considerations, if that is possible. The public health officer undoubtedly takes greater responsibility in his decisions than the physician, despite the fact that he may not be personally involved in the treatment of patients.

The concern to establish ethical standards, which goes back to the Code of Hammurabi, 2,500 years before Christ, reached a

* A Spanish version of this paper was published, with the agreement of CIOMS, in 'Edución Médica y Salud', Vol. 15, No. 1, 1981.

crisis in 1947 with the Nuremberg judgements, when it became clear that sometimes political and social pressures may exercise such influence on individuals that they are led to commit criminal acts by using the power that has been placed in their hands with alleged scientific interest as an excuse. The growing interest in ethical studies is also due, according to W. Reich,(2) to the fact that 'the issues of bioethics have captured the contemporary mind because they represent major conflicts in the area of technology and basic human values, those dealing with life, death, and health. Although many bioethical issues have been discussed since ancient times, the introduction of modern biomedical technologies, especially since the 1950s, has intensified some age-old questions and has given rise to perplexing new problems - the prolongation of life, euthanasia, prenatal diagnosis and abortion, human experimentation, genetic interventions and reproductive technologies, behaviour control and psychosurgery, the definition of death, the right to privacy, allocation of scarce health resources, and dilemmas in the maintenance of environmental health.'

Today we are living in critical times, in which all values are being called into question; those based on moral or religious standards which were formerly considered irrefutable are at present matters of dispute. The challenges new technologies have thrown down to man have made it necessary to revise our ideas and to adapt them to situations that must be solved. It must be borne in mind that health problems extend beyond the medical ambit and call for the assistance of multidisciplinary teams, in which the responsibility of the physician is shared with other professionals, as is the decision to adopt ethical standards that should be followed in the future. This is reflected in the concept inherent in the English word 'bioethics', which is a much broader term than medical ethics and goes far beyond the problem stemming from the physician-patient relationship to include all health professionals. Biomedical and behavioural research, for example, which may or may not be connected with therapeutic aspects and which may be conducted by professionals in different disciplines, who frequently use individuals or communities, call for special attention; this is because of the greater responsibility their conduct implies, since they frequently expose even healthy persons to risk.

The term 'bioethics' also includes all the ethical problems associated with social aspects, such as public health,

occupational health, international health and population control activities, and even embraces ecological and animal health problems (2).

We are not unaware of the concerns of the various medical and paramedical professional associations, which have been embodied in various declarations such as the Declaration of Geneva issued by the General Assembly of the World Medical Association in 1948 and the International Code derived from it, which was approved in London in 1949 (3). Some medical associations have been particularly active in updating their codes of ethics, including the American Medical Association (4) and the British Medical Association (5), and have adopted declarations in defence of patients, for example, the declaration issued by the American Hospitals Association in 1973 (2) or the legislation governing patients' rights issued by the United States Department of Health, Education and Welfare, which took effect on 2 December 1974 (6). On other occasions, efforts have been made to protect the most vulnerable groups of patients, as in the Declaration of General and Special Rights of the Mentally Retarded published by the International League of Societies for the Mentally Handicapped (2) or the Pediatric Bill of Rights recommended by the National Association of Childrens Hospitals and Related Institutions in 1975 (7). In 1973 the International Council of Nurses also approved a nursing code and in 1976 the American Nurses Association revised the code it had adopted earlier in 1950. It established a new code which we would go as far as to consider one of the most valuable models to be followed by similar associations, and which may very well be supplemented by a publication from the same association entitled Human Rights Guidelines for Nurses in Clinical and Other Research (8). This establishes the freedom of decision of nurses to participate in medical experiments with full awareness of their obligations towards patients. The American Associations of Pharmacists, Psychiatrists, Psychologists and Dentists have followed the same procedure and have prepared their own code of ethics.

In Latin America, the concern to regulate medical ethics made itself felt at the beginning of this century. Outstanding among those efforts is what is known as the Codigo Razetti (9) promulgated by the National Academy of Medicine of Venezuela in 1918, which was followed by the codes of Colombia in 1919 and of Peru in 1922, as well as by that adopted by the Sixth Latin American Medical Congress in Havana in 1922 with minor amendments.

The same holds true of the code adopted by the Brazilian Medical Association in 1931. It should be noted that the Codigo Razetti emphasized the fact that there are rules of medical deontology that apply to every medical association that includes physicians, surgeons, pharmacists, dentists, midwives, interns, and nurses.

The standards governing research on health problems, in which human beings participate as the subjects of experimentation or observation, are a matter of special concern both to health personnel and to the scientific community and the society in which they practice, and this concern is also shared by international health organizations. As I have already stated, when the case of the United States versus Karl Brandt was judged by the Military Tribunal of Nuremberg, the conscience of the world was awakened and found some response to its concern in which is known as the Nuremberg Code, a basic decalogue that guarantees the safety of subjects who voluntarily submit to experiments. Years later, what is known as the Helsinki Declaration, which was issued by the XVIIIth World Medical Assembly in 1964, and its revision in Tokyo by the XXIXth Assembly in 1975, established standards not only for experiments on volunteers but also for clinical trials on patients undergoing treatment. The Tokyo amendment sets forth more explicitly the conditions that should govern the experiment and adds that the results of research that does not meet these requirements should not be accepted for publication in scientific reviews. The Tokyo meeting also stipulated that it was necessary for the research protocols to be reviewed by an independent committee specially appointed to consider, comment on and guide research.

We shall not go further into the conditions of experimentation mentioned by those fundamental codes; we only wish to point out that, in each research project, there are special features that cannot be foreseen in any code of ethics and may escape the most experienced research worker even though he has placed the best goodwill in his protocol. In order better to cover that possibility, and to safeguard the interests not only of the community or the individual subject to risk, but even the investigator himself, committees to review the ethical aspects of research should be established at institutional, national and even regional levels, as has been recommended by our Organization.

Since its foundation, the World Health Organization has considered it one of its responsibilities to ensure the adoption of ethical standards, and, since 1976, it has entrusted to the

CIOMS Advisory Committee on Bioethics, whose Chairman is Dr Curran, the study of problems relating to this important aspect of health activities. This Committee will, we hope, produce guidelines for the scientific and professional communities, as well as for the governments of the countries that make up WHO. The information that it has obtained from the advanced countries and developing countries of the world will constitute a major contribution to the selection of the standards to be recommended.

The Pan American Health Organization, in turn, has undertaken a number of relevant activities, including since 1977 national and subregional meetings on regional health research policies. The agenda of these meetings always include the topic of ethics, and we have found that the scientific communities and the governments have felt sufficiently encouraged to revise their ethical standards for research. Argentina, Costa Rica, Colombia and Uruguay have established study groups for that purpose, and other countries intend to follow that example.

Within PAHO this concern was also widespread, and in 1974 the Review Committee on Research Ethics was established, as were committees in the Regional Centres, among which that of the Institute of Nutrition of Central America and Panama (INCAP) warrants mention because of its extensive experience. In 1979, the PAHO Advisory Committee on Medical Research appointed a sub-committee, composed of Dr Thomas Weller and Dr Hernando Groot, which made a study and reviewed the PAHO Standards and Control Methods for Protecting Human Subjects used in Medical Research; they presented it for approval to the Committee in June 1980 and the resultant recommendations were presented to the Director of the Pan American Sanitary Bureau.

Finally, I should like to emphasize the ethical problems involved in some clinical trials connected with the use of new drugs or biological products. There is no doubt that these trials are essential and that, although many previous trials are carried out on the most appropriate experimental animal, they cannot fully reproduce the human response. The same applies to the toxic or undesirable effect of a drug or biological product. Accordingly, clinical trials must be carried out with the greatest possible safety for the individuals or populations that are the subjects of the trial. In the countries in our hemisphere that are most advanced in their health legislation, there are regulations that specify the conditions that should govern these trials; in other countries, there is no legislation or the existing regulations are

not sufficiently explicit and result in failure to comply with the pertinent legal provisions. We believe that the most important way of ensuring the appropriate conduct of these trials is to create awareness in the physicians and professional personnel that conduct them of the responsibility incumbent upon them. But there will be even more of a guarantee if a requirement for each trial is the conduct of preclinical tests on experimental animals, safety measures for the subjects being studied, the establishment of appropriate records and/or reports, indications about obtaining the consent of the subjects and supervision by an Ethics Review Committee located at the most advisable supervisory level. One of the most important objectives of our Organization is to stimulate the establishment of conditions that, without hampering the progress of science, will ensure that the health and welfare of the inhabitants of all the countries of the Region are safeguarded.

PAHO/WHO has demonstrated special concern in ensuring that the benefits of scientific progress reach the communities most affected by health problems. The development of new effective drugs for the control of diseases affecting large population groups, their testing to ascertain their effectiveness and to make them accessible to the groups affected, may be the purpose of large-scale programmes. Such tests of biological products have already been sponsored by WHO; they were conducted in accordance with the strictest scientific and ethical standards and disclosed the effectiveness of certain vaccines. Some small-scale programmes on drugs have also been conducted. The WHO Special Programme of Research and Training in Tropical Diseases has established a mechanism for the coordination of its scientific working groups and the pharmaceutical industry so as to promote the production of low-cost antiparasitic drugs. The great research portential of the pharmaceutical industry and the technical and operational facilities of WHO may be pooled to ensure that the clinical trials of new drugs are carried out without commercial interest and for the benefit of the populations affected. The guarantee that PAHO/WHO can offer as regards the veracity of the results and the observance of the most exacting ethical principles can solve the problem of ascertaining the effectiveness or safety of drugs in trials carried out on human beings, which is already a constraint on the development of new therapeutic agents.

The cost of drugs undoubtedly influences the widespread use of an effective product; accordingly, PAHO included in the Expanded Programme on Immunizations the establishment of a

revolving fund which will enable the governments to purchase such products. The experience the operation of this programme has provided the Organization has now made it possible to expand it and thus to purchase biological reagents and drugs for health care programmes at a lower cost. It is not our intention to interfere with the drug trade but, within the framework of the strictest standards of medical ethics and even of commercial ethics, any cooperation with the pharmaceutical industry that benefits the peoples of the Member Countries will be welcomed.

Also connected with the topic of this Meeting, although marginally, is the problem of information on the quality and safety of drugs. Through the distribution of the Medical Letter, PAHO has for several years provided therapeutical guidance to the physicians of the Region. Since this publication has become commercial, we are replacing it by the Drug and Therapeutics Bulletin and are studying the possibility of using the information generously provided by the equivalent publication of the Mexican National Academy of Medicine, so that physicians receive the most useful information, provided with no commercial bias and in accordance with the strictest standards of medical ethics.

I should like to add something about the topic of this Conference. There is no doubt that, although medical deontology has been eliminated as a course in most medical schools, in any clinical course a good professor introduces ethical ideas and recommendations as an indispensable complement of the scientific knowledge he passes on to his students. The greater his concern to train good physicians, the greater his insistence on transmitting those ethical standards which he himself believes in and applies. We have already mentioned the Hippocratic oath as one of the sets of ethical standards that have had the greatest influence in the Western world, as did the Caraka Samhita in Hindu medicine. Western religions have also endeavoured to influence the physicians who profess them to follow the ethical precepts their moral codes teach. Catholics, Protestants and Jews have vied with one another in this endeavour.

In recent years, universities and schools of medicine have shown some interest in providing students with an opportunity to become familiar with ethical principles through sessions specially devoted to them or formal elective courses. This healthy tendency is to be observed in Sweden, Holland, Great Britain, Spain and the United States of America, as well as in socialist countries such as Hungary and the Soviet Union. In the last mentioned country, the Oath of the Soviet Physician (10), which all physicians and

medical students of that country must observe, was approved in March 1971 by the Presidium of the Supreme Soviet. The Institutes of Ethics founded in some countries, such as the Institute of Society, Ethics and the Life Sciences in Hastings-on-Hudson near New York or the Kennedy Institute of Ethics at Georgetown University in Washington, D.C., to mention only a few of the various institutes that exist in prestigious universities, are also enthusiastically devoting themselves to disseminating knowledge about ethics. But it is still medical professors on whom falls the greatest responsibility for the ethical training of future physicians, and the most prestigious medical associations such as this illustrious and century-old National Academy of Medicine of Mexico, are those that should support any such effort with their scientific and moral authority.

I should like to conclude my address to this important forum by quoting the words of Dr Armando Roa Rebolledo, the distinguished professor of medical ethics of the University of Chile: 'The ethics of generosity is what motivates the physician to study, to engage in research, to reach out his hand with love, to spare no effort in his care, to feel deep devotion towards his teachers, colleagues, students and all who work with him, so that his aid to his fellow men may be as effective as possible, without exacerbating the misfortunes caused by illness itself through his ignorance, the revelation of a secret, the undue use of drugs and psychotherapy or his arrogance. He who does his work in this way, as the profession has demanded since time immemorial, shall be dignified by attaining the state of grace reserved for the faithful servants of life.' (11)

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Propósitos de la Conferencia - ETICA MEDICA Y EDUCACION MEDICA

Héctor Acuña

Teniendo en cuenta que tanto la investigación clínica como la educación médica desempeñan una función de trascendental importancia para la salud de los pueblos, trataré de analizar a continuación la relación que existe entre estas disciplinas y la salud pública.

Cuando se otorga a un individuo tanta responsabilidad y confianza como la que se deja en manos del profesional de la medicina, es indispensable que quien reciba esa confianza sea digna de merecerla. De ahí la preocupación de aquellos que han entregado el saber médico a sus discípulos y que además de haberles enseñado el arte de curar, les han inculcado el deber de prestar servicios con honestidad y bondad. La sociedad, por su parte, ha entregado al médico el cuidado y mejoramiento de la salud y la vida de sus miembros, y éste, con frecuencia, ejerce sus funciones sin supervisión ni evaluación y actúa de acuerdo con su buen criterio científico y moral. Desafortunadamente, existen sentimientos e intereses que pueden pertubar esas buenas intenciones, y en un intento de transformarlas en un compromiso, cinco siglos antes de Cristo, Hipócrates las plasmó en su juramento, y posteriormente Maimónides en una plegaria: 'Haz que en el que sufre yo no vea más que al ser humano'(1).

Cuando la responsabilidad de conservar o restaurar la salud no se limita al individuo sino que se extiende a la comunidad, podríamos decir que las decisiones que se tomen requieren aún mayor juicio y consideraciones de carácter moral, si es que esto fuera admisible. Al profesional de la salud pública le corresponde indudablemente una mayor responsabilidad en sus decisiones, a pesar de que pueda ser ajeno al trato personal con el enfermo.

La preocupación por establecer normas éticas - que se remonta al Código de Hammurabi 2500 años antes de Cristo - hace crisis en 1947 con los juicios de Nuremberg, en donde se pone en evidencia que las presiones político-sociales a veces ejercen tal influencia en los individuos que los llevan a cometer actos criminales valiéndose del poder que se ha puesto en sus manos y con el pretendido interés científico como exculpante.

Se ha dicho recientemente (2) que también contribuye a acrecentar el interés por los estudios sobre ética:

> '... el que en los últimos tiempos se hayan presentado mayores conflictos en el área de la tecnología y los valores humanos básicos, como aquellos que tratan con la vida, la muerte o la salud. Aunque muchos conceptos bioéticos han sido discutidos desde los tiempos más antiguos, con la introducción de las modernas tecnologías biomédicas, especialmente desde 1950, han resurgido viejas inquietudes y se han originado nuevos e inquietantes problemas, tales como la prolongación de la vida y la eutanasia, el diagnóstico prenatal y el aborto, la experimentación en humanos, las intervenciones genéticas y las tecnologías en problemas de reproducción, el control del comportamiento y la psicocirugía, la definición de la muerte, el derecho a lo privado, la asignación adecuada de los recursos para la salud cuando ellos son escasos y los dilemas sobre la conservación de las condiciones de salud ambiental.'

Vivimos hoy en un mundo en crisis en el que todos los valores se están enjuiciando; los que antes se consideraban conceptos irrebatibles apoyados por normas morales o religiosas, actualmente son motivo de controversia. El reto que las nuevas tecnologías han puesto frente al hombre ha hecho necesario revalorar los conceptos y adecuarlos a las situaciones que se tienen que resolver. Hay que tomar en cuenta que los problemas de salud han rebasado la esfera médica para requerir el concurso de equipos multidisciplinarios en donde la responsabilidad del médico es compartida con otros profesionales, así como la decisión de adoptar las normas éticas que se deban seguir en el futuro. A ello responde el concepto que engloba el término de 'bioética', mucho más amplio que el de 'ética médica' y que va más allá de los problemas que origina la relación médico-paciente para incluir a todos los profesionales de la salud. Las investigaciones biomédicas y del comportamiento, por ejemplo, que pueden tener o no relación con aspectos terapéuticos y que pueden ser realizadas por profesionales de distintas disciplinas, quienes emplean con frecuencia individuos o comunidades, requieren una atención particular debido a la mayor responsabilidad que implica realizarlas, en muchas ocasiones exponiendo al riesgo aun a personas sanas. El término bioética incluye también a todos los problemas éticos que se relacionan con aspectos sociales, tales como las actividades de salud pública, salud ocupacional, salud internacional, y abarca problemas ecológicos y de salud animal.

No desconocemos las preocupaciones de diversas asociaciones profesionales de médicos y paramédicos, que han sido plasmadas en declaraciones tales como la Declaración de Ginebra, emanada de la Asamblea General de la Asociación Médica Mundial en 1948 y el Código Internacional que de ella se derivó y que fue aprobado en Londres en 1949. (3) Algunas asociaciones médicas se han ocupado de actualizar sus códigos de ética, entre éstas la Asociación Médica Americana (4) y la Asociación Médica Británica (5); otras han optado por declaraciones en defensa de los pacientes, como por ejemplo la emitida por la Asociación Americana de Hospitales en 1973 (6) o la reglamentación sobre estos derechos por la Secretaría de Salud, Educación y Bienestar de los Estados Unidos de América en 1974 (7). En otras ocasiones se ha tratado de proteger a los grupos más desvalidos de pacientes, como en la Declaración de Derechos Generales y Especiales de los Retrasados Mentales, publicada por la Liga Internacional de Sociedades para los Deficientes Mentales (8) o la Declaración de Derechos en Materia de Pediatría recomendada por la Asociación Nacional de Hospitales Infantiles e Instituciones Afines. (9) El Consejo Internacional de Enfermeras aprobó un Código para Enfermeras en 1973 (10) y en 1976 la Asociación Americana de Enfermeras revisó el que había adoptado en 1950 y estableció otro que puede considerarse como uno de los modelos más valiosos a seguir por asociaciones similares. Esta obra puede complementarse con la publicación de la misma Asociación que presenta una 'Guía de derechos humanos para las enfermeras en investigaciones clínicas y otras investigaciones' (11), que establece la libertad de decisión de la enfermera para participar en experimentos médicos con plena conciencia de sus obligaciones para con el paciente. Las Asociaciones Americanas de Farmacéuticos, Psiquiatras, Psicólogos y Dentistas también han elaborado sus códigos de ética.

En los países latinoamericanos de la Región, el interés por normar la ética médica se ha manifestado desde principios del presente siglo, a raíz de lograda la independencia de nuestros países. Entre los esfuerzos relizados en ese sentido es señero el llamado Código Razetti (12), promulgado por la Academia Nacional de Medicina de Venezuela en 1918, y al que siguieron los códigos de Colombia en 1919 y Perú en 1922, así como el adoptado por el Sexto Congreso Médico Latinoamericano reunido en La Habana en 1922, que prácticamente lo acogió con ligeras modificaciones. Lo mismo puede decirse del adoptado por el Colegio Médico Brasileño en 1931. Debe señalarse que el Código Razetti insiste en que hay reglas de deontología médica que son aplicables a toda la corporación médica, que incluye médicos, cirujanos, farmacéuticos, dentistas, obstetras, internos y enfermeras.

Las normas que deben regir la investigación de los problemas de salud en la que participan seres humanos como sujetos de experimentación u observación son motivo de especial preocupación para el personal de salud, la comunidad científica y la sociedad en que actúan, así como para las organizaciones internacionales de salud, como la OPS y la OMS.

Al iniciar esta exposición nos habíamos referido a los juicios de Nuremberg. En esa ocasión, cuando el Tribunal Militar juzgó el caso de los Estados Unidos vs Karl Brandt, se despertó la conciencia del mundo, que encontró cierta acogida a su inquietud en el llamado Código de Nuremberg, que garantiza la seguridad de los individuos que voluntariamente se someten al experimento. Años después, la llamada Declaración de Helsinki, producto de la XVIII Asamblea Médica Mundial en 1962, y su revisión hecha en Tokio por la XXIX Asamblea en 1975, establecieron normas para la experimentación con voluntarios y para los ensayos clínicos en enfermos sujetos a tratamiento. En la enmienda de Tokio se hacen más explícitas las condiciones que debe cumplir el experimento y se agrega que los resultados de las investigaciones que no cumplan con esos requisitos no deben ser publicados en las revistas científicas. También se señala que los protocolos deben ser revisados por un comité independiente especialmente designado para la consideración, comentario y guía de la investigación.

No vamos a abundar más en los detalles relativos a las condiciones de experimentación señaladas por estos códigos fundamentales. Sólo quisiéramos señalar que cada proyecto de investigación tiene características propias que no pueden ser previstas de antemano en ningún código de ética y que pueden escaparse al investigador más experimentado, aunque haya puesto su mejor buena fe en la elaboración del correspondiente protocolo. En vista de ello, y para salvaguardar los intereses de la comunidad y del individuo expuesto a riesgo así como del propio investigador, es conveniente el establecimiento de comités revisores de aspectos éticos de la investigación en niveles institucionales, nacionales y aun regionales, como lo ha venido recomendando nuestra Organización.

La Organización Mundial de la Salud, desde su fundación, ha considerado que una de sus funciones es velar por la adopción de normas éticas, y desde 1976 ha confiado al Comité Asesor sobre Bioética del Consejo de Organizaciones Internacionales de las Ciencias Médicas (COICM) el estudio de los problemas relacionados

con este importante aspecto de las actividades de salud. Esperamos que de los resultados de las labores de este Comité emanen guías que orienten a la comunidad científica y profesional, así como a los gobiernos de los países que integran la OMS. La información que se ha recogido de los países más avanzados del mundo y de los países en desarrollo aportará una gran experiencia en la selección de normas a recomendar.

La Organización Panamericana de la Salud, por su parte, ha emprendido una serie de actividades aprovechando las reuniones nacionales y subregionales sobre políticas nacionales de investigación en salud que se han venido realizando desde 1977. La agenda de estas reuniones siempre incluye el tema de ética, y hemos podido comprobar que la comunidad científica y los gobiernos se han sentido lo suficientemente interesados como para revisar sus normas de ética en la investigación. Argentina, Costa Rica, Colombia y Uruguay, por ejemplo, han establecido grupos de estudio con este propósito y otros países tienen la intención de seguir ese ejemplo.

En el seno de la OPS también existe gran interés por el asunto, y en 1974 se creó el Comité de Revisión sobre Etica de las Investigaciones, así como los comités técnicos asesores en los centros regionales, entre los cuales el del Instituto de Nutrición de Centro América y Panamá se destaca por su mayor experiencia. En 1979, el Comité Asesor sobre Investigaciones Médicas de la OPS designó un subcomité que se encargó de revisar las Normas y Métodos de Control de la OPS para Protección de Sujetos Humanos Empleados en la Investigación Médica, que fueron sometidas a la consideración del Comité en su reunión de junio de 1980 y de la cual se derivaron recomendaciones que se presentaron al Director de la Organización.

Quisiera hacer énfasis en los problemas éticos que se presentan en algunos ensayos clínicos relacionados con el empleo de nuevos medicamentos o productos biológicos. Es indudable que estos ensayos son imprescindibles y que por más pruebas previas que se realicen en animales de experimentación, éstas no podrán reproducir íntegramente la respuesta humana. Lo mismo podríamos decir en relación con el efecto tóxico o indeseable de los medicamentos. Por lo tanto, es preciso que las pruebas clínicas se realicen con el máximo de seguridad posible para los individuos o las poblaciones sujetas a la prueba. En los países que en nuestro Continente han avanzado más en su legislación sanitaria, existen reglamentos que disponen las condiciones que deben exigirse para estas pruebas;

en otros no existe legislación alguna o la reglamentación existente no es bastante explícita, lo que redunda en la falta de cumplimiento de las disposiciones legales correspondientes. Creemos que el paso más importante para garantizar la realización adecuada de estas pruebas es crear conciencia en los médicos y en el personal que las ejecuta sobre la responsabilidad que les compete. Y mayor garantía habrá si en cada ensayo se exigen pruebas preclínicas en animales de experimentación, medidas de seguridad para los sujetos en estudio, establecimiento de cuestionarios e informes adecuados, indicaciones sobre la obtención del consentimiento de los sujetos, y la supervisión de un comité de revisión de ética en el nivel más conveniente de supervisión. Uno de los objetivos más importantes de nuestra Organización sería estimular el establecimiento de estas condiciones que, sin entorpecer el progreso de la ciencia, garanticen la salud y el bienestar de los habitantes de todos los países de la Región.

La Organización se ha mostrado especialmente interesada en hacer llegar los beneficios del progreso científico a las comunidades afectadas por los problemas de salud. El desarrollo de nuevos medicamentos efectivos para combatir las enfermedades que afectan a grandes grupos de población, el ensayo de los mismos para comprobar su efectividad y el hacerlos accesibles a los grupos afectados podrá ser el objetivo de grandes programas. Ya existen antecedentes de ensayos de biológicos de gran magnitud patrocinados por la OMS, siguiendo las más estrictas normas científicas y éticas, que dieron luz sobre la efectividad de algunas vacunas; también se han realizado algunos programas en menor escala con relación a medicamentos. El Programa Especial de Investigaciones y Enseñanzas sobre Enfermedades Tropicales de la OMS ha establecido un mecanismo de coordinación entre sus grupos científicos de trabajo y la industria farmacéutica, con objeto de promover la producción a bajo costo de medicamentos antiparasitarios. El gran potencial de investigación de la industria farmacéutica y las facilidades técnicas y operativas de la OMS pueden conjugarse para que los ensayos clínicos de nuevos medicamentos se realicen sin interés comercial y en beneficio de la población afectada. La garantía que la OPS y la OMS pueden ofrecer en cuanto a la veracidad de los resultados y la observación de los principios éticos más exigentes puede resolver el problema de la comprobación de la efectividad e inocuidad de los medicamentos en ensayos realizados en seres humanos, lo que ya está siendo una limitación en el desarrollo de nuevos agentes terapéuticos.

El costo de los medicamentos indudablemente influye en la amplia utilización de un producto eficaz. Por eso la OPS incluyó en el Programa Ampliado de Inmunización la creación de un Fondo Rotatorio que permitiera la adquisición de vacunas por los gobiernos. La experiencia que la operación de este programa ha proporcionado a la Organización ha permitido ahora ampliarlo para adquirir reactivos biológicos y medicamentos a menor costo para los programas de atención de salud. No pretendemos interferir en el comercio de los medicamentos, pero, dentro de las más estrictas normas de ética médica, y aun de ética comercial, cualquier cooperación con la industria farmacéutica que redunde en beneficio de las poblaciones de los países tendrá buena acogida.

También relacionado con el tema de la reunión, aunque en forma marginal, está el aspecto relativo a información sobre la calidad y la inocuidad de los medicamentos. La OPS, mediante la distribución de la Carta Médica, ha proporcionado desde hace algunos años orientación terapéutica a los médicos de la Región. Al comercializarse esta publicación, la estamos sustituyendo por el Boletín de Medicamentos y Terapéuticos (traducción del Drug and Therapeutics Bulletin), y se está estudiando la posibilidad de aprovechar la información ofrecida generosamente por la publicación equivalente de la Academia Nacional de Medicina de México para proporcionar el médico de la Región, sin ningún interés comercial, la información más útil y que cumpla las normas más rigurosas de ética médica.

Volviendo al tema de esta reunión, quisiera agregar que es indudable que aunque en la mayoría de las escuelas de medicina se ha eliminado la deontología médica como una asignatura del currículo, en cualquier cátedra de clínicas un buen profesor introduce conceptos y recomendaciones éticas como complemento indispensable de los conocimientos científicos que entrega a sus alumnos. Mientras mayor sea su preocupación por formar buenos médicos, más es su insistencia en transmitir esas normas éticas en las cuales él mismo cree y aplica. Ya citamos el juramento hipocrático como uno de los conjuntos de normas éticas que mayor influencia han tenido en el mundo occidental, como lo fuera 'Caraka Samhita' en la medicina hindú. Las religiones occidentales también se han preocupado por influir en los médicos que las profesan para que sigan los preceptos éticos que sus códigos morales les señalen; católicos, protestantes y judíos han rivalizado en este empeño.

En los últimos años ha surgido cierto interés en las universidades y escuelas de medicina por brindar al estudiante la oportunidad de que se familiarice con principios éticos, a través de sesiones especiales o cursos formales de tipo electivo. Esta sana tendencia se observa tanto en países como Suecia, Países Bajos, Reino Unido, España o los Estados Unidos de América, como en los países socialistas, tales como Hungría o la Unión Soviética. En este último país el Presidium del Soviet Supremo aprobó en 1971 el Juramento del Médico Soviético (13), que deben acatar todos los médicos y estudiantes de medicina de ese país. Los institutos de ética fundados en algunos países - como el Institute of Society, Ethics and Life Sciences en Hastings-on-Hudson, cerca de Nueva York, o el Kennedy Institute of Ethics de la Universidad de Georgetown, en Washington, D.C., por citar sólo dos entre los varios institutos existentes en prestigiosas universidades - también se dedican con entusiasmo a difundir conocimientos sobre ética. Sin embargo, es aún en los catedráticos de medicina en quienes recae la mayor responsabilidad en la formación ética de los futuros médicos y siguen siendo las asociaciones de mayor prestigio médico, como lo es esta centenaria e ilustre Academia Nacional de Medicina de México, las que con su autoridad científica y moral deben respaldar cualquier esfuerzo.

Quisiera terminar mi presentación ante este importante foro repitiendo unas palabras del Dr Armando Roa Rebolledo, notable profesor de ética médica de la Universidad de Chile:

> 'La ética de la generosidad impele al médico al estudio, a la investigación, al gesto cariñoso, al cuidado extremo, a la devoción intensa hacia maestros, colegas, discípulos y a cuantos laboran con él, a fin de que la ayuda al prójimo sea lo más eficaz posible, sin aumentar por ignorancia, ruptura de secreto, uso indebido de fármacos y psicoterapias u orgullo personal las desventuras provocadas por la enfermedad misma. Quien obra así, en acuerdo a lo solicitado a su vocación desde el fondo de los tiempos, se dignificará alcanzando la gracia destinada a los fieles servidores de la existencia.' (14)

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FIRST SESSION

ETHICAL REVIEW OF CLINICAL RESEARCH

Moderator: Alfred Gellhorn

ETHICAL ISSUES IN HUMAN EXPERIMENTATION

John Ladd

Ethical issues relating to human experimentation are complicated, controversial and confused. To begin with, they are complicated because the term 'human experimentation' is used to cover such an enormous variety of procedures: it applies to many different kinds of experiment, to many quite different kinds of subject, to procedures undertaken for quite different kinds of reasons and under quite different conditions. Because of this wide variety of procedures gathered together under the single term 'human experimentation', it would be foolish to try to make any general statements about the ethics of experimentation that might be expected to hold for every situation. In order to pare down the list for the purposes of this paper, I shall concentrate on what is generally known as non-therapeutic experimentation, that is, experimentation whose purpose is scientific rather than therapeutic, and only as it applies to adults who are competent.

My theme will be that there is no single 'philosopher's stone' that can be used across the board to tell us what is right and wrong in human experimentation per se and that ethical aspects of human experimentation are dependent on the context, that is, on the specific character and conditions of the experimentation in question. Along the same lines, I shall argue that there is no special ethics of experimentation, that is, no special set of ethical principles that apply specifically and uniquely to human experimentation as distinct from other human activities. I should begin by admitting quite frankly that I find almost everything that has been written on the subject of the ethics of human experimentation to be rubbish; even if not all of it is rubbish, most of it is, in any case, very confused. The first part of my paper will be devoted to calling attention to some of these confusions.

Confusion 1: Ethics and Law not Properly Distinguished and Separated

The first confusion is that of moral questions about experimentation with legal questions. (1) Legal questions about

(1) Some of the ideas presented here are set forth in greater detail in my 'Legalism and medical ethics', in J.W. Davis, B. Hoffmaster, and S. Shorten, eds., Contemporary Issues in Biomedical Ethics. Clifton, N.J., Humana Press, 1978. Published in a shortened version in The Journal of Medicine and Philosophy, 4, No. 1 (1979).

human experimentation are essentially questions about public regulation: what sorts of public regulation of human experimentation should there be, what sort of activities ought to be regulated, how ought they to be regulated, who should regulate them, and why ought they to be regulated? Regulations are, or at least should be, adopted in order to prevent abuses of one sort or another or, on the other hand, to encourage certain practices. In the USA, the principal institutionalized form of regulation is the so-called Institutional Review Board (IRB); the chief concern of IRBs, from the ethical point of view, appears to be the protection of the rights of the experimental subjects, particularly through the requirement of 'informed consent'. (2)

The notion of 'informed consent' is, of course a complicated one and I do not have the expertise to comment on it in detail. It is not, however, a moral notion but a legal one, derived historically from customary legal conceptions relating to trespass. Its chief social function is to provide some sort of legal control over the power exercised by physicians over their experimental subjects, over the conditions of experimentation, and over the risks and benefits to the subject of the experimentation. Because physicians often assume that 'informed consent' is a moral rather than a legal requirement, they fail to recognize its real basis, purpose and limits. As a legal requirement, it is accepted grudgingly and disdainfully and often carried out merely pro forma. From a strictly moral point of view, the concept of 'informed consent' is a confused one; its ethical basis and scope are not at all clear.

If we take a rather sceptical view of the legal approach to human experimentation, we might make the assumption that 'informed consent' is a necessary and sufficient condition for rightful human experimentation to be a reflection of a bourgeois conception of the relationship between experimenter and experimental subject, the former playing the role of the entrepreneur and the latter the role of the exploited worker. The notion of informed consent ensures a bourgeois kind of freedom that allows the experimental subject to be free to consent to being an experimental subject or to refuse - the kind of freedom that a poor person has when he is free to buy a Cadillac or to refuse to buy it, or free to take a job or to refuse to take it - a kind of freedom that completely ignores a poor person's real inability to pick and choose any of these things. Informed

(2) Some writers, it should be noted, take a more cynical view of the function of IRBs.

consent, one might conclude, provides a built-in rationale for the exploitation of underprivileged and captive populations, such as poor people, prisoners and inmates of mental institutions. Prisoners, it is often alleged, should have the right to consent to be experimental subjects, just as they have the right to refuse. Indigenous populations living in poverty ought to have the right to participate in experimental drug research just as they have the right, the theoretical right, to refuse. In all such cases, the freedom to choose, represented by the notion of informed consent, is just a cover-up for the freedom of experimental entrepreneurs to exploit. Law, in this case, serves to protect the interest of the rich to exploit the poor.

I do not know whether this kind of analysis can be defended; I mention it only in order to bring out the point that the notion of informed consent does not, in certain cases at least, provide a sufficient basis for the morality of an experimental project. Another, perhaps more philosophical, objection is that it construes the ethical issues in adversarial terms as arising out of conflicts of interest between experimental subjects and medical investigators.

In addition to these considerations, the almost exclusive emphasis on informed consent in the evaluation of experimental project leads to questions about the purpose and quality of the projects being ignored, although they should surely be taken into account in determining the ethicality of experiments. Experimental projects that exploit helpless indigent populations in the furtherance of the vested interests of institutions such as drug companies, do not seem to be as justified ethically as those that aim directly at the discovery of a cure for some sort of devastating disease. It seems quite obvious that in order to be justified ethically, a project should have scientific (and social) merit as well as being conducted according to principles involving informed consent.

Far be it for me to say that, in an imperfect world, these legal requirements are to be despised. But from a philosophical point of view, not only are they artificial and legalistic, but they also do not seem to relate to ethics as such, for ethics, in my view, is based on a moral conception of the proper relationship of human beings to each other. On the contrary, the legalistic view under discussion construes the relationship between the experimenter and experimental subject, for the most part, as a business relationship, perhaps even a contractual

relationship, in which the subject performs his part for a consideration, usually financial remuneration of some kind. There are, of course, important ethical issues involved here, but they are not uniquely related to human experimentation but to the much larger issues of the exploitation of the have-nots by the haves.

Confusion 2: Ideologies and Mythologies

The second source of confusion in discussions of the ethics of human experimentation is ideological. Speaking in extremes, we have a confrontation between those who are anti- and those who are pro-experimentation. (I shall call them restrictionists and enthusiasts, respectively.) Both sides are absolutist and represent what is clearly a 'one track' approach to the problems of human experimentation. Without mentioning names, which I am sure are well known to all of you, there are some writers, calling themselves 'ethicists', who maintain that any sort of human experimentation is a threat to human dignity, that it is an abrogation of the 'sacrosanctity of the individual'. A theological version of this position is found in the traditional notion that experimentation, especially when it relates to fundamental aspects of human life and reproduction, constitutes an impingement on the designs of a Divine Providence; to experiment with a view to discovering ways of changing nature is an impious act of human pride; it is 'playing God'. As one author says, human experimentation threatens us with the 'erosion of moral values' and it is an area where 'sin and guilt' can hardly be avoided.

The dogmatic character of the anti-experimentation ideology of the restrictionists is matched by that of the pro-experimentation ideology of the enthusiasts, who believe in the ethics of scientific progress. According to this ideology, variously formulated, scientific progress is invariably and inevitably beneficial to mankind; indeed, it is sometimes believed to be the summum bonum of mankind. (3) As a corollary, it is asserted that any addition, however miniscule, to the sum total of scientific knowledge advances human progress. The proponents of this position point to the enormous benefits brought to mankind by the discovery of the etiology of infectious diseases, the invention of antibiotics, new medical treatments, and the

(3) See, for example, Jacques Monod, Chance and Necessity. New York, Random House, 1972.

benefits to be anticipated from DNA research. They conclude that the results of any and every kind of medical research will of necessity benefit mankind; and such research, of course, requires human experimentation. Hence, insofar as it is directed at the advance of medical knowledge, human experimentation is, other things being equal, a morally worthy undertaking. It is not only morally permissible; it is morally obligatory. Subjects of human experimentation have an obligation to submit themselves to experimentation and the organs of society have a duty to encourage and facilitate by whatever means necessary the participation, without restriction, of these individuals as subjects in scientific experimentation. Here again, as with the restrictionist ideology, we are dealing with dogmatic affirmations, without supporting arguments, that are based on what can only be called 'blind faith'. Exactly how one would be able to assess critically the claims of the enthusiasts is not at all clear; it should be clear, however, that their reasoning, such as it is, is based on a careful selection of positive evidence and the careful exclusion of counter-instances.

Both ideological positions, restrictionist and enthusiast, suffer from the typical defects of absolutism; for not only are they difficult to defend as absolutist theories, but they also inconsistently bend their absolutist principles to accommodate obvious objections - both admit exceptions for extreme cases. Thus, the restrictionist is generally willing to admit that there are certain crucial cases of human experimentation that it is difficult to conceive of as being wrong and immoral; the enthusiast, for his part, is generally ready to concede that there have been abuses of scientific privilege, notably, the experimentation of the Nazi doctors. But, apart from these concessions, the absolutist positions themselves are unacceptable on a number of other grounds, the principal one being that they try to resolve concrete problems by abstract, vague and inflexible principles, a procedure that requires considerable ethical acrobatics. More importantly, perhaps, both absolutist ideologies ignore the essential connection between medical experimentation on human beings and the relief of human suffering. Reference to compassion, which is a basic ethical virtue, is singularly missing in both ideologies. But without bringing in compassion, it is impossible to arrive at a proper moral evaluation of human experimentation, which may be regarded as a peculiarly human undertaking directed to peculiarly human problems, namely, the relief of suffering.

Confusion 3: Question-begging Formulations of the Problem

The third source of confusion is the question-begging character of prevailing formulations of moral problems relating to human experimentation. Many discussions begin with a question that is very much like the question: when did you stop beating your wife? Some say that the ethical question is how to determine when, if ever, it is permissible to invade another persons's body for scientific purposes unrelated to any benefit that that person might receive from the experiment undertaken on him; and, if and when it is permissible, why it is so. Accordingly, (non-therapeutic) experimentation is defined as doing something to another person's body that is not to his benefit. (4) Carefully disregarding questions about what is and what is not to a person's benefit, the restrictionist considers experimentation to be simply using 'another human being as a means alone', a means for the advancement of science. It should be clear that when the problem is formulated in ways like these, the question is begged against human experimentation.

On the other hand, the problem might be formulated as a question about whether human experimentation is any different from other kinds of experimentation. Life is full of risks, progress comes from risk-taking; so one might ask what is so special about human experimentation? Why shouldn't a person be asked or required to take risks on behalf of bettering conditions of life for mankind in the future?

If we probe more deeply, we can see that much hinges on the term 'experimentation': for some, it is a pejorative term, raising spectres of little boys experimenting by pulling wings off butterflies, while for others experimentation is part of being human. Perhaps the difference here is between pointless experimentation and purposeful experimentation. But behind these differences there is a much deeper difference in conceptions of experimentation. Physicians, who are inclined to be enthusiasts, are fond of pointing out that all therapy is experimental.

> 'Medical experimentation on human beings, in its broadest meaning and for the good of the individual patient takes place continually in every doctor's office. Hence the general

(4) One might ask in this regard, is donating a kidney to one's own child to save his life not something that is also to one's own benefit?

question of human experimentation is one of degree rather than of kind.' (5)

The assumption seems to be that if experimentation is acceptable in the therapeutic context, then it must be acceptable in other contexts - perhaps because one cannot always draw the line between therapeutic and non-therapeutic experimentation. But that kind of argument is obviously absurd: it is all right, even a good thing, for a surgeon to cut open a person's body to operate for appendicitis. It does not follow, however, that it is all right for him to cut open a person's body for other purposes. Using a knife on a person is not always acceptable simply because it is sometimes acceptable. The non-sequitur of arguments of this kind is palpable, but, unfortunately, such arguments are all too frequent.

It may be worthwhile to examine the concept of experimentation more closely. The core meaning is that of a procedure 'adopted in uncertainty whether it will answer the purpose', that is, it is a procedure that is untried or tentative where the outcome is not certain. Any layman who has ever been treated for a minor ailment knows that his doctor sometimes has to try out several drugs before he finds the right one to cure the ailment. There is obviously nothing wrong with experimentation of this kind, but it is important to observe that the success or failure of the experiment is determined by whether or not the desired outcome, e.g. a cure, is achieved. If the doctor keeps trying new drugs and none of them work, then his experimentation has been a failure.

A purely scientific experiment, however, is not like this. Here the purpose is to determine whether a particular hypothesis is true or false (let us disregard questions about probabilities). An experiment that shows that the hypothesis is false is, in this case, a successful experiment, since its purpose was to test the hypothesis and not to bring about a certain state of affairs. As Karl Popper tells us, the progress of science proceeds by falsification of hypotheses. Hence, even if Popper's is not the whole story, falsification of hypotheses is an important part of the scientific method. (6)

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(5) Quoted from M.B. Shimkin by Geoffrey Edsall in 'A Positive Approach', Experimentation with Human Subjects, ed. Paul Freund. New York, George Brasiller, 1969, p. 278.

(6) See Sir Karl Popper, The Logic of Scientific Discovery. New York, Basic Books, 1959. This is a translation with additions of Karl R. Popper, Logik der Forschung, Wien, 1934.

Now, I submit, the restrictionists take for granted that in human experimentation we are dealing with experimentation in the scientific sense, i.e. where a falsification has as much scientific value as a verification - perhaps more. Hence, in the extreme case, an experiment designed to test a hypothesis that a specific intervention will cure a particular condition would be successful, even if the subject died. As the saying goes 'the experiment was successful, but unfortunately the patient died'. If then the purpose of human experimentation consists of simple hypothesis testing along the lines just mentioned, then we might be justified in claiming that is treating the subject as a means only, by which we mean that we are using his body in the same way that we use chemicals in a laboratory.

We should note, however, that not all experimentation is merely hypothesis testing of the sort just mentioned, not even in science. Where the thing we are experimenting on is very valuable or, perhaps, irreplaceable, we do not take chances with its being destroyed. A good experimental design includes provision for avoiding unnecessary risks. Suppose, for example, that a scientist has spent months cultivating and isolating a certain microorganism and he wants to perform experiments on it; he will certainly try to devise experiments that include safe-guards against the destruction of the precious organism. Falsification may have some scientific value per se, but it is not the only value to be taken into consideration in devising an experimental project. The scientist may wish the organism to reproduce itself and so he will devise experiments that he hopes, although he does not know, will do the job. The experiments are successful if he succeeds in reaching his objective, and they are unsuccessful if the organism is destroyed in the process. Further reflection should make it clear that most experimentation of a practical kind is like this, e.g. the testing of a new model of airplane. We would not say that the test had been successful if an hypothesis about the plane's capability is falsified by the plane crashing! For convenience, I shall call this kind of experimentation practical experimentation, the distinctive thing about it being that its success or failure is determined by whether or not the desired objective is reached.

In practical experimentation, value considerations guide and set limits to the procedures that are adopted, and they define the conditions of success or failure. Except for some very trivial cases, human experimentation is almost invariably

practical experimentation in this sense and its logical character resembles that of the cases already mentioned. Consider, for example, the analogies between testing a therapeutic drug and testing a plane. To begin with, the uncertainty that we want to remove by undertaking the experiment is whether or not the drug or plane that is being tested is better than those currently in use. To make an experiment of the practical kind without some prior assurance that the outcome will not be fatal would simply be both reckless and unscientific. In this respect, the experiments in question are like therapeutic experimentation, which is done on a particular patient with a view to curing a particular disease from which he suffers; the experiment is a success if the patient recovers. The obvious difference between therapeutic experimentation and the other types of experimentation that have been considered here is that a therapeutic experiment is successful if a particular patient recovers, whereas a non-therapeutic experiment will be successful if it generally leads to beneficial results for cases of the same type, e.g. planes of the same model or drugs for patients with the same disease.

The mistaken assumption of the restrictionists is that the principal aim of the scientific inquiry employing human experimentation is the augmentation of the stock of human knowledge, the advance of science; the whole enterprise of scientific progress in pursuit of this aim is regarded by them as 'gratuitous'. The enthusiasts would, of course, agree with this general description of the aim of science and of human experimentation. The difference between the two positions is that the restrictionists hold that this aim is not sufficient to justify human experimentation, at least when it requires the invasion of another person's body, whereas the enthusiasts hold that it does provide ample justification for human experimentation. The point that I want to challenge here is their common assumption that the aim of medical science and, consequently, of human experimentation is simply to increase the pool of human knowledge. As I have argued elsewhere, science for its own sake is not an unquestionable value; and I believe that it can be shown that, if consistently followed, the view that medical science should be pursued for its own sake leads to all sorts of abuses, including the performance of unjustified human experimentation.(7) (Perhaps this mistaken view of the aim of medical science lies behind the abuses of the Nazi doctors.)

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(7) See my 'Are science and ethics compatible' in Callahan, D. and Engelhardt, T., eds. Science, Ethics and Medicine. Hastings, Institute of Society, Ethics and the Life Sciences, 1976.

The alternative to this general position is the view that the aim of medicine and of human experimentation connected with it is, either directly or indirectly, the alleviation, through medical means, of human suffering. Accordingly, the context of medical injury is the context of human needs, in particular, physiological needs, which when not cared for lead to suffering. If we approach medical experimentation on human subjects from this point of view, our understanding of the ethical aspects of human experimentation will be quite different from that of either the restrictionists or the enthusiasts. It follows from this view of medicine and human experimentation that the value and validity of the scientific projects that themselves require the experimentation must always be taken into account in assessing the moral quality of particular experiments involving human subjects. It goes without saying that projects and experiments should be connected in some way, however indirectly, to the alleviation of human suffering in the sense intended here. If we take this approach to human experimentation, then it should become apparent that the current formulation of the problem of human experimentation is much subtler and more complicated than is assumed in the customary formulations adopted by restrictionists and enthusiasts.

Ethical Issues

So far I have argued that the two extreme positions concerning the ethics of human experimentation have muddied our understanding of the real issues. Let us now turn to a more direct consideration of what I take to be the real ethical issues associated with human experimentation. At once, I should warn you that I am not an ethicist; I do not come with ready-made solutions to ethical problems, including the problems connected with human experimentation. All that I can do is to offer you some philosophical thoughts on the subject.

At the very beginning, we must recognize that, as in our other encounters with human beings, scientific experimenters and physicians in general have no special dispensation that allows them to be devious, dishonest, and cruel in their relations with their fellow human beings, however destitute and abject the people they have to deal with may be. Ordinary human sensibilities, which physicians may be expected to possess to the same degree as anyone else, ought to restrain them from committing the kinds of abhorrent immoral acts that we find in notorious cases such as the Sloan-Kettering case, where cancer

cells were injected into elderly, chronically ill patients without their knowledge. (8) The kinds of acts involved in abuses like these are simply violations of the norms of human decency. One does not have to study medical ethics to know that.

Returning to points made earlier, I have argued that the aim of medical experimentation on human subjects should and must be, even if only indirectly, the alleviation of human suffering. The physician, as medical practitioner and as medical scientist, has it within his power to help relieve suffering. Medical science and the development of new medical knowledge increases his power to help those in need of medical treatment and care, and medical experimentation is one of the principal means for increasing a physician's power to help. If medical experimentation on human beings is approached from this point of view and in this context rather than in terms of its contribution to scientific progress in general, then it would seem to follow that the human subject who submits himself to experimentation is not doing something for the scientist who conceives and administers the project, but for those who stand to gain from the results of the experiments, that is, those whose suffering will be relieved. Thus, from the subject's point of view, considered as a moral being, the crucial consideration is and should be the outcome of the experiment as it relates to the suffering of particular, although not yet identified, people. That is why the design of the experiment itself is of critical importance, for it must provide the bridge, so to speak, between the experimental subject and the unknown sufferers he is helping. If the project is poorly designed, the experimental subject's purpose of helping others in need will be defeated.

At this point, it is necessary to introduce a new concept, which I shall call relationship. The experimental subject has a peculiar relationship to the beneficiaries of the experiments that he undergoes, for, although they may not know each other personally and may never be able to do so because of, say, barriers of distance and time, nevertheless they do stand in a relation of helper and helped. The relationship exists simply because, as helper, the subject who is experimented on contributes through the experiment to the alleviation of the suffering of those whom he thus helps.

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(8) For further discussion and references, see Geoffrey Edsall, 'A Positive Approach', (cited in footnote 5), p. 281.

But why, one might ask, should one person help another by submitting himself to experimentation, especially if doing so is quite inconvenient, risky and possibly even painful? The answer is not easy; it may be found, I submit, in the ethical character of various relationships that exist between human beings. As I conceive it, ethical relationships between people arise in many different ways, e.g. from being members of the same community and from being similarly situated - as in having the same physical defects or in being susceptible to or having had the same disease. Insofar as the sufferer from a disease can identify with other fellow sufferers, even though they are personally unknown to him, he belongs, as it were, in the same community and by virtue of that fact sufferers, past, present and future, have a special relationship to each other, especially if they suffer from the same kind of condition. (9)

It is impossible here to explain the ethical notions behind my remarks in more detail. Suffice it to say that they entail that the experimental subject should be taken very seriously as a moral agent and, if he bears no relationship whatsoever to possible beneficiaries of the experiments performed on him, even in the very attenuated type of relationship mentioned here, then the moral claims on him become very weak indeed and the use of him as an experimental subject may properly be described as exploitation. Furthermore, as I have just pointed out, if the experimental project is ill conceived and actually does not fulfill the promise of providing benefits for others in the future, then the sacrifices on the part of the subject are of no avail and he has not contributed to the alleviation of suffering as he intended.

My tentative conclusion is that three factors must be taken into consideration in determining the moral quality of a medical experiment on a human subject: first, the amount and degree of risk for the subject; second, the adequacy of the project and its potentiality for reducing suffering in future patients; and third, the relationship between experimental subject and those who stand to benefit from the experiment. Although none of them can be entirely ignored, it is easy to see that each of these three factors may vary enormously in kind and degree and so we may be

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(9) I have set forth this concept of community in greater detail in an essay entitled 'The idea of community', New England Journal, 1, issue 1. American Institute of Planners, New England Chapter, August 1972.

required to balance one against another; if there is less of one, then there must be more of one of the others. But, apart from a particular context, no simple answer can be given to the question: what sorts of experimentation are good and what sorts are bad. (10)

Resumen

Los problemas éticos que se plantean en relación con la experimentación en el hombre son complicados, controvertibles y confusos. Esto obedece a que el término se usa para abarca una variedad muy grande de procedimientos, aplicados en contextos diferentes, en diferentes clases de sujetos humanos y con diversos objetivos. El autor se refiere en su trabajo a una categoría particular de experimentos en el hombre, a saber, la que generalmente se conoce como experimentación no terapéutica, y la estudia únicamente en relación con los experimentos en adultos competentes.

No existe una 'piedra filosofal' que permita señalar lo que es bueno o malo per se en la experimentación en el hombre, debido a que todos sus aspectos éticos importantes dependen del contexto. Casi todo lo que se ha escrito sobre el tema de la ética de la experimentación en el hombre tiene poco valor, principalmente por confuso.

La primera confusión consiste en la falta de distinción entre las cuestiones morales y las cuestiones legales. Las cuestiones legales de la experimentación en el hombre se refieren a las leyes y los reglamentos, y versan sobre el tipo de reglamentación que debe existir, la clase de actividades que deben ser reglamentadas y otras materias de la misma índole. En los Estados Unidos de Norteamérica, la principal institución de reglamentación es el llamado Institutional Review Board, cuyo principal objetivo es la protección de los derechos del sujeto de experimentación, particularmente mediante el requisito del llamado 'consentimiento informado'.

Si se adopta una actitud escéptica acerca del enfoque legal de la experimentación humana, se puede llegar a la conclusión de que el 'consentimiento informado' responde a una concepción burguesa de la relación entre el experimentador y el sujeto de experimentación, y refleja una relación de explotación. El

(10) I am very grateful to my friend and colleague Robert P. Davis, M.D., for his help and advice in working out the ideas presented in this paper.

concepto de consentimiento informado, en efecto, ofrece al individuo una libertad ficticia, análoga a la libertad de comprar o no un coche de lujo; en ambos casos, el sujeto puede simplemente no estar en situación de poder ejercitar su libre albedrío.

Es obvio que para poder justificar desde el punto de vista de la ética un proyecto de investigación, éste debe presentar interés científico e interés social, y ha de ser ejecutado, además, conforme a los principios que reconocen la necesidad del consentimiento informado.

El autor considera que el tipo de legalismo que reduce los principios éticos de la experimentación en el hombre a la cuestión del consentimiento informado deja de lado la esencia de los verdaderos problemas éticos, que es la relación moral entre el sujeto, el experimentador y los futuros beneficiarios del experimento.

La segunda fuente de confusión es ideológica. Hablando de posiciones extremas, existe una contraposición entre los adversarios de la investigación y los partidarios de ella, a quienes el autor llama respectivamente restriccionistas y entusiastas. Unos y otros son absolutistas. En un extremo, algunos escritores, que se autodenominan 'eticistas', sostienen que cualquier tipo de experimentación en el hombre constituye una amenaza para la dignidad humana. Por otro lado, los entusiastas consideran que el progreso científico es invariablemente y forzosamente beneficioso para el ser humano; como corolario, estiman que cualquier adición a la suma total de los conocimientos científicos, aún cuando sea minúscula, mejora el bienestar humano. Desde el momento en que la experimentación en el hombre favorece el progreso de la ciencia médica, no solamente sería moralmente permisible sino moralmente obligatoria.

La tercera fuente de confusión es la índole particular de la formulación que suele hacerse de los problemas morales relativos a la experimentación en el hombre, y que se basa en posiciones tendenciosas. Muchas discusiones comienzan con una cuestión que se parece estructuralmente a la clásica pregunta: '¿Cuándo dejaste de golpear a tu esposa?' Con arreglo a esta técnica de construcción, la experimentación no terapéutica se define como la que ejecuta en el cuerpo de otra persona una acción que no redunda en su beneficio. Olvidando cuidadosamente las cuestiones acerca de lo que es y lo que no es realmente en beneficio de una persona, los restriccionistas consideran que la experimentación es simplemente el uso de otro ser humano como un medio, un medio

para lograr el progreso de la ciencia. De esta manera, la cuestión ética se convierte en la pregunta: '¿Cuándo es correcto utilizar a un ser humano como un medio?'

Por su parte, en cambio, un entusiasta puede formular la cuestión ética como una pregunta acerca de por qué razón, desde el punto de vista ético, se debe considerar diferente la experimentación en el hombre de cualquier otro tipo de experimentación. La vida está llena de riesgos, y el progreso se consigue a fuerza de correr riesgos. Cabe así preguntar: ¿Qué tiene de especial la experimentación humana? ¿Por qué razón no puede pedirse o exigirse a una persona que corra un riesgo en beneficio del mejoramiento de las futuras condiciones de vida de la humanidad?

Por otra parte, se arguye, puesto que la experimentación es aceptable en el contexto terapéutico debe ser también aceptable en otros contextos.

Tratando de analizar más profundamente la cuestión, se puede observar que es muy importante el significado que se atribuya al término 'experimentación': para algunos, en efecto, es un término peyorativo, que evoca fantasmas de niños arrancando las alas a las mariposas, en tanto que para otros la experimentación es parte del hecho de ser humano.

Es necesario examinar más de cerca el concepto de experimentación. El significado central del término experimentación es el de un procedimiento adoptado sin tener la seguridad de que permita obtener un objetivo determinado. La cuestión crucial se refiere al objetivo buscado en la experimentación. En estos casos, el objetivo es la curación, y el éxito o el fracaso del experimento se determina respecto a si se logró o no el objetivo deseado.

Por otra parte, el experimento científico puro es otra cosa. En él, se trata de determinar si una hipótesis en particular es verdadera o es falsa. El objetivo, pues, no es la curación, como en la experimentación terapéutica, sino el establecimiento de la veracidad o la falsedad de la hipótesis puesta a prueba. Desde este punto de vista, un experimento que muestra que la hipótesis es falsa es un experimento logrado, puesto que su objetivo era poner a prueba la hipótesis y no llegar a un resultado positivo o negativo predeterminado.

A juicio del autor, los restriccionistas consideran que la experimentación en el hombre es experimentación en el sentido científico del término. De esta manera, en el caso extremo, un experimento diseñado para verificar si una intervención específica cura una condición particular, puede considerarse logrado aún cuando la condición física del sujeto del experimento se deteriore o aún si muere, simplemente por el hecho de que se demostró la falsedad de la hipótesis en si misma. Si es así, es decir, si el objetivo de la experimentación en el hombre consiste simplemente en verificar hipótesis siguiendo las líneas mencionadas, entonces estaremos en lo cierto al considerar que se trata al sujeto de experimentación únicamente como un medio.

Así pues, en los casos extremos, tenemos dos objetivos diferentes de experimentación: el descubrimiento de un tratamiento que lleva a una curación, por un lado, y la determinación del valor-verdad de una hipótesis por el otro.

El autor sostiene que la experimentación médica debe ser terapéutica y no tener únicamente por objeto la verificación de hipótesis.

Tanto los restriccionistas como los entusiastas adoptan, al parecer, el punto de vista equivocado, según el cual el objetivo principal de la encuesta científica en la que se emplea la experimentación humana en el hombre es el progreso de la ciencia. Partiendo de este punto, toda la acción de desarrollo científico que persigue este objetivo es considerada por los restriccionistas como gratuita y por los entusiastas como progresista. La diferencia entre ambas posiciones consiste, simplemente, en que los restriccionistas sostienen que la base científica no basta para justificar la experimentación en el hombre, por lo menos cuando requiere la intervención en el cuerpo de otra persona, en tanto que los entusiastas estiman que la justifica ampliamente. Una tercera posición posible es la de considerar que la medicina y la experimentación en el hombre deben tener siempre por objeto, directa o indirectamente, aliviar el sufrimiento humano por procedimentos médicos.

Planteada esta posición, se puede intentar hacer consideraciones más directas acerca de los problemas éticos reales, asociados con la experimentación en el hombre.

Es por demás obvio que ni los científicos ni los médicos en general gozan de licencia especial para ser deshonestos, falsos

y crueles en sus relaciones con los seres humanos. Así, el planteamiento ético de la experimentación en el hombre puede tomar la siguiente forma: El objetivo de la experimentación médica en seres humanos es y debe ser, aunque sólo sea de manera indirecta, el alivio del sufrimiento humano.

Si la experimentación médica en seres humanos se enfoca desde este punto de vista, debe reconocerse que quien se somete a la experimentación no lo hace en favor del científico sino de los que habrán de beneficiarse del resultado, es decir, de aquellos cuyo sufrimiento será aliviado.

Esta es la razón por la cual el diseño del experimento adquiere importancia crítica; este diseño, en efecto, debe proveer la conexión entre el sujeto de experimentación y los pacientes desconocidos a quienes eventualmente beneficiará. Si el proyecto está mal diseñado, no se alcanzará el objetivo del sujeto de experimentación, que es ayudar a otros.

Pero, ¿por qué una persona debe ayudar a otra sometiéndose a un experimento? La contestación no es fácil. Quizá la respuesta se encuentre en el carácter ético de las relaciones que existen entre los seres humanos. Tal como lo concibe el autor, estas relaciones éticas aparecen bajo formas diferentes, y pueden derivarse, por ejemplo, del hecho de ser miembros de la misma comunidad, de padecer una misma enfermedad, etc.

Se llega así a la conclusión de que para determinar la calidad moral de un experimento médico en un sujeto humano deben tenerse en cuenta los tres factores siguientes: 1. El grado de riesgo para el sujeto; 2. La buena calidad del proyecto y su potencial para reducir el sufrimiento de futuros pacientes, y 3. La relación entre el sujeto de experimentación y las personas que pueden beneficiarse del experimento.

THE VALUE AND LIMITATIONS OF ETHICAL REVIEW COMMITTEES FOR CLINICAL RESEARCH

Robert J. Levine

In the United States, Institutional Review Board (IRB) is the generic name for committees that review research proposals for purposes of safeguarding the rights and welfare of human research subjects. Virtually every institution in the United States that conducts research involving human subjects has one or more of these committees. Since the term IRB does not suggest the purpose of the committee, most institutions retain the more descriptive titles they had before Congress assigned the generic title in 1974; these names include Human Investigation Committee, Committee for the Protection of Human Research Subjects, and so on. Throughout this paper I shall refer to these committees as IRBs; among other things this reflects my lack of familiarity with committees other than those operating in the United States according to federal regulations.

My assignment is to discuss the value and limitations of these committees. In response to the first half of my assignment, I wish I could provide data indicating that the existence of IRBs has reduced the frequency of violations of the rights or welfare of human research subjects; however, no such data are available. The only empirical data I have been able to find that are relevant to the value of IRBs were published by Gray, Cooke, and Tannenbaum [1]; the vast majority of investigators in their national survey held the opinion that IRB review not only protected the rights and welfare of human subjects but also improved the quality of research done in their institutions. Rather than discuss the value of IRB review, I shall discuss the values that IRB review is expected to uphold. Then I shall discuss some of the factors that limit the capacity of the IRB to foster these values and some of the efforts that are being made in the United States to mitigate some of these limiting factors.

The Values of IRB Review

The various purposes of IRB review were articulated well by the National Commission for the Protection of Human Subjects of Biomedical and Behavioural Research (the Commission) in its report on IRBs: [2]

> 'The ethical conduct of research involving human subjects requires a balancing of society's interests in protecting the rights of subjects and in developing knowledge that can benefit the subjects or society as a whole...Investigators should not have sole responsibility for determining whether research involving human subjects fulfills ethical standards. Others who are independent of the research must share this responsibility, because investigators are always in positions of potential conflict by virtue of their concern with the pursuit of knowledge as well as the welfare of the human subjects of their research.'
>
> '....The rights of subjects should be protected by local review committees operating pursuant to federal regulations and located in institutions where research involving human subjects is conducted, Compared to the possible alternatives of a regional or national review process, local committees have the advantage of greater familiarity with the actual conditions surrounding the conduct of research. Such committees can work closely with investigators to assure that the rights and welfare of human subjects are protected and, at the same time, that the application of policies is fair to the investigators. They can contribute to the education of the research community and the public regarding the ethical conduct of the research community and the public regarding the ethical conduct of research. The committees can become resource centres for information and concerning ethical standards and federal requirements and can communicate with federal officials and other local committees about matters of common concern.'

Evolution of the IRB. Systematic review of research by committees having as their principal responsibility the safeguarding of the rights and welfare of research subjects is a very recent development. While it is difficult to determine when the first such committee was established, it is not likely that it was over 25 years ago. Apparently the first committees were established in university medical centres and, for the first few years of their existence, functioned without much publicity. At first these committees were truly 'peer review' groups in that they were composed of peers of the investigators. Subsequently, while membership of these committees has been diversified, the informal designation of peer review group has been maintained. Now, of course, it is unclear as to whose peers are involved.

The early history of the IRB was reviewed in detail by Curran (3). More recently, Veatch (4) has discussed the history of the IRB, concentrating particularly on the evolution of federal requirements for diversity of membership. Much of the following discussion is derived from these two papers; they may be consulted for some specific citations of government and other documents that I have omitted.

The first suggestion that a physician should consult with peers before proceeding with research or innovation is generally attributed to Thomas Percival; it is contained in the following oft-quoted paragraph from his Medical Ethics (cited in (4), p. 32):

> 'Whenever cases occur, attending with circumstances not heretofore observed, or in which the ordinary models of practice have been attempted without success, it is for the public good, and in special degree advantageous for the poor (who, being the most numerous class of society, are the greatest beneficiaries of the healing art) that new remedies and new methods of chirurgical treatment should be devised. But in the accomplishment of the salutary purpose, the gentlemen of the faculty should be scrupulously and conscientiously governed by sound reason, just analogy, or well-authenticated facts. And no such trials should be instituted without a previous consultation of the physicians or surgeons according to the nature of the case.

The Nuremberg Code and the original Declaration of Helsinki make no mention whatever of committee or peer review; these documents place all responsibility for experimental design, safeguarding the rights and welfare of subjects, and so on, on the investigators. In the revision of the Declaration of Helsinki at the XXIVth World Medical Assembly in Tokyo in 1975, committee review is mentioned:

> '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'(Helsinki, I.2).

The document is otherwise silent on the matter of committee review. It is of interest that the authority of the committee is limited to '....consideration, comment and guidance'.

Apparently, the first federal document requiring committee review was dated November 17, 1963 ((4), p.32). This consisted of a set of guidelines entitled 'Group Consideration for Clinical Research Procedures Deviating from Accepted Medical Practice or Involving Unusual Hazard'. These guidelines applied only to intramural research at the National Institutes of Health (NIH). However, earlier there were reports of committee activities in medical schools. In 1961, Welt reported on the results of a questionnaire he sent to each university department of medicine in the country ((5), p. 889). He received responses from 66 departments; of these, 8 had procedural documents and 24 had committees to review research involving human subjects. There was a mixture of strong opinion as to whether there should be such procedural documents or committees. In 1962, a similar survey was conducted by the Law-Medicine Research Institute at Boston University ((3), p. 407). Of 52 departments of medicine responding, 9 institutions had procedural documents and 5 more indicated that they were in the process of developing such documents; 22 departments had committees.

The first federal policy statement on protection of human subjects was circulated over the signature of the Surgeon General of the United States Public Health Service (USPHS) on February 8, 1966. This specified that ((3), p. 436 et seq):

> 'No new, renewal, or continuation research or research training grant in support of clinical research and investigation involving human beings shall be awarded by the Public Health Service unless the grantee has indicated in the application the manner in which the grantee institution will provide prior review of the judgement of the principal investigator or programme director by a committee of his institutional associates. This review should assure an independent determination: (1) Of the rights and welfare of the individual or individuals involved, (2) of the appropriateness of the methods used to secure informed consent, and (3) of the risks and potential medical benefits of the investigation. A description of the committee of the associates who will provide the review should be included in the application.'

On July 1, 1966, a revision of this policy statement extended the requirements for prior review of research involving human beings to all USPHS grants. This revision also revoked the requirement of individual assurances of compliance and replaced

it with a requirement for institution-wide assurances covering all grant proposals emanating from a single institution. Institutions that wished to use this mechanism were requested to file 'general statements of assurance' of compliance with USPHS policies which were to include, among other things, a description of the review committee.

In a subsequent revision of the policy statement in December 1966, the grantee institution is informed that it is responsible for assuring that investigations are'....in accordance with the laws of the community in which the investigations are conducted and for giving due consideration to pertinent ethical issues'.

In 1968, NIH analyzed the activities of 10% of the committees operating in institutions with general statements of assurance ((3), p.443). Of 142 institutions thus examined, 73% of the committees were limited in membership to immediate peer groups; i.e. they were exclusively composed of scientists and physicians without the addition of theologians, lawyers, philosophers, or lay members. Interdisciplinary groups in which co-professionals of the investigator were in a minority were found in only 11 institutions. Twenty-six institutions had some representatives of other professions or laymen. Of these, 18 had lawyers on the committees, 16 had laypersons and 1 had both lawyers and clergy.

Since 1966 there have been several revisions in USPHS policy which reflect evolving federal expectations regarding the composition and duties of IRBs. A revision of the guidelines dated May 1, 1969, suggested for the first time that a committee composed exclusively of biomedical scientists would be inadequate to perform the functions now expected of the committee. '....The committee must be composed of sufficient members of varying backgrounds to assure complete and adequate review....' Further, '....the membership should possess not only broad scientific competence to comprehend the nature of the research, but also other competencies necessary in the judgement as to the acceptability of the research in terms of institutional regulations, relevant law, standards of professional practice, and community acceptance'. The requirements for filing general assurances now request specific information on each of the committee members including '....position, degrees, board certification, licensures, memberships, and other identifications of experience and competence'.

On May 30, 1974, these policies and guidelines were revised and issued as Department of Health, Education and Welfare (DHEW)

regulations [6]. The new language calling for differences in committee membership includes the following: the committee must be composed of not fewer than five persons and must include capacity to judge the proposal in terms of community attitudes. 'The committee must therefore include persons whose primary concerns lie in these areas of legal, professional, and community acceptability rather than in the conduct of research, development, and service programmes of the type supported by DHEW.' It is further required that no committee or quorum of a committee shall consist entirely of employees of the organization where the research will be conducted. Further, no committee or quorum of a committee shall be composed of a single professional or lay group.

In 1975, DHEW published 'technical amendments' to these regulations [7]. Subsequently, in 1979, DHEW - now the Department of Health and Human Services (DHHS) - proposed major revisions of all regulations that govern the protection of human research subjects [8]. These proposed regulations were based on the extensive recommendations that had been published one year earlier by the Commission [2]. The Food and Drug Administration (FDA) has also published proposed regulations to establish standards for IRBs [9]. Readers who are interested in an analysis of these proposed regulations and the ways in which they differ are referred elsewhere [10-12]. The proposals are not designed to alter the general principles of IRB review. Rather they are concerned with some of the details of what the IRB is expected to accomplish and some of the procedures it must follow.

The 'Values'. Most discussions of the ethics of research involving human subjects tend to concentrate on issues related to informed consent. Consequently, it is a widely held misconception that the activities of the IRB are confined to reviewing the plans for securing the informed consent of the research subject. While this activity occupies a good deal of the time of the IRB, it is also accountable for seeing to it that other ethical concerns receive due consideration.

The ethical issues with which the IRB must be concerned are expressed in the codes and regulations that provide guidance for the conduct of research involving human subjects. It is convenient to view these behaviour prescribing and proscribing statements as various expressions of six general ethical norms [13]. I shall summarize these and provide examples of how they are expressed in ethical codes and federal regulations.

1. There should be informed consent.

   The voluntary consent of the human subject is absolutely essential (Nuremberg 1).

   ....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 (Helsinki I.9).

   Legally effective informed consent will be obtained by adequate and appropriate methods....(DHEW, 46.102b.3).

2. There should be good research design.

   The experiment should be so designed and based on the results of animal experimentation and a knowledge of the natural history of the disease or other problem under study that the anticipated results will justify the performance of the experiment (Nuremberg 3).

   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 (Helsinki I.1).

3. There should be competent investigators.

   The experiment should be conducted only by scientifically qualified persons. The highest degree of skill and care should be required through all stages of the experiment of those who conduct or engage in the experiment (Nuremberg 8).

   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.... (Helsinki I.3).

4. There should be a favourable balance of harms and benefits.

   The degree of risk to be taken should never exceed that determined by the humanitarian importance of the problem to be solved by the experiment (Nuremberg 6).

Biomedical research involving human subjects cannot legitamately be carried out unless the importance of the objective is in proportion to the inherent risk to the subject (Helsinki I.4).

The risks to the subject (must be) so outweighed by the sum of the benefit to the subject and the importance of the knowledge to be gained as to warrant a decision to allow the subject to accept these risks.... (DHEW, 46.102b,1).

5. There should be equitable selection of subjects.

This is a norm that is not yet expressed clearly in our ethical codes and regulations. However, in its Report on IRBs (2) the Commission recommended:

'The IRB shall determine that....selection of subjects is equitable...' (Recommendation 4B).

In the commentary under this recommendation the Commission elaborates its intent ((2), p.22):

'The proposed involvement of hospitalized patients, other institutionalized persons, disproportionate numbers of racial or ethnic minorities or persons of low socio-economic status should be justified.'

Concerns for special protections for vulnerable individuals in 'non-therapeutic research' are also expressed in the Declaration of Helsinki:

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

As I have discussed elsewhere [14] this recommendation is based upon the spurious distinction between therapeutic and non-therapeutic research; consequently, it is ignored by IRBs.

6. There should be compensation for research-induced injury.

This is another emerging ethical norm that has not, as yet, found expression in our ethical codes and regulations. Strong support for this concept has been provided by the International Conference on the Role of the Individual and

> Community in the Research, Development and Use of Biologicals [15], the Report of the DHEW Secretary's Task Force on the Compensation of Injured Research Subjects [16], and in various reports of the Commission.
>
> Most institutions in the United States do not have plans for compensation of injured research subjects. However, in 1978 a regulation was promulgated by DHEW requiring the following amendment to the definition of informed consent [17]:
>
> 'With respect to biomedical or behavioural research which may result in physical injury, an explanation as to whether compensation and medical treatment is (sic) available if physical injury occurs, and, if so, what it consists of or where further information may be obtained' (DHEW 46.103c.7).
>
> With slight modifications this requirement is retained in proposed regulations published both by DHHS [8] and FDA [9].

The six general ethical norms are not expressions of ultimate values. Rather, they are designed to embody and uphold the requirements of more fundamental ethical principles. In its Belmont Report [18], the Commission identified these fundamental ethical principles as respect for persons, justice and beneficience.

> 'Respect for persons incorporates at least two basic ethical convictions: First, that individuals should be treated as autonomous agents, and second, that persons with diminished autonomy and thus in need of protection are entitled to such protection'((18), p.4).

Justice requires a fair share of burdens and benefits. There is considerable disagreement as to what constitutes fairness in the distribution of burdens and benefits. For example, is it 'fair' for persons to be treated differently on the basis of their needs, their accomplishments, their purchasing power, their social worth, their past records or future potentials? The position adopted by the Commission interprets 'fairness' to require special protection for those who are weaker, more vulnerable, or less-advantaged than others ((18, pp. 8-10).

> 'The term, beneficience, is often understood to cover acts of kindness or charity that go beyond strict obligation. in this document, beneficience is understood in a stronger sense, as an obligation. Two general rules have been formulated as complementary expressions of beneficent actions in this sense: 1) Do no harm, and 2) Maximize possible benefits and minimize possible harms'((17), p.6).

Some authors have argued that the concept of beneficience might be clarified if it were separated into two separate fundamental ethical principles, beneficience (maximize good) and non-maleficence (do no harm) (13).

Statements of ethical norms contained in the codes and regulations are often too general or too vague to provide precise direction to the IRB in its review of specific protocols. Some commentators have argued that the remedy for this situation is to write increasingly complicated and detailed regulations that will provide specific direction to the IRB to deal with any and all contingencies. I believe that this is a mistake; more satisfactory results can be achieved with regulations that provide general requirements for IRBs. When the IRB encounters a proposal that is not covered specifically in regulations, it can usually achieve a satisfactory solution by looking behind the norms to the fundamental ethical principles to determine what fundamental values it should attempt to uphold. Levine and Lebacqz (13) have provided some examples of this approach to resolving problems presented by the conduct of randomized clinical trials in Veterans Administration Hospitals.

In its review of protocols, the IRB does not necessarily give equal attention to the requirements of each of the six general ethical norms. Almost always the IRB examines meticulously plans to negotiate and document informed consent. By contrast, IRBs customarily perform rather superficial review of scientific design when they are aware that the investigators are applying for funds from some agency outside their own institution. In most cases in which research is funded by the U.S. Government or by a private philanthropy, such agencies provide a very careful review by a panel of experts in the field of specialization of the research. For example, at the National Institutes of Health, there are Initial Review Groups (IRGs), commonly known as Study Sections. Rigorous review by IRGs of the research design is, in general, the basis for their funding decisions. The IRB tends to review with much more care the scientific design of research

proposals for which 'outside support' is not being sought. The principle that seems to guide the IRB is that each protocol should have careful review to see that the requirements of each of the general ethical norms are given due consideration. However, when the IRB knows that review for compliance with one of the norms is being performed by another competent agency - often one having much greater competence than the IRB - it may assume that its obligations with regard to that norm are being discharged satisfactorily.

Limitations of IRB Review

Now let us turn our attention to some of the factors that limit the capacity of the IRB to perform its functions. In my opinion, the single most important factor that contributes to the successful functioning of the IRB is its credibility within the institution that it serves and within the community that the institution serves; my arguments supporting this opinion are published (19). The factors that limit the capacity of the IRB to perform its functions are, in general, those that tend to undermine the IRB's credibility. Following is a list of those that I consider to be the most important.

1. IRBs invest too much time and energy in doing unimportant things. This phenomenon has two major consequences. First, it consumes the time and energy of IRB members and staff that might more fruitfully be devoted to performance of the IRB's legitimate and consequential functions. Secondly, it creates within the institution an image of the IRB as a group that is totally preoccupied with trivia and therefore to be avoided (12, 20, 21).

To a large extent, the diversion of the time and energy of IRBs to relatively unimportant activities has been a consequence of excessive and, in some cases, defective regulations (10, 11). Some relief from this problem is expected shortly. Based upon the Commission's recommendations, DHHS has proposed regulations that would permit 'expedited review' for some classes of research activities and, further, would exempt some other classes of research activities from coverage by the regulations (11). With expedited review, a convened IRB meeting is not needed to review a protocol. Rather, one member of the IRB may examine the protocol to ascertain its eligibility for expedited review. DHHS has proposed a list of procedures that might be considered eligible - given adequate assurances of confidentiality - for expedited review ((8), Section 46.111); examples include:

1) collection of blood samples by venipuncture, in amounts not exceeding 450 millilitres in a 6-week period, 2) collection of excreta and external secretions including sweat, saliva, and placenta expelled at delivery, and 3) moderate exercise by healthy volunteers. Among the research activities that are being considered for complete exemption from coverage by the regulations are many types of social science activities and research involving solely the study of documents, records, or pathological or diagnostic specimens, if information taken from these sources is recorded in such a manner that subjects cannot be reasonably identified ((8), Section 46.101).

A special problem is presented to investigators who conduct studies involving multiple institutions - for example, multi-institutional clinical trials and survey research. Apparently, each IRB interprets the regulations differently and imposes requirements for revision of protocols that may be inconsistent. A dramatic example of the problems this presents to investigators was published by Kavanagh et al. (22). Their proposal to conduct survey and interview research on genetic counselling services in 51 institutions was reviewed by IRBs in each of these institutions. Securing final authorization to proceed with the research took over a year and involved 384 distinct communications between IRBs and the investigators. Of the 51 institutions, 11 decided that IRB review was not required, 28 approved the protocol as submitted and 12 approved the protocol after requesting one or more modifications.

2. The IRB must sometimes enforce defective regulations. Members of the IRB are expected to perform important educational functions (supra). For example, they can explain how various IRB policies, guidelines, and regulations have their roots in important ethical principles and, therefore, should be respected. During the 1960s and early 1970s it was a matter of satisfaction in some institutions that their IRBs were routinely following procedures that seemed important before they were included in various guidelines and regulations. This seems to enhance confidence within institutions that these procedures made sense and, in fact, should be followed whether or not they were required through regulation.

However, members of the IRB cannot create respect for guidelines and regulations that they do not themselves respect. To this end it is very important to avoid developing regulations that do not have reasonable bases. When this happens, IRB members often find it necessary to apologize for the regulations.

They must acknowledge to investigators that the regulations make no sense; however, they are obliged to comply in order to secure money from the federal government to conduct their research. An example of an illegitimate policy was analyzed in detail by Holder and Levine (20). This policy required documentation of full-fledged informed consent to do research on specimens obtained at either surgery or autopsy. Proposed DHHS regulations would no longer require this time-consuming and pointless activity (8, 11). The proposed regulations also remove requirements for several other meaningless activities (10, 11).

3. Some IRBs have developed 'double standards' - institutional policies that impose inconsistent procedural requirements on research projects for illegitimate reasons. For example, in some institutions, only the research that is funded by agencies that require IRB review is subjected to IRB review. Other research projects which do not differ in any relevant respect are permitted to proceed without IRB review. Double standards create within the institution the often accurate impression that the procedural requirements - in the view of the institution - have no inherent value and, therefore, are to be evaded.

As early as 1969, Barber et al. found that the great majority (240 of 282) of IRBs they studied reviewed all clinical investigations conducted within the institution (23). Further, they found that in those institutions in which all clinical investigation was reviewed, 55% of respondents said that the work of the IRB was 'very well received', while in those in which the IRB reviewed less than all clinical research, only 38% of respondents reported that the committee was 'very well received'.

In this regard, it is encouraging that in the DHHS proposed regulations that provide for exemption of certain classes of research activities from coverage by the regulations, the exemptions are based on the nature of the research rather than on some irrelevant criterion.

A second type of double standard tends to develop in response to truly pointless or counterproductive requirements of funding or regulatory agencies. In such cases, the IRB may apply the rule apologetically to those projects that are funded by the agency that developed the rule while ignoring it in other very similar projects. Such practices similarly undermine investigators' confidence in the IRB system.

4. Some federal policies and practices tend to preempt the authority of the IRB. An example of a current problem: Study Sections (Initial Review Groups (IRGs)) at NIH and the Alcohol, Drug Abuse and Mental Health Administration (ADAMHA), in their review of research proposals, repeatedly make decisions that are more properly in the domain of the IRB. When they make such decisions they may recommend disapproval of a research grant application on 'ethical grounds'. This practice has at least two unfortunate consequences. First, when investigators learn that their project which had been approved previously by the IRB has been rejected on ethical grounds, they may question the competence of the IRB.

A second, and perhaps even more important consequence, is the impact that such decisions may have on the motivation and behaviour of IRB members. IRB members do not believe that IRGs are competent to make many of these decisions. IRGs are composed exclusively of scientists who are expert in the field in which they are reviewing research. As such, they are highly qualified to make judgements about the scientific design of the proposed research. However, they do not have the additional expertise and perspectives that are necessary to make other judgements for which the IRB is responsible. Some examples of incompetent decisions made by IRGs may be found in a recent publication [12].

When confronted with these unfortunate reversals of their decisions, IRB members tend to lose their motivation to review protocols carefully. In addition, it is clear to IRB members that any protocol they approve might be rejected at the national level, while protocols they disapprove will never even be seen at the national level. Consequently, some IRBs might consider relaxing their standards, operating according to the maxim 'give each questionable protocol its day in court'.

5. IRBs cannot be certain that research is actually conducted in accord with the protocols they have approved. In fact, it has been demonstrated that in some cases investigators proceed inconsistently with the agreements they have reached with the IRB [24]. This has caused several commentators to suggest that IRBs should be required by regulations to monitor the actual conduct of research in order to assure compliance with the approved protocol [24, 25].

It is my opinion that the IRB must not be turned into a police force. The current presumption that informs the so-called

monitoring activities of most IRBs is that members of the institution are to be trusted until some contrary evidence is presented (19). If the IRB is obliged to function as a police force, it can only indicate to the community of investigators that it is operating from presumptions of mistrust. Presumptions of mistrust cost a lot of time and energy of IRB members, most of whom have no training in police work in the first place. An even more important cost would be the loss of the basic presumption of trust itself; this presumption is fundamental to the existence of the academic community. Further, if the IRB is perceived as a police force by members of the institution, it is likely to lose what I have referred to as its 'informal monitoring system', that is, unsolicited reports by students, nurses, physicians, and so on ((19), pp. 45-47).

6. IRBs sometimes have difficulties recruiting as members individuals who command the respect of the institution and the community served by the institution. The Commission has recognized that it is crucial to the successful functioning of the IRB that it be composed of individuals having'....sufficient maturity, experience, and competence to assure that the Board will be able to discharge its responsibilities and that its determinations will be accorded respect by investigators and the community served by the institution....' ((2), p. 13). In general, this means that the IRB should have among its members senior and distinguished members of the academic faculty. In most institutions, there are very few senior professors who have as their primary scholarly interest matters germane to safeguarding the rights and welfare of human research subjects. While many are willing to serve the academic community through membership on committees, membership on the IRB consumes a large amount of time and energy. The various factors that I have identified as limitations each tend to create serious disincentives to service on an IRB.

Summary

The IRB is a rather recent social invention. Over the past twenty years there has been a rapid evolution of our understanding not only of the values that the IRB is expected to uphold, but also of the sorts of members it should have and types of procedures it should follow in order to become increasingly effective in performing its functions. Along the way several mistakes have been made; for example, we have developed various policies and practices that are detrimental to the successful function of the IRB. Recently, several important steps have been taken to correct these errors and, through so doing, to enhance the capacity of the IRB to accomplish its purposes.

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Resumen

En los Estados Unidos, reciben el nombre de consejos de examen institucional (IRB) los que examinan los proyectos de investigación con objeto de proteger los derechos y el bienestar de los seres humanos que son sujetos de la investigación. El autor se propone estudiar el valor y las limitaciones de estos comités. Considera que la mayoría de los investigadores sostienen que los IRB no solamente protegen los derechos y el bienestar de los seres humanos, sino que mejoran además la calidad de la labor de investigación realizada en sus instituciones.

Los diversos objetivos de la acción de los IRB se basan en varias consideraciones. La ética de las investigaciones en sujetos humanos exige un equilibrio entre los intereses de la sociedad que ha de proteger los derechos de sus súbditos, y la conveniencia de perfeccionar unos conocimientos que pueden beneficiar a estos mismos sujetos o a la sociedad en su totalidad. Los derechos de los seres humanos sujetos de investigación deben ser protegidos por comités locales, que tienen la ventaja de estar más familiarizados con las condiciones reales que rodean la conducción de la investigación.

El examen sistemático de los proyectos de investigación a cargo de comités responsables de la protección de los derechos y el bienestar de los sujetos de investigación es una práctica reciente, que, al parecer, no se remonta a más de 25 años.

El autor revisa la historia inicial de los IRB y sus bases, que se encuentran en diversas declaraciones internacionales, entre otras la declaración de Helsinki y su modificación de Tokio. Se hace referencia a un estudio practicado en 1968, en el que los Institutos Nacionales de Salud de los Estados Unidos analizaron las actividades de un grupo de comités que operaban en instituciones. En el estudio se comprobó que los miembros del 76% de los comités

estaban relacionados directamente con los investigadores, es decir, que esos comités estaban compuestos exclusivamente por científicos y por médicos, sin participación alguna de teólogos, abogados, filósofos o profanos.

En 1966 se empezó a revisar la política de los órganos federales de los Estados Unidos, y en 1969 se sugirió por primera vez que los comités compuestos exclusivamente por científicos de la rama biomédica no son adecuados para juzgar los aspectos éticos de la investigación. En 1974 se señaló que los comités deberían estar compuestos por no menos de 5 personas capacitadas para juzgar las propuestas en función de las actitudes comunitarias. Así, el comité debería incluir personas que cubrieran las áreas de la aceptabilidad comunitaria, profesional y legal, más bien que los detalles técnicos de la investigación.

Las discusiones sobre la ética de la investigación que utiliza sujetos humanos tienden a concentrarse en problemas relacionados con el consentimiento informado. Sin negar la importancia de este requisito, debe aceptarse que existen otras consideraciones éticas que es preciso tomar en cuenta.

El autor enumera 6 normas éticas generales y menciona ejemplos de la forma en que se expresan esas normas en los códigos éticos y en las reglamentaciones federales.

1. Debe existir el consentimiento informado.

2. El diseño del proyecto de investigación debe ser correcto.

3. Los investigadores deben ser competentes.

4. Debe haber un balance favorable en términos de daños y beneficios.

5. La selección de los sujetos debe ser correcta.

6. Debe haber una compensación para los daños ocasionados por la investigación.

Estas 6 normas éticas generales no son expresión de valores últimos, sino que obedecen a unos principios éticos más fundamentales, que se han identificado con referencia a las personas, a la justicia y a la beneficencia.

Respecto a las personas, existen por los menos dos principios básicos: 1. Que los individuos deben ser tratados como seres autónomos, y 2. Que las personas con autonomía disminuída y que, por lo tanto, necesitan protección deben gozar de esta protección.

La justicia requiere una distribución equitativa de los quehaceres y de los beneficios. La posición que debe adoptarse entiende que el concepto de equidad exige especial protección para los más debiles, los más vulnerables o los que gozan de menos ventajas que otros.

Aunque el término beneficencia se refiere a menudo a los actos de bondad o de caridad que van más allá de la obligación estricta, desde el punto de vista de la ética la beneficencia se entiende como una obligación.

Dos reglas generales expresan en forma complementaria las acciones benéficas: 1. No dañar, y 2. Incrementar los beneficios posibles y minimizar los sufrimientos.

La expresión de las normas éticas en los códigos y reglamentos a menudo es demasiado general o vaga para poder facilitar directrices precisas a los IRB en su examen de los diversos protocolos. Algunos autores sostienen que el remedio de esta situación consiste en promulgar reglamentos cada vez más complicados y más detallados. Se considera que esto es un error, y que se obtendrán resultados más satisfactorios con reglamentos que contengan normas generales.

El factor que más contribuye por sí solo al buen funcionamiento de los IRB es el crédito de que gozan dentro de la institución a la que sirven y dentro de la comunidad atendida por esa institución. Los factores que limitan la capacidad de los IRB para lograr sus objetivos son generalmente los que tienden a disminuir su crédito, como por ejemplo:

1. Se puede considerar que los IRB emplean demasiado tiempo y energía en actividades carentes de importancia.

2. Los IRB se ven obligados a aplicar reglamentos inapropiados.

3. Algunos IRB han establecido un doble juego de reglas políticas institutionales, que tienden a imponer requisitos de procedimiento inconsistentes, por razones que no son legítimas.

4. En los Estados Unidos, algunas políticas del Gobierno Federal tienden a minar la autoridad de los IRB.

5. Los IRB no pueden estar seguros de que la investigación sea realmente ejecutada de conformidad con los protocolos aprobados.

6. Los IRB suelen tener dificultades para lograr la participación de los miembros que gozan del mayor respeto en la institución y en la comunidad por ella atendida.

ETHICAL ISSUES IN GASTROENTEROLOGY

Francisco Vilardell

Introduction

Medical care is a continuous process. Many decisions have to be made by the physician on matters which involve value judgements. The patient's own views and expectations have also to be taken into account and the physician has to make a choice and select the best course that will help both of them. All this implies an ethical decision. In fact, even in minor matters, clinical decision making has an ethical component. In recent years, there has been a renewed interest in this subject, and CIOMS has played a crucial role in sensitizing the medical profession to these problems by organizing meetings such as this one, and by issuing several publications on medical ethics and the protection of human rights (1).

In 1976 a Symposium on Ethical Problems in the Management of Gastroenterological Patients was organized by Professor Vince Varro, President on the Hungarian Society of Gastroenterology at the time of the 10th European Congress of Gastoenterology. The symposium was well attended and the discussions were published in the proceedings of the Congress. An enlarged version also appeared as a supplement of the Scandinavian Journal of Gastroenterology (2). In this paper I will try to summarize some of the important points that were discussed there, as well as other developments in the field of digestive diseases.

Definitions

As I was appointed Moderator of the 1976 Symposium, a task for which I had neither the authority nor the qualifications, I had to start from the very beginning. First, how to define ethics, and most particularly medical ethics: for this purpose I consulted various dictionaries where many definitions related to moral standards or professional conduct can be found. However, the definition which I prefer is the following:

'Ethics is concerned with those matters of right and wrong on which persons of intelligence and humanity can sincerely differ.' I believe that this definition emphasizes the main characteristic of the medical care process, decision-making, on which two honest, human and intelligent physicians may truly not agree.

Secondly, how to look for practical criteria which may be used for establishing value judgements in clinical decision-making: I found an enormous amount of literature, ranging from the metaethical analysis of the logic of language to the study of Bayesian probability calculus and of decision-theory as applied to clinical and ethical judgements, including such things as the calculation of the 'weighted desirability' of an operation or a diagnosis test. Whether or not one believes that mathematical theory is necessary for everyday clinical practice, it seems quite clear that in any case, ethical choices will always be made on the basis of some degree of uncertainty. In the long run, I have found it important to take into account what Campbell (3) terms the 'respect for persons', that is 'the feeling of fellow humanity applied consistently and without personal bias'. This places the value of the individual above the benefit to the society and implies the keeping of a physician-patient relationship at the highest possible level.

Risk and its Assessment

A thoughtful evaluation of medical actions, whether diagnostic or therapeutic, calls on judgements on the nature of safety decisions, and requires an assessment of safety and risks. This seems particularly important in gastroenterology, a specialty which has suffered a complete and radical change due to the advent of fiberoptics. The endoscopic diagnosis, as it will be seen later, has led to a tremendous increase in the number of 'invasive' examinations done by gastroenterologists. In my own service in Barcelona, for instance, the number of fiberoptic endoscopies and other invasive procedures, such as transhepatic cholangiography, laparoscopy, intubations, intestinal biopsies, etc. represents more than 3,000 examinations every year. This is a threefold increase in the number of aggressive procedures done up to 1960, which was around 1,000 a year, mostly sigmoidoscopies, gastric analysis procedures and gastroscopies. If one takes into account therapeutic actions derived from endoscopy, such as biopsies, polypectomies, etc. the differences are even greater.

There are good dictionary definitions of risk, such as 'the possibility of loss, injury, disadvantage or destruction', or 'hazard, chance of bad consequences, exposure to mischance, chance of injury or loss' or my preferred one taken from the French dictionary Littré, 'danger with which the idea of chance is associated'. These are rather formidable definitions; they rightly emphasize the relativity of the concept of safety and imply not only that risk should be quantified in some way, but

also that a value judgement, an ethical evaluation, should be made about the acceptability of the risk.

I found interesting guidelines for the 'measurement' of risk in a fascinating book by Lowrance [4] on 'acceptable risk'. In it, Lowrance stresses the following criteria for the acceptability of risk: 1) whether it is assumed voluntarily or not; 2) whether there is a less risky alternative; 3) whether exposure is unavoidable or a 'luxury'; 4) whether the instrument, or the technique, or the operation, will be used as intended or if it is likely to be misused; and finally, 5) whether the consequences are reversible or not. Risk is then a sort of a measure of the probability and severity of adverse effects which may be judged acceptable or not (see Table 1).

Several elements must be analyzed when speaking of risk: they include mortality, morbidity, and many unmeasurable things such as pain, anxiety, discomfort and possible sequelae, among which the possibility of anemia due to excessive sampling for blood tests seems the most far-fetched and dramatic, but has been observed and even reported in the literature.

At the European Congress of Gastroenterology in Budapest, a classification of risk factors that may harm the patient subjected to diagnostic tests for gastrointestinal disease was presented. Some of the risk factors may be due to the instrument itself, or to improper care; other factors include the preparation for the examination, such as intubations, enemas or allergies to contrast materials. Other risks depend on the actual technique which may cause unavoidable complications such as perforation, obstruction, etc. The operator may be responsible for harming the patient. He may be inexperienced, careless, or worse, he may be greedy, wanting to project his image, overdiagnosing to protect himself, looking for rare diseases worthy of publication, or suffering from 'iconolatry', a term coined by the late Professor Charles Debray that speaks for itself. The interpretation of the test may involve another set of risk factors because of technical defects, such as faulty sampling, or because of inexperience of the interpreter. Finally, some factors involved are due to the patient himself. Sometimes he may be a poor risk case; occasionally he may be uncooperative (see Table 2).

Some of these factors are unavoidable, but others obviously are not. Unfortunately, there is a lack of reliable data on the

true impact of gastroenterological diagnostic procedures on the safety of patients because in the evaluation of procedures, the factor accidents/patients at risk cannot be calculated because the denominator is not known, due to the lack of sufficient prospective studies. In many published reports, the number of incomplete, unsuccessful or useless examinations is often not indicated, and the mishaps arising from these unfortunate experiences are often ignored. Moreover, successful or beneficial results of diagnostic procedures are more likely to be published than other less favourable data.

The Hazards of Gastroenterologic Procedures

Tables 3 and 4 show the major hazards of diagnostic techniques used in the management of gastrointestinal patients. The main complications are listed as well as the mortality of the procedure. Most of these figures have been collected from smaller series and are representative only of the best available practice. I do not believe that they indicate the true situation outside academic highly specialized institutions. I would now like to briefly consider the fate of diagnostic procedures. A perusal of current books on gastroenterological diagnosis shows that techniques come and go, and it would be interesting to analyze whether any serious consideration was ever given originally to their safety or their acceptability. Table 5 shows some of the tests that are waning in popularity, from the string test for bleeding, quite popular in the 1950s, to peritoneoscopic cholangiography, a technique used during the 1960s.

Yet, new techniques appear almost every day, the safety of which quite often remains unproven. During the two years 1977-1979, at least 12 new diagnostic and therapeutic procedures were published in two leading journals, one European and the other American, on gastrointestinal endoscopy: duodenoscopic biopsy of the bile ducts, endoscopic lithotripsy, descending sphincterotomy through a T-tube, endoscopically created artificial fistulae, so-called plunging biopsy, sclerotherapy of pancreatitis, choledochofiberscopy, new instruments for polypectomy, new probes for sphincterotomy, techniques for insertion of esophageal tubes, methods for treatment for stenotic anastomoses, a revival of sclerotherapy of esophageal varices. It is hoped that all these procedures will be submitted to proper controls.

Remedies

The main problem, as I see it, is clearly stated by Etzioni [6]: 'Medical procedures, unlike new drugs, are on the market until proven invalid. They don't have to be proven safe first, as drugs.' Several steps might be taken to improve on this situation. In the first place, a registry of accidents might be started and divulged as widely as possible as soon as a procedure becomes popular. Multicentric prospective studies, like the one recently reported by Kreek and Balint [5] on Chiba Needle cholangiography should be encouraged, since they represent the only way to acquire knowledge about potential complications of a procedure in a relatively short time. This was done rather easily and cheaply in the aforementioned study.

Secondly, it would be also helpful to have all new medical diagnostic and therapeutic instrumentation reviewed by institutional committees. New techniques and tests should be submitted to the same rigid controls as new drugs. After many years of use, quite a few techniques, such as angiography, isotopic methods and others, have not found a definitive place in the diagnosis of gastrointestinal diseases, and they may well be replaced by other methods because of all kinds of external pressures, even if their true potential has not been sufficiently evaluated. Suggestions for the maintenance of ethics in medical investigations have been recently put forward by Geoffrey Watkinson (*): medical audit committees should be set up by local authorities to supervise current investigative methods in a given speciality. The committee would invite reports from clinicians on the indications, technique, value and complications of a given procedure. These data would form the basis of a central registry of information about diagnostic tests. In this way data banks could be created, and I believe that the World Organisation of Gastroenterology might act as a clearing house for this purpose and provide an adequate forum for discussion at the time of each World Congress and through appropriate publications.

Thirdly, it would seem necessary to reinforce any provisions about the informed consent of the patient in relation to diagnostic investigations. As Gibinski [7] has stated at the XIIth CIOMS Round Table Conference, patients will readily consent to a new test being performed on them since they often believe

(*) personal communication

that the opportunity of being examined with a new, sophisticated instrument constitutes a lucky event, no matter what the personal experience of the operator with the instrument might be. Even if the key ethical issue is the nature of the doctor-patient relationship and the right of the patient to participate in decision-making as it is relevant to his own future, we may ask ourselves if truly informed consent is really possible when the issue is a new diagnostic or therapeutic procedure.

Finally, ethical problems should be regularly discussed in medical congresses and should be part of training programmes in gastroenterology. This seems necessary, because the real situation, in spite of the efforts of a few, is still far from satisfactory, at least in the field of gastroenterology.

A survey of 12 current gastroenterological journals from different countries shows that only three of them (Gastroenterology, Digestive Diseases, American Journal of Gastroenterology) include ethical guidelines in the instructions to the authors.

An analysis of the papers presented at the Sixth World Congress of Gastroenterology [8] in Madrid in 1978, shows that there were 257 papers reporting results of therapeutic trials in human subjects, of which only 25% of them were 'controlled'. This represented only 5.1% of all papers read at the meeting. If we compare these data with those obtained from an analysis of papers presented at the First World Congress of Gastroenterology [9] which took place in Washington DC 20 years before, it will be seen that at that time only 1.0% of the papers were concerned with controlled trials with proper safeguards for the patients. Thus, after all, some progress has been made.

The lack of interest of the practising physician in ethical matters is also striking. Another survey conducted during the World Congress of Gastroenterology in 1978, in which roughly 3,000 participants were given short questionnaires asking whether they were aware of the Helsinki Declaration and the Tokyo Amendments as well as whether there was an ethical committee at work in their own institution was answered by only 147 people, in spite of the wide publicity given to the survey. The answers can be seen in Table 6. They are not very satisfactory, since the great majority were unaware of the Tokyo Amendments, and review committees were active in only a minority of cases.

The new directives from the Council of Europe in which recommendations are made for each European country to establish

a system enabling authorities to be kept aware of planned clinical trials, including conditions governing technical procedures, are very good news. It is hoped that these measures will provide the gastroenterologist with effective help in making decisions on how to minimize the risk and maximize the consent of patients when confronted with any new diagnostic or therapeutic procedure.

Table 1. Empirical criteria for acceptability of risk considerations influencing safety judgements (modified from Lowrance (4)).

Risk	
Assumed voluntarily	Borne involuntarily
Alternatives	
No alternative	Many alternatives
Exposure	
Unavoidable	'Luxury' exposure
Instrument	
Will be used as intended	Likely to be misused
Consequences	
Reversible	Irreversible

Table 2. Factors involved in harm to the patient.

A)	Instruments
1.	Inherent to the instrument i.e., rigid versus flexible oesophagoscope.
2.	Improper care of instrument i.e., blunted biopsy needles, risk of infection.
B)	Techniques
1.	Preparation of examination may involve risk i.e., intubations, enemata, allergies to contrast materials.
2.	Risks of the technique itself i.e., haemorrhage, perforation, obstruction
3.	Secondary and delayed effects i.e., venous and arterial thrombosis, infections.
C)	Operators
1.	The operator is inexperienced i.e., faulty practical training, ignorance of contra-indications, etc.
2.	The operator is careless i.e., routine precautions not taken or inadvertently omitted.
3.	The operator is greedy i.e., overdiagnosis to protect himself, looking for rare diseases, 'iconolatry', image boosting.
D)	Interpretation
1.	Technical defects i.e., faulty sampling (biopsies, cytologies), poor films.
2.	Inexperience of the interpreter.
E)	The patient
1.	Poor risk patients i.e., coagulation defects, mucosal atrophy causing bleeding or perforation, unknown lesions (hydatid cysts, angiomata, etc. causing problems in blind liver biopsy).

Table 3. Risk of diagnostic procedures (collected series).

Technique	Number of cases	Main complication	Mortality
Rigid Oesophagoscopy	109,053	perforation (0.16%)	0.018%
Gastric fiberscopy	395,162	perforation (0.03%)	0.005%
Blind gastric biopsy	35,044	haemorrhage (0.15%)	-
Big snare biopsy of the stomach	230	haemorrhage (1.30%)	-
Small bowel biopsy	18,255	haemorrhage (0.14%)	-
Rectal biopsy	925	haemorrhage (0.32%)	-
Colonoscopy	35,892	perforation (0.14%)	0.02%
E.R.C.P.	12,421	pancreatitis (0.65%)	0.009%
Percutaneous cholangiography (Chiba Needle)	1,050	peritonitis (0.76%)	-
Laparoscopy	63,845	mixed (2.5%)	0.029%

Table 4. Risk of therapeutic endoscopy.

Technique	Number of cases	Morbidity	Mortality
Gastric polypectomy	790	18 (2.2%)	0
Colonic polypectomy	7365	190 (2.5%)	8 (0.1%)
Endoscopic papillotomy (collected series)	2039	161 (7.9%)	19 (0.93%)

Table 5. Waning tests in the diagnosis of gastrointestinal disease.

String test for upper gastrointestinal bleeding
Mecholyl test for achalasia
Palmer test for ulcer (acid perfusion)
Duodenal drainage for bile analysis
Bromosulphtalein retention test
Evocative enzyme tests for pancreatic disease
Spleen aspiration
Diagnostic pneumoperitoneum
Laparoscopic cholangiography

Table 6. Results of a questionnaire given to 3,000 participants to the World Congress of Gastroenterology, Madrid, June 1978, on awareness of the Tokyo Modification of the Helsinki Declaration.

Countries	Number of answers	Know the text	Ethical Committee in institution
Western Europe	67	14	23
Socialist countries	9	7	4
Other Mediterranean countries	7	-	2
North America	11	3	8
Latin America	36	2	14
Asian-Pacific	17	7	10
Totals	147	33	61

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Resumen

La atencion médica es un proceso continuo. Muchas decisiones del médico se refieren a problemas que requieren juicios de valor, y que pueden tener que confrontarse con los puntos de vista del paciente. Seleccionar la mejor conducta para ambos requiere por parte del médico una decisión ética.

El primer problema es el de definir la ética y, en particular, la ética médica. Según la definición que el autor prefiere, 'La ética trata de cuestiones que se refieren a juicios sobre lo que es 'correcto' y lo que es 'erróneo' en las que personas con inteligencia y sentido de humanidad, pueden diferir sinceramente.' Esta definición subraya la característica principal del proceso de la atención médica, a saber, la adopción de decisiones, en la cual dos médicos honestos e inteligentes pueden realmente no estar de acuerdo.

Las decisiones éticas siempre presentan cierto margen de incertidumbre. A largo plazo, es importante tomar en cuenta lo que Campbell llama 'el respeto para la persona', que es el sentimiento de humanidad, aplicado consistentemente y sin prejuicios personales. Esta actitud valora al individuo por encima del beneficio a la sociedad, e implica mantener una relación entre el médico y el paciente al más alto nivel posible.

La evaluación de las acciones médicas requiere un juicio sobre riesgo y seguridad. Una buena definición de riesgo es 'la posibilidad de pérdida, daño, trastorno o destrucción' o bien 'peligro que se asocia con la idea de azar'. Estas definiciones ponen de relieve la relatividad del concepto de seguridad, e implican no solamente que el riesgo debe ser cuantificado sino también que debe formularse un juicio de valor, una evaluación ética, con respecto a la aceptabilidad del riesgo.

Lowrance subraya los siguientes criterios de evaluación del riesgo: 1. Si se asume voluntariamente o no. 2. Si es posible aplicar una acción menos arriesgada. 3. Si la exposición al riesgo es inevitable. 4. Si el instrumento, la técnica o la operación será utilizado como debe ser o si es fácil que sea mal empleado. 5. Si las consecuencias son reversibles o no.

En el Congreso Europeo de Gastroenterología que se celebró en Budapest, se hizo una clasificación de los factores de riesgo. Algunos de éstos son inevitables, pero otros obviamente no lo son. El autor presenta en forma de tablas una lista de procedimientos, que muestra los principales riesgos de las técnicas diagnósticas usadas en el caso de los pacientes gastroenterológicos, y enumera las complicaciones principales y la tasa de mortalidad del procedimiento.

En prácticamente todos los campos de la medicina aparecen casi diariamente nuevas técnicas cuya seguridad a menudo no se ha comprobado aún. El principal problema ha sido claramente

expresado por Etzioni: 'Los procedimientos médicos (quirúrgicos), a diferencia de los nuevos medicamentos, aparecen en el mercado y permanecen en él hasta que se comprueba que son inútiles. No es obligatorio su ensayo previo, que, en cambio, es imperativo en el caso de los fármacos.' Para remediar esta situación se pueden tomar varias medidas:

En primer lugar, tan pronto se popularice algún procedimiento se puede establecer un registro de los accidentes causados por el mismo y divulgarlo lo más ampliamente posible. Se debe fomentar además la creación de estudios prospectivos multicéntricos.

En segundo lugar, sería muy útil que todos los nuevos métodos diagnósticos y todos los procedimientos de instrumentación terapéutica fueran examinados por comités institucionales.

En tercer lugar, parece necesario reforzar las disposiciones acerca del consentimiento informado de los pacientes en relación con las investigaciones diagnósticas.

Finalmente, los problemas éticos deben ser discutidos regularmente en los congresos médicos y deben formar parte de los programas de adiestramiento en gastroenterología. Un examen de doce revistas de gastroenterología publicadas en diferentes países muestra que solamente en tres de ellas se incluyen orientaciones éticas entre las instrucciones a los autores.

Un análisis de los trabajos presentados en el VI Congreso Mundial de Gastroenterología mostró que se presentaron 257 trabajos sobre resultados de pruebas terapéuticas practicadas en sujetos humanos, de las cuales solamente el 25% estaban 'controladas'; por lo tanto, es de suponer que sólo en éstas se adoptaron las adecuadas garantías para los pacientes.

Es sorprendente la falta de interés del médico practicante por los problemas éticos. En una encuesta practicada en el mencionado Congreso Mundial de Gastroenterología en 1978, en la que se repartieron entre 3000 participantes sendos cuestionarios en los que se les preguntaba si conocían la Declaración de Helsinki y si existía un Comité Etico en su institución, contestaron únicamente 143 personas.

Es de esperar que las nuevas directrices del Consejo Europeo, en el que se recomendó que cada país europeo estableciera un sistema que permita a las autoridades vigilar las investigaciones clínicas, ayuden a despertar el interés del gastroenterólogo por la búsqueda de decisiones beneficiosas para sus pacientes.

ETHICAL REVIEW PROCEDURES FOR RESEARCH INVOLVING HUMAN SUBJECTS *

John F. Dunne

GENERAL COMMENTARY

The generalized application of experimental scientific method to medical research is a product of the present century. Many fundamental discoveries were made before this time, but the sustained progress subsequently achieved in patient care through application of advanced technology to medical practice offers incontestable evidence of the value of contemporary biomedical and clinical research techniques.

Much basic and developmental biomedical research can be undertaken successfully in animal models. However, absolute reliance cannot at present be vested in these models as indicators of physiological, pharmacological or toxicological responses in man. All innovative diagnostic, prophylactic or therapeutic measures need ultimately to be evaluated in human subjects.

In the past such studies have been undertaken predominantly in highly-developed countries and directed to diseases of global relevance. However, wide acceptance of the need for increased technical collaboration with developing countries and awareness of the far-reaching benefits that would derive from successful control of the transmissible diseases, malnutrition and unconstrained population growth now endemic in these areas raises the prospect that more applied medical research will henceforth be undertaken in these countries.

Pressures may also arise, however, for research unrelated to local priority issues to be transferred to these areas. As research and development costs rise to inhibitory levels in more developed countries, a tendency for work to be undertaken wherever it can be done least expensively and with least restriction is liable to gather momentum.

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* This document was prepared within the framework of a joint WHO/CIOMS project for the Development of Guidelines for Ethical Review Procedures for Research Involving Human Subjects. The original version was reviewed by WHO/CIOMS Working Group in July 1980 and presented at the Twenty-second Session of the WHO Global Advisory Committee on Medical Research in October 1980.

Consideration is thus required in developed and developing countries alike as to whether prevailing legal provisions and administrative arrangements ensure that the welfare and human rights of subjects involved in medical research are adequately considered and protected in conformity with the ethical principles prescribed in existing international codes, notably the 1947 Nuremberg Code, the 1964 Declaration of Helsinki and the 1975 Tokyo Amendment.

The Objectives and Scope of Research Involving Human Subjects

The objectives and the design of studies vary considerably but, in broad terms, they are divisible into three categories:

(1) Detailed studies of a physiological or pathological process or, of the response to a specific intervention - either physical, chemical or psychological - in one or more individuals who, according to requirements, may either be healthy subjects or patients with a specific disease state.

(2) Prospective controlled trials of specific therapeutic regimens in larger groups of patients conforming to specified criteria, with a view to demonstrating a specific treatment effect against a background of individual biological variations.

(3) Field studies in which the consequences of specific prophylactic or therapeutic measures are determined within comparable communities.

Having regard to this classification, and for the purpose of the guidelines proposed in this document, research involving human subjects is defined as follows:

'Any investigation involving human subjects, including healthy volunteers that may - or may not - carry expectation of personal benefit but which cannot be regarded as an element in accepted clinical management or public health practice, and that involves either:

- physical or psychological intervention or observation, or

- collection, storage and dissemination of personal information.

Such investigations include not only planned interventions on human subjects but research in which environmental factors are manipulated in a way that could place incidentally-exposed individuals at undue risk.'

These terms of reference are framed broadly, in order to embrace field studies of pathogenic organisms and toxic chemicals under investigation for medical purposes. Analogous risks are recognized to arise in research directed to other objectives including food production and biological or chemical warfare, but non-medical research does not fall within the scope of this document.

Determination of Research Policies

In no country is public funding of medical research adequate to satisfy every need. Particularly when pressures upon resources are intense, both the subjects involved and the public at large have a legitimate expectation that their contributions, both in services and funds, will be competently used to the general benefit of society.

Only through the medium of a national research policy, in which priorities are appropriately defined, and activities effectively coordinated, can such assurance be offered. However, the need to establish accountability for research expenditure is not adequately served solely by the institution of formal administrative procedures. Flexibility of approach and technical judgements of high calibre are required to identify fields in which progress may realistically be anticipated and to ensure that promising leads are actively pursued.

Specific Considerations Applying to Research in Developing Countries

The ethical implications of research involving human subjects are identical in principle wherever the work is undertaken: they relate to respect for human dignity, and protection of the welfare and rights of human subjects. In particular, assessment of inherent risks is a pre-eminent concern. A number of subsidiary considerations, however, have particular relevance to work undertaken in developing countries.

(1) External sponsorship. Research activities in developing countries are frequently sponsored - and sometimes administered or conducted - by external agencies including international

organizations, nationally-based funding agencies, foundations, research councils, universities and research-based pharmaceutical companies.

Active and generous support from these sources is essential if required research is to be fostered on an adequate scale in the developing world, but external sponsorship may carry with it certain implications that require careful preliminary assessment:

- foreign investigators and sponsors may not possess adequate insight into local mores, customs and legal systems.

- the absence of any long-term commitment to subjects involved in the research, and withdrawal of out-posted personnel on completion of their task, may result in local disillusionment.

- lack of accountability can arise that may frustrate the resource of subjects to any form of compensatory process for incidental injury.

If externally sponsored research is undertaken, whenever feasible, through the agency of - or in collaboration with - an established local institution, and if some tangible commitment can be offered simultaneously to the host country and its scientific community in terms of service and training, these difficulties may frequently be assuaged. Nonetheless, indigenous medical manpower is a scarce and valuable resource in developing countries, and diversion of highly-trained personnel to research activities can be advantageous only when the objectives are clearly attuned to important issues of local relevance.

(2) Assessment of risks and benefits. Without a full assessment of the attendant risks no investigation involving human subjects is warranted. Proposed interventions need to be justified in terms of the declared objectives, and the experimental design must be statistically sound to ensure that the required information will be efficiently obtained from the minimum number of subjects.

In some instances, and particularly when the effects of novel synthetic or biological substances are investigated in man, challenging technical judgements arise. Responsibility is particularly onerous when, as may be anticipated repeatedly in the developing world, the disease in question and the candidate treatment both carry material risk.

Few developing countries command the resources or expertise - notably in toxicology or clinical pharmacology - to support the complex regulatory apparatus now considered a mandatory complement to new drug development in industrialized countries. However, since the anticipated benefits and risks of drugs can only be determined in terms of their intended use in defined circumstances, decisions relating to their investigation and subsequent use need to be formulated on local judgement and experience. To what extent international advisory mechanisms might prove a useful resource to developing countries faced with such responsibilities remains an open question.

(3) Economic and social considerations. If exploitation of the under-privileged is to be avoided, it is axiomatic that social deprivation should not be turned insensitively to experimental advantage through vindication of studies which, in other situations, could never reasonably be entertained. Nonetheless, deprivation creates its own demanding challenge: when stocks of essential therapeutic substances or staple food are manifestly inadequate, or when immediate reinfection is a virtually inevitable sequal to radical treatment of a transmissible disease, available resources need to be used to the optimum advantage of the community. In these circumstances field research must be directed to practicable options rather than unattainable ideals, and the community itself should be equitably represented in the planning of such investigations.

Informed Consent

The involvement of human subjects in research must be contingent, whenever feasible, upon freely-elicited informed consent and upon liberty to withdraw collaboration at any stage without fear of prejudice. No alternative basis exists for effectively protecting the freedom of choice of the individual and ensuring that clinical research finds acceptance with opinion at large.

Nonetheless, by itself, the procedure of consent provides an insecure mechanism for protecting the welfare of subjects on several counts:

- Some important categories of individuals, including children and mentally incapacitated patients, are incompetent to provide legally valid consent. Moreover, elimination of any suggestion of coercion or exploitation may be difficult when subjects are drawn

from classes of individuals who, either directly or indirectly, are in a dependent or subordinate relationship to the investigator.

- Reward or other inducement may be offered to elicit consent that exceeds reasonable compensation for services rendered and inconvenience sustained. Unjustifiable assurances may also be given, inadvertently or otherwise, concerning risks or inconvenience, in which case consent may operate to reduce the legal liability of the investigator for incidental injury rather than to protect the interests of the subject.

- Provision of complete information on all possible risks arising from participation in a study may not be feasible. An adverse effect may occur that was unanticipated by the investigator and, possibly, totally unpredictable. More frequently, the potential subject may be unable adequately to comprehend the proposition. In some communities the very concepts of scientific method and experimental evaluation of therapy are alien and inconsistent with cultural precepts. Consent can then merely signify innate confidence in the judgement of the investigator.

Whereas, ideally, each potential research subject should possess the intellectual capacity and insight to provide valid informed consent, and enjoy the independence to exercise absolute freedom of choice over the extent of the collaboration without fear of discrimination, many investigators, and particularly those intended to subserve the interests of under-privileged communities and vulnerable minorities including children and the mentally ill, would be debarred if these preconditions were accepted as mandatory criteria for recruitment.

It is consequently of prime importance to consider whether research involving such subjects can be vindicated and, if so, by what mechanism their welfare can be protected and the ethical proprietary of the research be assured.

Research Involving Children

Children should never be involved as subjects in research that could appropriately be undertaken in adults.

However, the results of much research undertaken in adults cannot be extrapolated freely to apply to younger individuals.

Unique physiological adjustments occur during transition from intra-uterine to extra-uterine life, while the physiology and pathology of all physical and mental processes, and particularly of growth, maturation, and degeneration are manifestly age-dependent. Better understanding of these processes, and of the mechanisms by which they are regulated, holds benefit for all individuals. Indeed, inadequate knowledge of physiological development has on more than one occasion resulted in widespread misapplication of therapeutic measures in children through lack of appreciation of evident hazards. Many reported cases of blindness resulting from oxygen-induced retrolental fibroplasia, of fatalities attributable to sulphonamide-induced kernicterus, and of chloramphenical-induced marrow aplasia establish a cardinal need for thorough initial assessment of new therapeutic measures as they are introduced into pediatric - and particularly neonatal - care.

Furthermore, some important childhood diseases are virtually incompatible with survival into adult life. In other instances infants are highly vulnerable to conditions, including diarrhoea, malnutrition and malaria, that are better tolerated within the adult population. Improved management of these conditions is unlikely to occur save from results of research undertaken in the population at risk.

If these arguments are conceded, the proposition that either therapeutic or non-therapeutic research on children is inherently unethical becomes untenable. In the vast majority of situations, however, no intervention can be countenanced that involves any risk to health or prospect of unreasonable psychological disturbance, physical discomfort or pain.

Strong justification is always required for any invasive procedure, including even blood sampling in children, but very small quantities of biological fluids or tissues may often be obtained incidentally and innocuously for research purposes when such materials are in any event required for diagnosis or routine management. The same reservation also applies to the use of X-rays or isotopes for research purposes. The International Commission on Radiological Protection, however, considers that exposure could be justified in some situations provided the total additional radiation lies within the limits of variation in natural exposure.

Even in the case of drugs or vaccines intended ultimately for use in children, the quality of the preparation should be assured, and safety and efficacy studies in adults be well advanced before tests are contemplated in younger subjects. There is no merit, however, in unduly delaying such tests when these are appropriate: marketed drugs will otherwise be used in children without the benefit of knowledge obtained from appropriately designed clinical studies.

With rare exceptions - such as a comparison of two alternative emergency treatments - the understanding and agreement of parents or guardians is essential and, in all cases, the protocol should have the approval of an appropriate independent review body. Consent should, as far as is practicable, be regarded as a decision of the family unit and, particularly in non-therapeutic research, it is advantageous for the parents to be present during the procedure.

Research Involving Pregnant Women

The incidental involvement of pregnant women in therapeutic trials raises an ethical issue of fundamental importance. It is crucial to ascertain at the earliest possible opportunity any influence a therapeutic intervention - and particularly a new drug - may exert on fetal development. However, any question of deliberately exposing a fetus to the uncertain consequences of an experimental intervention unrelated to the pregnancy is unacceptable save in circumstances in which the mother's life is at issue. To avert all possibility of fetal damage, it is frequently prudent specifically to exclude from clinical investigations any woman who is, or may become, pregnant.

Knowledge concerning the potential teratogenic effects of drugs under development is thus vested exclusively in results of animal studies. Direct information on any possible hazard they may present to the human fetus can only emerge from epidemiological data subsequently obtained under routine conditions of use.

Different considerations apply to research directed specifically to sustaining normal pregnancy. Nonetheless, teratogenic and latent carcinogenic changes have been reported in individuals exposed *in utero* to exogenous hormones administered both for diagnostic and therapeutic purposes. A need is therefore established for extensive preliminary investigation and authoritative independent consideration of possible adverse

consequences of any proposed experimental intervention contemplated in pregnant subjects.

Research Involving the Mentally Ill

The benefits that medical research has brought to the mentally ill over the past two decades have been particularly impressive. The development of new psychotropic drugs has been matched by a sharp reduction in the morbidity associated with the psychoses, in the mortality resulting from depression, and in the need for long-term institutional care.

Since animal models of human psychiatric disease are grossly inadequate, and because many psychoactive agents have little effect on the behaviour and mood of normal individuals, a clear indication of the therapeutic potential of these substances can usually be obtained only from investigations on subjects drawn from precisely-defined groups of patients.

Although freely-elicited informed consent must remain the ideal objective for all research involving human subjects, the capacity of schizophrenic, severely depressed, or mentally defective patients to collaborate on these terms is inevitably compromised and often completely lacking. In some instances a second clinician's opinion of the patient's competence to provide consent can be used as a determinant of his suitability to serve as a research subject. In circumstances in which consent is not a feasible requirement, the research protocol should have the approval of an appropriate independent review body, and the participation of individual patients should, where applicable, be contingent upon the consent of the legally recognized guardian.

Community-Based Research

The provision of basic prophylactic care on a community basis is the aim and the obligation of every public health service. These measures, moreover, are often accorded force of law on the thesis that any incidental infringement of individual liberties is decisively out-weighed by benefit to the community as a whole. In some instances this care commits individuals, either singly or collectively, to exposure to biologically active substances. Compulsory vaccination and implementation of vector control programmes offer obvious examples, while addition of iodine to table salt, of vitamins to staple foods, of nitrite to meat products and of fluoride to public water-supplies further

illustrates the scope of such provisions. The benefits are incontestable, but apprehension concerning risks - both hypothetical and apparent - has, on occasion obstructed their acceptance.

Wherever interventionist public health policies are accepted as a function of government, a complementary need to assess and to monitor the consequences of such measures from the time they are planned - and for as long as they remain in operation - must be accepted, not only by the responsible authorities, but by the community at large. Observations on considerable numbers of subjects are usually required if reliable estimates of performance, both beneficial and adverse, are to be obtained. Moreover, these effects may be measurable only in terms of a collective response and comparisons between treated and untreated communities may initially be required to discern them.

Identical considerations apply in even greater measure in many developing countries where comparative field trials undertaken on a community basis frequently offer the only practicable means of objectively determining policies relating to issues as diverse as nutritional requirements, environmental and/or occupational health regulations, vaccination programmes and other measures applied in the control of transmissible disease.

When the possibility of eliciting adequately-informed consent from every individual implicated in a field study is manifestly impracticable, investigations can only proceed upon the basis of meticulous preliminary experimentation and assessment, competent technical advice, and an acceptable procedure for delegation of the power of consent from the individual subject to an independent representative body charged to protect community interests.

The precise mechanism through which delegation of consent is achieved will be influenced by political philosophy, the nature and inter-relationships of govermental and professional institutions, the degree of centralization of administrative processes, the structure of society, cultural precepts, and the degree of sophistication of the communities directly involved in the matters at issue. Whatever the circumstances, the responsibility for such studies must rest, directly or indirectly, with government which must ensure that the ethical considerations applied to research on individuals will be translated into the community context in every possible respect.

Independent Prospective Review

The limited application of the informed consent procedure, and its vulnerability to abuse, render it inadequate as an exclusive means of protecting the human rights and welfare of research subjects, and it fails most decisively when the target population from which the subjects are drawn is most vulnerable.

Even when valid consent is obtainable, both the subjects and the investigator should have assurance to proceed in the knowledge that the research is sanctioned by representative professional and lay opinion. This requires an independent impartial prospective review of all protocols with the aim of establishing that:

- the objectives of the research are directed to a justifiable advancement in biomedical knowledge that is consonant with prevailing community interests and priorities.

- the interventions are justifiable in terms of these objectives; the required information cannot be obtained from animal models; and the study has been designed with a view to obtaining this information from as few subjects as possible who will be exposed to a minimum of risk and inconvenience.

- the responsible investigator is appropriately experienced and commands facilities to ensure all aspects of the work will be undertaken with due discretion and precaution to protect the safety of the subjects.

- adequate preliminary studies have been undertaken to define, as far as practicable, the risks inherent in participation.

- every effort will be made to inform prospective subjects of the objectives and consequences of their involvement, and particularly of identifiable risks and inconvenience.

- any arrangement to delegate or waive individual informed consent has adequate justification and appropriate safeguards will be instituted to ensure that the rights of the subjects will be in no way abused.

- appropriate measures will be adopted to ensure the confidentiality of data generated in the course of the research.

The size, composition and terms of reference of existing committees vary within wide limits. Two principles, however, generally determine representation. First, committees must command the technical competence and judgement to attempt to reconcile the physical and psychological consequences of participation with both the welfare of the subjects and the objectives of the investigation. Secondly, they must also accommodate respected lay opinion as well as professional expertise in a manner that provides effective representation of both community and medical interests.

Where administrative functions are highly centralized, and research activities are concentrated predominantly or exclusively in officially-designated specialized centres, an integrated national review mechanism may be practicable. Through appropriate organization of sub-committees a centralized committee may itself possess the full range of specialized competence to assess all technical information bearing upon the safety of the proposed interventions, as well as the complementary ethical considerations.

Where research activities are conducted more diffusely within the medical community, a need emerges to dissociate these two functions. A centralized committee of experts is still best equipped to provide an authoritative technical pronouncement on the safety and efficacy of investigational agents including new drugs and devices, whereas it might not be suitably constituted to consider large numbers of research protocols generated by every clinician with a research interest working under its aegis. In any case, peripheral committees, operating on an institutional or regional basis, are inherently better placed through awareness and understanding of local factors, not only to assess the ethical aspects of individual studies, but to monitor their progress as necessary.

Although the organization of ethical review committees in many countries has been determined by governmental policy, professional organizations have a responsibility to recommend appropriate standards of operation and to assume a harmonizing role. In particular, bodies representative of pediatricians, psychiatrists and many other clinical specialities are uniquely

qualified to address the problems of research involving individuals lacking the capacity to offer informed consent. Not least, sponsoring agencies, which also have a strong vested interest in developing and maintaining acceptable ethical standards, might advantageously demand evidence of independent committee review as a mandatory pre-condition of funding.

Compensation for Personal Injury

Accidents resulting in serious disability or death are rarely encountered in medically-oriented research involving human subjects. When such an event does occur, the subject, or the dependants, may qualify for an ex-gratia payment, or they may have the right to institute proceedings on grounds of negligence in a court of law. In either case the outcome is uncertain, and the process of litigation, which readily becomes protracted and embittered, can also be unreasonably detrimental to the reputation of the investigator.

Such provisions are widely regarded as inadequate and inappropriate in most cases, and alternative systems have recently been advocated or introduced in several countries. These are based on two principles:

- strict liability which is determined by the courts, not only on the basis of negligence, but solely on the ability of the claimant to prove association of cause and effect.

- no-fault compensation, which provides for claims to be made on a similar basis against an insurance fund derived from public or private sources and administered by an arbitration board.

Ideally - save, perhaps, when punitive damages are considered appropriate in cases of gross negligence - all disability should be compensated on an equitable basis regardless of its cause. This is likely to remain an impracticable objective in the majority of countries for the foreseeable future. Nonetheless, natural justice demands that every subject participating in medical research should have automatic entitlement to reasonable and expeditious compensation for any injury sustained as a result of participation. It is inevitable that such provision will create anomalies, but this objection cannot negate the obligation adequately to protect those who offer their services altruistically to the benefit of the community.

PROVISIONAL GUIDELINES

1. Few appreciable improvements in health standards are likely to materialize in any country without committed pursuance of coherent, socially-relevant research activities. These endeavours are everywhere dependent upon public support and collaboration, and both governments and the health professions share a responsibility to ensure that community and professional interests are joined in developing policies and procedures that will engender widespread confidence in research practice.

In particular, assurance should be available that priorities observed in the allocation of resources are attuned to community needs, and that adequate measures are adopted to protect the rights and the welfare of human subjects consonant with the Declaration of Helsinki of the World Medical Association adopted in 1964 and revised in 1975 in Tokyo (see Annex).

2. These requirements may be effectively fulfilled through the operation of two general principles:

2.1 Provision by the subject of freely-elicited informed consent and an explicit assurance providing for freedom to withdraw at any stage without frear of recrimination.

2.2 Sanction of research proposals by an appropriately-constituted independent body that has considered the justification for each intervention in relation to the welfare of the subject.

3. Two considerations, however, establish a need for flexibility of approach:

3.1 Difficulty arises in consistently differentiating between therapeutic research and routine clinical management. What passes for an investigative procedure in one context may be regarded as professional care in another. This applies, in particular, to comparative assessments of established therapeutic regimes. Nonetheless, patients have an expectation to be consulted whenever a proposed readjustment of treatment or supplementary investigation is contemplated primarily to subserve a research requirement.

3.2 Insensitively interpreted, the need for full discussion of the objectives of a study and the potential implications of participation could engender needless anxiety and neuroticism

among subjects involved in some therapeutic research. In other cases, provision of this information is liable to compromise or frustrate the outcome of the study.

4. The complexity of these issues lays a responsibility on representative professional bodies to provide the investigator with a framework of reference which will also serve to guide funding agencies, and to assist administrative bodies and the courts. National and international organizations representing specialist medical interests are ideally qualified to issue guidelines on ethical aspects of research related to their competence.

5. The health professions are also uniquely qualified to organize and implement, through a process of peer review, a system of ethical assessment of research well adapted to find acceptance with investigators and subjects alike, particularly if committee representation is broadened to include lawyers and lay representatives.

6. Professional experience and insight are crucial to any review procedure since informed assessment of research is contingent upon:

6.1 provision of a detailed protocol of the study comprising:

- a clear statement of the objectives, having regard to the present state of knowledge, and a justification for undertaking the investigation in human subjects.

- a precise description of all proposed interventions including intended dosages of drugs and planned duration of treatment.

- a statistical plan indicating the number of subjects to be recruited and the criteria for terminating the study.

- the criteria determining admission and withdrawal of individual subjects.

6.2 reference to any relevant collateral technical information bearing upon:

- the safety of each proposed intervention;
- the quality and safety of any drug or device submitted to investigation;
- the presumed benefits to be derived from the research.

6.3 evidence that the investigator is appropriately qualified and experienced, and commands the facilities required for the safe and efficient conduct of the research.

6.4 full details of the procedure by which informed consent will be elicited or, when this is not possible, satisfactory assurance that the guardian or family unit will be appropriately consulted and the interests of each subject will be adequately protected by a clinician with no involvement in the trial.

6.5 a description of any measures that will be adopted to ensure confidentiality of personal data generated during the course of the research.

7. Nationally operative factors will determine how, and on what authority, these provisions are administered, but two considerations are broadly applicable:

7.1 Authority to offer general recommendations on the safety and quality of medicines and devices intended for use in man is most effectively vested in a multi-disciplinary advisory committee operative at national level. Clinicians, pharmacologists, toxicologists, pathologists, pharmacists and statisticians have important contributions to offer to these assessments.

7.2 Many countries at present lack resources to undertake independent assessments of technical data according to procedures and standards now considered mandatory in many highly-developed countries. Improvement in their capability to subserve this function is dependent, in the short term, on more efficient exchange of relevant information internationally.

8. In a highly centralized administration, a national committee may be suitably constituted to review individual research protocols from both technical and ethical standpoints. In countries where medical research is not centrally directed, however, protocols are most conveniently reviewed at local or regional level. The basic responsibilities of locally operative committees are two-fold:

8.1 to verify that all proposed interventions, and particularly the administration of drugs under development, have been assessed by a competent expert body as acceptably safe to be undertaken in human subjects.

8.2 to ensure that all other ethical considerations arising from a protocol are satisfactorily resolved both in principle and in practice.

9. Research undertaken on a community basis - save for epidemiological surveys involving no more than a negligible risk - raises special considerations. In general, it is justified only by the need to determine an important element of public health policy and, as such, responsibility for its implementation must lie within the apparatus of national or local government. Whatever the circumstances, the ethical considerations and physical safeguards applied to research on individuals must be translated, in every possible respect, into the community context.

10. To avoid the involvement of unnecessarily large numbers of human subjects in research it is important not only to design investigations efficiently, but to strive to reduce unproductive duplication of effort. Every research proposal should be based upon a comprehensive survey of relevant information, and the feasibility of compiling central classified registers of some categories of ongoing research, on the basis of review committee notifications, merits consideration.

11. Serious injury rarely arises as a consequence of medical research. However, when it does occur in a subject who has clearly rendered a service altruistically to the community, provision should exist for reasonable and expeditious compensation. In many countries this is at present dependent either upon ex-gratia payment or litigation. Both procedures have evident shortcomings and experience with the principle of 'no-fault compensation' already operative in some countries should have wide relevance internationally.

Declaration of Helsinki

Recommendations guiding medical doctors in biomedical research involving 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 recognized 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.

I. 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 forseeable benefits to the subject or to others. Concern for the interests of the subject must always prevail over the interest 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 if 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 (I,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 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.

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Resumen

Comentario General. La aplicación generalizada del método científico experimental en la investigación médica es un fenómeno del siglo XX. Muchas de las investigaciones básicas pueden efectuarse en modelos animales; sin embargo, en estos modelos no se puede lograr una fidelidad absoluta, por diversas razones, y todos los procedimientos nuevos, tanto de diagnóstico como profilácticos y terapéuticos, deben evaluarse en fin de cuentas en seres humanos.

En el pasado, estos estudios se realizaban sobre todo en los países desarrollados y estaban dirigidos a enfermedades de importancia mundial. Sin embargo, la comprensión universal de las ventajas que ofrecen ciertas medidas como la lucha contra las enfermedades transmisibles y la contención de la explosión demográfica ha hecho que cada vez sean más las investigaciones médicas que tienen lugar en países en desarrollo.

Por otra parte, se ejercen presiones para que las investigaciones médicas se realicen en estos países, habida cuenta de la elevación de los costos de estas investigaciones cuando se ejecutan en países desarrollados.

Importa, pues, cada vez más, considerar si las normas jurídicas y administrativas garantizan el bienestar y los derechos humanos de los sujetos sometidos a investigaciones médicas, de conformidad con los principios éticos reconocidos en los códigos internacionales, tales como el Código de Nuremberg de 1947 o la Declaración de Helsinki modificada en Tokio en 1975.

El autor hace una minuciosa revisión preliminar de diversos aspectos éticos de la investigación en seres humanos, a saber:

1. Los objetivos y el enfoque de la investigación en seres humanos.

2. La manera de determinar las políticas de investigación.

3. Las consideraciones específicas que deben aplicarse a la investigación en los países en desarrollo.

4. El mecanismo de obtención del consentimiento informado, y los factores que limitan este consentimiento.

5. Las condiciones que deben cumplirse en las investigaciones practicadas sobre niños.

6. Las condiciones que deben cumplirse en las investigaciones en mujeres embarazadas.

7. Las condiciones de la investigación en los enfermos mentales.

8. Las condiciones de las investigaciones en materia de salud pública.

9. Los requisitos que deben satisfacerse en las revisiones prospectivas independientes.

10. Bases para la compensación de los daños personales ocurridos como resultado de una investigación.

A partir de estas consideraciones, el autor presenta las pautas provisionales que la Organización Mundial de la Salud desea que sean examinadas y evaluadas por la clase médica. Estas pautas provisionales se traducen literalmente a continuación.

Pautas provisionales.

1. Muy poco podrán mejorarse los niveles de salud en los países donde no se ejecuten actividades de investigación coherentes y de importancia social. Estas investigaciones necesitan en todo el mundo el sostén y la colaboración de las autoridades, y los gobiernos y las profesiones de la salud comparten la responsabilidad de velar por que los intereses comunitarios y profesionales converjan en políticas de desarrollo y en procedimientos que puedan generar confianza en la práctica de la investigación.

En particular, debe conseguirse que las prioridades aplicadas en la distribución de los recursos correspondan a las necesidades comunitarias y que se adopten medidas adecuadas para proteger los derechos y el bienestar de los sujetos de investigación, de conformidad con las disposiciones de los códigos internacionales existentes, tales como el Código de Nuremberg de 1947, la Declaración de Helsinki de 1964 y la modificación de Tokio de 1975.

2. Estos requisitos pueden lograrse mediante la aplicación de dos principios generales:

2.1 Los sujetos de investigación deben poder otorgar su consentimiento libremente, después de recibir la información adecuada y de habérseles garantizado explícitamente que podrán retirarse en cualquier momento sin temer recriminaciones.

2.2 Los proyectos de investigación deben ser aprobados por un órgano independiente, apropiadamente constituido, que haya considerado la justificación de cada intervención en relación con el bienestar del sujeto.

3. Sin embargo, en aras a la flexibilidad necesaria, deben tenerse presentes las dos consideraciones siguientes:

3.1 Es difícil distinguir consistentemente entre investigación terapéutica y tratamiento clínico normal. Lo que pudiera ser considerado como procedimiento de investigación en un contexto puede aparecer como atención profesional en otro. Así ocurre en particular en el caso de la valoración comparativa de regímenes terapéuticos establecidos. Sin embargo, los pacientes deben ser consultados siempre que se haga una modificación del tratamiento o que se considere la conveniencia de una investigación suplementaria, si ésta tiene por objeto primorial obtener un dato de investigación.

3.2 Interpretada sin la debida consideración, la obligación de discutir en forma completa los objetivos de un estudio y sus implicaciones puede engendrar ansiedad inútil y neurosis en los sujetos sometidos a investigación terapéutica. Por otra parte, en ciertos casos, el hecho de facilitar esta información puede comprometer y aún frustrar el resultado del estudio.

4. La complejidad de estos problemas obliga a las corporaciones profesionales representativas a facilitar al investigador un marco de referencia que también deberá servir para orientar a los organismos que financian los estudios y para ayudar a los órganos administrativos y a los tribunales de justicia. Las organizaciones nacionales e internacionales que representan intereses médicos especializados están calificadas en forma óptima para elaborar pautas sobre los aspectos éticos de las investigaciones relacionadas con su esfera de competencia.

5. Las profesiones de la salud también están calificadas para organizar y aplicar, mediante un proceso de revisión a cargo de sus iguales profesionales, un sistema de evaluación ética de la investigación que esté bien adaptado y encuentre aceptación entre

los investigadores y entre los sujetos de investigación, en particular si la composición de estos comités se amplía para incluir a abogados y representantes de la sociedad en general.

6. La experiencia y los conocimientos profesionales son fundamentales en todos los procedimientos de revisión, puesto que la vigilancia informada de la investigación requiere:

6.1 La presentación de un protocolo detallado del estudio que comprenda:

- La expresión clara de los objetivos que se persigan, teniendo en cuenta el estado actual de los conocimientos así como las razones que justifiquen la investigación en sujetos humanos.

- La descripción precisa de todas las intervenciones propuestas, incluidas las dosis de fármacos y la duración planeada del tratamiento.

- El plan estadístico que indique el número de sujetos que deban ser empleados y los criterios que se aplicarán para decidir la supensión o terminación del estudio.

- Los criterios que determinan la admisión y el retiro de cada sujeto respecto al proyecto de investigación.

6.2 Las referencias de información técnica colateral pertinente que tenga que ver con:

- La seguridad de cada intervención propuesta.

- La calidad y seguridad de cualquier fármaco o instrumento que sea sometido a la investigación.

- Los beneficios que cabe esperar que se deriven de la investigación.

6.3 Pruebas de que el investigador está capacitado, tiene experiencia y dispone de las facilidades necesarias para la conducción eficiente y segura de la investigación.

6.4 Detalles completos del procedimiento por el cual se obtendrá el consentimiento informado, o, cuando esto no sea posible, seguridad satisfactoria de que el responsable o la unidad familiar

fueron consultados y de que los intereses de cada sujeto estarán protegidos adecuadamente por un clínico que no participe en el proyecto de investigación.

6.5 Descripción de todas las medidas que se adoptarán para garantizar la confidencialidad de los datos personales generados durante la investigación.

7. Los órganos operativos nacionales determinarán cómo y bajo qué autoridad se vigilará el cumplimiento de estas provisiones, pero existen dos consideraciones que son de aplicación universal, a saber:

7.1 La autoridad que puede ofrecer con más eficacia información general sobre la seguridad y la calidad de los medicamentos y otros recursos que deban ser usados en seres humanos será un comité multidisciplinario que opere a nivel nacional. Los clínicos, farmacólogos, toxicólogos, patólogos y expertos en estadística tienen contribuciones importantes que aportar al respecto.

7.2 Muchos países carecen actualmente de recursos para efectuar la evaluación independiente de los datos técnicos según los procedimientos y normas que se consideran obligatorios en muchos países altamente desarrollados. El mejoramiento de su capacidad para esta función requiere, a corto plazo, un intercambio de información internacional más eficaz y más pertinente.

8. En una administración pública muy centralizada, un Comité Nacional puede ser adecuado para revisar los distintos proyectos de investigación, tanto desde el punto de vista técnico como ético. En los países donde la investigación médica no depende de una dirección central, los protocolos de investigación se pueden revisar con más eficacia en el plano local o regional. La responsabilidad básica de los Comités Cooperativos locales es doble:

8.1 Verificar que todas las intervenciones propuestas, y particularmente la administración de fármacos en proceso de desarrollo, han sido evaluadas por un cuerpo competente de expertos que las considera aceptablemente seguras para ser aplicadas a sujetos humanos.

8.2 Velar por que todas las consideraciones éticas que se deriven del protocolo estén resueltas satisfactoriamente tanto en principio como en la práctica.

9. Las investigaciones que se desarrollan sobre la base de la comunidad, excepto en el caso de las evaluaciones epidemiológicas en las que los riesgos son insignificantes, requieren consideración especial. En general, están justificadas únicamente por la necesidad de determinar un elemento importante de la política de salud pública, y, por lo tanto, la responsabilidad de su ejecución incumbe a las autoridades nacionales o locales. Cualesquiera que sean las circunstancias, las consideraciones éticas y de seguridad física que se aplican a las investigaciones en los individuos deben aplicarse, en todos sus aspectos posibles, en el contexto comunitario.

10. Para limitar al mínimo indispensable el número de sujetos de investigación, es importante no solamente diseñar la investigación eficientemente, sino reducir en lo posible la duplicación inútil de esfuerzos. Cada propuesta de investigación debe estar basada en un examen completo de la información pertinente, y es preciso considerar seriamente la posibilidad de establecer para ciertas categorías de investigación registros centrales en los que se recojan las notificaciones de los comités de revisión, debidamente clasificadas.

11. Raras veces se producen daños importantes como consecuencia de una investigación médica. Sin embargo, cuando tal cosa ocurre en un sujeto que, sin lugar a dudas, ha prestado altruísticamente un servicio a la comunidad, debe preverse una compensación razonable y expedita. En muchos países esta compensación adopta la forma de una indemnización voluntaria o fijada por los tribunales en caso de litigio. Ambos procedimentos presentan evidentes desventajas y convendría difundir al máximo, en el plano internacional, la experiencia positiva adquirida en la aplicación del principio llamado de la 'compensación sin culpa'.

DISCUSSION - DISCUSION

OPENING COMMENTS - COMENTARIA INICIAL

Adolfo Martinez-Palomo

The various presentations on ethical issues of clinical research that we have heard during this fruitful morning have logically started with a sceptical overview on the philosophy of human experimentation, followed by the examination of the value of ethical review committees. The second part contained a project on general proceedings for research involving human subjects, and specific examples of the practical and immediate value of various procedures applied to a given clinical specialty, gastroenterology.

Dr Ladd has purposely started with a dogmatic assertion of the alleged futility of what has been written on the subject of the ethics of human experimentation. This has left us wondering about his previous reading. At any rate, the uncertain quality of Dr Ladd's past bibliograhy was certainly absent from today's presentations and from the proceedings of previous CIOMS conferences.

We should agree with Butler that the foundations of morality are like all other foundations: if you dig too much, the superstructure will come tumbling down. However, our purpose here is not to dig, but to construct, to define guidelines that would reconcile the continuous advancement of medical scientific knowledge with a clearly structured ethical framework.

We basically agree with Dr Ladd when he insists that moral attitudes should regulate the ethics of human experimentation, rather than the blind application of legal notions. But rules and morality can blend, as the proposed WHO/CIOMS guidelines and Dr Vilardell's practical suggestions have well exemplified. If morality consists in accepting the standard of one's age, it is our challenge to define such standards.

Another controversial issue is the ideological extreme assumed to be represented by scientists. According to it, investigators would consider scientific progress as invariably beneficial to mankind and thus, human experimentation as morally obligatory. Such contentions have not been expressed by leaders of the modern biologic revolution, such as Monod, who clearly stated at least in the French original edition of his Le hasard et la nécessité: 'la science remet aux mains de l'homme les immenses pouvoirs qui l'enrichissent et le menaçent, le libèrent, mais pourraient aussi l'asservir'.

I would like to end this brief comment with a suggestion concerning the proposed international ethical guidelines for human experimentation. In particular, the specific considerations related to research in developing countries that, I believe, should be reexamined. The sudden burst of experimentation in certain underdeveloped countries originated by the Special WHO programme on Research on Tropical Medicine should take into consideration the ethical issues derived from the interaction with culturally deprived populations bound and limited by prejudice, poverty and religion. In these instances, the exploitation of the have-nots by the haves should be of particular concern. Within its widest context Spencer's assertion should remain in our minds: 'Absolute morality is the regulation of conduct in such a way that pain shall not be inflicted'.

Riis: I will comment on a few main items without going too much into details. Page 2 of the WHO/CIOMS document presented by John Dunne refers to 'any investigation involving human subjects, including healthy volunteers, that may or may not carry expectation of personal benefit, but which cannot be regarded as an element in accepted clinical management or public health practice...'. Here the word 'accepted' is very crucial. One can define it as: What most clinicians do. But this would exclude vast fields of clinical research, seriously needed for the coming years. If, on the other hand, it means the rather low percentage of scientifically proven clinical methods, I can accept it, provided it is defined much more in detail.

Then there is the problem of which kind of activities or data should be included in a scientifically ethical discussion. We have to accept a very important delineation between simple retrograde compilation of clinical data and real research projects.

The third problem is the key word 'therapeutic'. We are still speaking of 'therapeutic research' and 'non-therapeutic research'. But is 'therapeutic' actually only dealing with treatment, or should our discussions include diagnostic approaches and preventive matters? According to my opinion, certainly yes.

The fourth problem is informed consent. Some of the speakers have exempted the most difficult situations, but I - as many other clinicians - am most interested in not excluding them. Think of the severely intoxicated patient, the unconscious patient, the traffic victim, the severely depressed patient, and the small

child or the premature newborn. By excluding them, we make it easier for ourselves to discuss these matters, but we create a distance from the clinical situations in which some of us repeatedly find ourselves.

The fifth problem is the inclusion of social-medical projects in the group of projects involving ethical aspects. Using even anonymous data does not relieve us from considering the ethical aspects. By publicly reporting serious follow-up results, you can stigmatize a group of patients, even if every-one entering the study has been anonymous.

My sixth comment is on the scientific-ethical spectrum on which I would like the speakers and discussants to comment. It is rather easy to discuss scientific ethics dealing with ascorbic acid tablets in the treatment of common colds. There is a very little risk involved, and easy clinical models such as this have influenced discussions on the ethics of controlled designs too much. But if we proceed to the more serious, non self-limiting, diseases, and the corresponding therapeutic measures, the risks and ethical dilemmas increase rapidly. From the psychological aspects, the patients' expectations and the clinicians' are very different. Patients expect clinicians to be almost omnipotent from knowing everything. Thus, to prepare the public opinion for the fact that we have to do controlled clinical experiments we have to admit that compared to the amount of safe scientific evidence of effective clinical methods the supposed omnipotence of the ordinary clinician has been heavily idealized, and such heart-searchings are rather painful for some members of the medical profession, although they represent an inevitable development.

As a last comment I would point out that the balance between public and scientific interests in an ethical sense is not a static, but a dynamic one. During the last 5 to 10 years the discussion of these matters between the public and scientists have taken place, and as a result there is a growing understanding that clinical and non-clinical research are necessary, also from the citizens' point of view.

Yet public attitudes change rather slowly. The experience from Denmark, and probably from the other Nordic countries, is that such a change in understanding and attitudes needs more time. International discussions of the matter, as the present one, are very important, because the participants can go back and influence national development, by projecting local problems into an international reference framework.

Farber: I am speaking as Chairman of the Ethics Committee of the World Medical Association.

I have noticed from the available documents, and also from the discussions, that our main exercise today consists in trying to improve on the Helsinki Declaration with the Tokyo amendment. I am not sure that any decisive modification of the original text is necessary as a consequence of our discussion. However, it seems to me that a major contribution of our endeavours can be an effort to explain and to comment on the Helsinki Declaration.

We might give practical guidance to those involved in the field of medical research. In the first place guidance is necessary as far as the actual functioning of ethical review bodies is concerned. Secondly the scope of their activity should be determined and thirdly we should be more cognizant of existing discrepancies between different countries.

For instance I was very impressed this morning by Dr Ladd's contribution, though I do not agree with everything he said. I would like to emphasize the portion of his paper where he makes a clear difference between the law and medical ethics.

Those of you who are not familiar with some of our Western Europe legislations will find it unbelievable that in many developed countries, such as France or Belgium, a doctor can only lawfully render professional service to a patient with a view to preserving his health.

This means clearly that a healthy person who obviously has no need of medical attention cannot be subject to medical or surgical procedures for experimental reasons, even with his informed consent.

One consequence of this legal situation is that no insurance company would compensate for accidents arising from experiments on healthy people. In these countries it is very important that public authority should be convinced that an Ethics Committee is checking and monitoring experimental medical activities particularly on healthy subjects.

Now, looking through this very interesting and important document on 'Ethical Review Procedures for Research Involving Human Subjects' there are, of course, some remarks to be made, and especially on the section dealing with informed consent.

Informed consent is questionable when the patient is not an adult and not able to understand fully what is asked of him. One point that has been raised is the problem of research involving children. I think the case has been presented very clearly in a very sensitive situation from the viewpoint of public opinion.

We should, however, emphasize that if we want pediatrics to be founded on firm scientific basis and on sound evaluation of therapeutics, experiments on children are unavoidable. The same can be said of course of the fetus and the pregnant woman. And even more so about the mentally ill. I noticed that nobody addressed himself to the problem of experiments on prisoners, although there are obvious advantages in favour of research on that category of subjects. However, some people believe that informed consent given by a prisoner is always obtained under some kind of pressure.

Now, it can be argued that the same applies to experiments done on medical students, on nurses or other volunteers, and of course also on patients for experiments unrelated to their actual disease.

It is in such circumstances that the Ethics Committees have the most important part to play. They have to measure the risk incurred, and the inconvenience, against the probable benefits for the individual patient and for society.

I venture to prolong my presentation because I want to make one last comment. If CIOMS were able to produce usable guidelines that would apply to research personnel in different cultural and economical situations, we would have made a very important step to removing undue obstacles on the road of medical progress.

I clearly remember some press conferences held during various meetings of the World Medical Association. Most local and international representatives of the press felt astonished at the amount of experimentation necessary to advance modern medical science. This came as a surprise to most of them because they assumed that medical progress was due to sheer genius and not to the steady accumulation of experimental knowledge. However, the public has to accept that advances in the health sciences depend on the scope of and the resources devoted to research on human subjects.

Now, in the last few years, a trend seems to develop in Western countries towards 'natural medicine'. But this sweet and

nice unscientific body of knowledge does not appear to be based on experimental proof. In conclusion, we cannot fight quackery, in the best interests of patients, without resorting to experimental techniques, while protecting at the same time the rights of the individual.

Kimura: I appreciated very much Dr Levine's analytical presentation on Institutional Review Boards, based on experience at Yale Medical School. I don't agree, however, with his generalization criticizing IRBs for consuming too much time and energy on 'minor' problems. He might be right in the case of Yale, but I have the impression, from my research work in the USA, that IRBs are a unique and effective mechanism for the protection of human rights. Since we do not yet have the IRB mechanism in Japan, I think it is very important to introduce it in the positive way described in the articles of the US National Research Act of 1974. I would like to ask, therefore, if Dr Levine really thinks that IRBs in the USA are dealing principally with 'minor' and 'trifling' issues, and that they are, consequently, simply causing discouragement among medical researchers.

Gomaa: I have two comments to make. The first is to Dr Levine. I noticed that among the general norms which he gave there was no mention of the privacy and confidentiality of the information, especially in the case of health services research or surveys, whether using interviews or medical examinations. This point is very essential in the context of medical research and medical ethics. The second point arises from the fact that the United States is sponsoring many research projects on mutual health cooperation between it and other countries. I would like to ask whether the ethical criteria and norms used within the United States are also applied to this joint research which is conducted in overseas countries.

The other comment is on the WHO/CIOMS document on 'Ethical Review Procedures for Research Involving Human Subjects'. I was very much impressed and interested in the proposed guidelines, but I think that the document should include also what we are going to do, or the implementation of these guidelines in the future, particularly in the developing countries. There should be a clarification and definition of responsibilities of each organization or agency, the government, and the international organizations, particularly the WHO and the CIOMS. Every body

concerned should know its responsibility, and there should be a sort of critical path and a time-scheduling for this plan as a complement to these guidelines.

Miller: As the lay member of the Institutional Review Board of the University of Pittsburgh I would like to make several comments about human research.

First, it is important for all of us here to remember that research on human subjects is not a right of the medical profession or any group. Human research is a co-operative venture between the medical profession and the society which it serves. The public tolerates human research because it assumes that the progress of scientific inquiry will improve the human condition and bring health benefits to the individual and to the society. The medical profession must ask permission of the public to pursue human experimentation. The whole idea of the informed consent process is to encourage understanding and co-operation between the researcher and the subject. The public and the individual subject have the right to refuse to participate in human research or to withdraw from such research without recrimination. The right to refuse and the right to withdraw are extremely important points within the provisional Guidelines and the other international codes because they emphasize the co-operative nature of research and alert the researcher to his or her responsibilities to the subject and society.

Second, in my personal view, Institutional Review Boards function in several ways. Our first duty is to protect the subject from undue risks and to insure adherence to the informed consent process. Our second function is to protect the institution by insuring scientific merit and ethical review of research proposals. Our third and ultimately most important function is to sensitize the researcher to his or her ethical as well as scientific obligations to the individual subject and to society.

Noach: With reference to paragraph 11 of the Provisional Guidelines, on injury compensation for experimental subjects, I should like to report on the system for such compensation that has been developed at the University Hospital and Faculty of Medicine, University of Leiden, Holland. Under this system, insurance covers all financial damage to experimental subjects, in addition to guaranteed free medical care in case this should be needed as a consequence of participation in an experiment.

At the same time, our system largely prevents experiments on humans that have not been presented to, or approved by the IRB. This is accomplished because only investigations which have been approved by the IRB can be insured. All other investigations are, by agreement with the insurance company involved, considered not to be insured at all, which means that the investigator will be held personally liable in case any injury should be inflicted to experimental subjects as a consequence of the experiment. All investigators qualified to initiate experiments in humans are very clearly and repeatedly notified about this rule.

Experiments on humans may be covered by either of two kinds of insurance. The first one is liability insurance which covers damage caused by negligence or faulty procedure from the side of the investigator or somebody working under his responsibility. The majority of clinical investigations in which patients are involved are covered by this type of insurance. Since the University has a collective liability insurance, in such cases no extra premium has to be paid. However, if damage by negligence should be inflicted during a non-approved experiment the insurance company will turn down compensation claims. Of course in cases of very serious negligence, as in serious malpractice cases, investigators can be held responsible under criminal or comparable charges.

The second kind of insurance is accident insurance, for those cases where no negligence is present and the investigator has strictly and rightly adhered to an IRB-approved research protocol. Such a 'no-fault'-accident may for instance occur if an hitherto unknown and unpredictable side-effect occurs in an investigation on a new drug, or during several types of other experiments in healthy subjects. It has been our experience that most medical investigators are not aware of the fact that such accidents are not covered by liability insurance. In fact, most insurance companies do not realize this either. Those who do know this have great trouble in determining a reasonable insurance premium, since hardly any experience exists on actual risks in well-conducted medical experiments. In our case, the insurance company is very cooperative and charges a premium of about US$ 25.- per person, which covers a large compensation sum in case of death or disability, in addition to coverage guaranteed by national social legislation.

The decision as to whether there should be an accident insurance rests wholly with the IRB, which therefore has to make a very cautious estimate of possible risks. Of course, only

minor risks are accepted within the framework of ethical acceptability of an experiment. In the majority of accepted research projects, the risk for experimental subjects is negligeable, and hence extra insurance is deemed unnecessary.

Taking the years 1979 and 1980 together, of a total of about 100 IRB-approved investigations the IRB ordered in 8 cases that an accident insurance had to be taken. Fortunately, it has never been necessary up to now to claim insurance compensation, since neither in the 'liability', nor in the 'accident' insurance compensation, has any accident occurred. More details on this system of insurance coverage will be published elsewhere.

Ladd: I deeply appreciate all the comments that have been made on my paper and I accept most of them. I would like to make two or three general remarks to provide some of the ethical background of my paper, which was admittedly incomplete. The first point is that the key concepts that we are dealing with in a discussion of this sort are 'fuzzy', that is, vague, imprecise and ambiguous. Concepts like experimentation, health, and suffering have come to be known in philosophical circles as open-textured concepts; they are sometimes called 'cluster-concepts'. This view of the nature of concepts, especially those with ethical import, has become a rather fashionable part of philosophy as a result of work of Wittgenstein. What it means is that we cannot define such concepts exactly and precisely and without reference to their function. In this sense they are in fact not capable of straight definition, that is, they cannot be defined in terms of necessary and sufficient conditions.

Now, Dr Martinez suggested that I might have used the concept of health instead of the concept of the alleviation of suffering as the outcome of medicine. Perhaps he is right. My reason for choosing the 'alleviation of suffering' as the governing principle in my analysis is that it probably has greater power ethically than does the promotion of health. On the other hand, 'health' itself is, of course, a very broad term, it has many different meanings and uses. It is sometimes used narrowly as a medical concept, as equivalent to the absence of disease, but can also be used very broadly as in the WHO definition; again, it can be used metaphorically for the health of the community or in an extended sense for a person's general health covering such things as going out jogging and eating health foods. Health is again one of the open-textured concepts that has already been mentioned.

So also is the term 'experimentation'. What we consider to come under experimentation really depends on what we are trying to do with the term in a particular context. It depends on what we are talking about and what questions we are addressing. Again the same thing is true with the term 'therapy'. 'Experimentation' and 'therapy' refer to many different kinds of activities, which we classify under these terms for purely practical purposes, which may vary from one context to another.

The second point that I want to make is about law and ethics. I am glad that my comments on this were so well received by so many people. The principal difference between law and ethics might be put in a nutshell by saying that law is something we can create, change, and rescind. Law is something that is made by a person, group, or institution; in traditional terms, law is often said to be created by an act of the will of a particular individual, of a community, of a legislative body or of an organization of some sort. Its existence typically depends on enactment by an authoritative organ of some kind or other. As such, it can be changed, as can be seen in the example that Dr Farber gave of the legal restrictions on doctors experimenting in some countries; he implied that the laws could and should be changed.

Now ethics, by contrast, at least in the sense of general, normative ethics, is not subject to change by an act of will, i.e. by fiat. However authoritative he is, a person cannot simply decide that there is going to be the ethics or something or other. Ethics is something that has to be; it's more like a science in the sense that its truths are discovered or established by argument and not by decree.

The third point I would like to make is that ethics is not a simple, one-track discipline or subject; again, it is rather like the sciences in this regard - i.e. like medicine and other disciplines, in that there are many different levels and many different ways in which the problems arise and are handled. There are, of course, some philosophers and many non-philosophers who subscribe to the idea that ethics has or should have all the answers and that all you need to do is to set up a supreme principle and then derive or deduce from it the answers to all your questions. But in my view ethics is not as simple as this. It operates at a number of different levels. The level that I was concerned with in my paper was theoretical. I was trying to give a rationale for the kinds of guidelines you might or might not wish to establish as guidelines for institutions or as guidelines for individual conduct. But, as I would argue, one level

cannot simply be derived deductively from another by a simple logical operation, as some have attempted to derive all of them from a single ideological principle. It is essential for our purposes, then, to recognize the complexity of ethics, its many different facets and different levels. I've only mentioned a few of the complexities here. So I hope that you will construe what I said in my paper in this light as intended to be an analysis in rather general terms and therefore as probably being quite consistent with what Dr Levine, Dr Dunne and others have said about the ethical issues.

Levine: I will answer some of the questions that were addressed to me. Firstly, it was pointed out that in my survey of the general ethical norms, I made no mention of privacy or confidentiality. There are two reasons for this: In our ethical codes these matters are not isolated as separate entities. When I discuss the general ethical norms, I tend to subsume issues of privacy under the norm calling for informed consent. Specifically, we ask for an invitation to invade a person's private space or, as Professor Ladd put it, permission to do what otherwise would be considered a trespass. Similarly, I usually consider confidentiality as one of the components of developing a favourable balance of harms and benefits. Breaches of confidentiality often produce social harms.

I was asked why I took such a strong exception to the distinction between 'therapeutic' and 'non-therapeutic' research'. I cannot discuss adequately all of the problems that have been created by those who use this spurious distinction. In my paper which is to be published with the proceedings of this conference, I have provided a reference to an extensive discussion of these problems. I shall give one example now in order to alert you to their gravity: A literal reading of Principles II.6 and III.2 of the Declaration of Helsinki creates a requirement to use only 'healthy persons or patients for whom the experimental design is not related to the patient's illness' as subjects for research on the pathogenesis of a disease; this, of course, effectively rules out all rational research on the pathogenesis of diseases. The term 'therapeutic research' is a contradiction in terms. All documents that use it and distinguish it from 'non-therapeutic research' come to at least some illogical - and occasionally embarrassing - conclusions.

Finally, I shall respond to the challenge to my statement that we ought to behave as if researchers can be trusted. Perhaps I was not clear enough in stating that I know that some persons are

not trustworthy. However, I want to emphasize the importance of developing our policies based on presumptions that persons can generally be trusted. We should generally trust people until some evidence is brought forward that one or some cannot be trusted.

Regulations based on presumptions of distrust tend to be excessively detailed and inflexible. They tend to require various agents - e.g., IRB members - to consume enormous amounts of time and energy in developing the paper documentation of the apparent protection of the rights and welfare of human research subjects. They tend, also, to call for large numbers of advocates, auditors, and other types of persons having monitor or police functions. I am inclined to resist policies that call for the incessant harrassment of the majority of investigators in the interests of finding the occasional wrongdoer. I am not merely concerned with the fact it tends to discourage honest investigators from doing good clinical research, causing them to consider returning to laboratory bench research or some other alternative occupation. I am not merely concerned about the enormous amounts of time, energy, and money wasted in such activities. I am not merely concerned about the facts that such activities don't seem to catch many wrongdoers anyhow. I am most concerned that presumptions of distrust are alien to the most fundamental presumptions of the university community. We cannot sustain our university communities if we require colleagues to police and harrass each other because they think there is a high likelihood that any particular other is dishonest. Argument and dialogue - so crucial to the existence of the academic community - are impossible in an environment of distrust. I can argue with a colleague only if I can presume that he or she will only use what he or she believes to be true to support the counterargument.

Assumptions of trust are much less costly whether the costs are expressed in terms of dollars, human resources, or the quality of our social structures. Finally, I am aware of no evidence that such assumptions are associated with a higher frequency of wrongdoing. I believe that persons generally behave as they are expected to behave; most of them live up (or down) to the community's expectations.

Vilardell: I would like to thank Professor Riis for his kind comments. Our decisions are certainly influenced by the outcome of experiments and trials of all kinds. The only way

to obtain solid information is through controlled experimentation. I am not implying that controlled trials per se are necessarily ethical, in fact they may not be ethical at all. On the other side, I strongly believe that wasting time doing uncontrolled experiments is a very unethical thing to do. I fully agree with our Mexican colleague that one should find out as soon as possible the outcome of any investigation involving human beings.

Dunne: I would merely like to take the opportunity to thank the participants for their help and encouragement and to ensure that everything possible will be done to incorporate their suggestions into a revised draft. We take note, specifically, of the need for a commentary on the involvement of prisoners in research, and on ethical aspects of publication. Some rearrangement of the guidelines will also be considered with a view to clarifying the apportionment of responsibility in ethical decisions.

As I know you will appreciate, not all the points that have been made during the course of this Conference can be accommodated in an international text simply because an international text needs to reflect rather than to determine prevailing opinion. But, thank you all very much for your help.

SECOND SESSION

ETHICAL REVIEW OF CLINICAL RESEARCH

Moderator: Francisco Vilardell

CLINICAL RESEARCH AND THE PROTECTION OF THE SUBJECT IN ARGENTINA

Santiago Pavlovsky

As a clinical researcher working on therapeutic trials in patients with oncohematologic diseases, it would have been very easy for me to speak about experiences in that field and the methodology for the protection of the patient. However, when speaking of medicine as a whole in the Argentine Republic, the field is much wider and more complex, and one has to investigate several different levels. Argentine medicine is polarized into a number of sectors: 1) hospitals of national jurisdiction, 2) provincial hospitals, 3) communal hospitals (.e.g. all the hospitals in the municipality of Buenos Aires), 4) hospitals belonging to different national communities (e.g., Spanish, Italian, German Hospitals, etc.), 5) social securities belonging to the unions (e.g., metallurgical, textile, etc.), 6) University hospitals (e.g., Hospital de Clinicas of the Universities of Buenos Aires, Córdoba, etc.), 7) private hospitals (e.g., Hospital Privado de Córdoba, Guemes, etc.), 8) finally, several small clinics or hospitalization centres dependent on medical societies. The relationships between these centres are generally complex and often inexistent. It is very common for a physician to work in 2 or 3 of these centres simultaneously.

For the purposes of this lecture we interviewed the Secretary of Public Health of Argentina, Dr Iran Campos and other officials of that Secretariat; Dr Santiago A. Muzzio, chief of the Research Division of the Secretariat of Public Health of the Municipality of Buenos Aires; Prof. Alfredo Lanari, former full-time professor of the Medical Clinics of the University of Buenos Aires; chief physicians of pharmaceutical products' companies and members of the Scientific and Technical Research Council. Both the national Secretariat of Public Health and the Secretariat of Public Health of the Municipality of the city of Buenos Aires agree with the Helsinki Declaration of 1964, which determines the highest ethical code with reference to the use of human beings as experimental subjects.

The same Declaration states that clinical research in a human being cannot be carried out without his informed free consent, and if the person is legally incompetent the consent of the guardian must be obtained. Furthermore, at any time during the course of the clinical research, the patient has the right to

revoke his consent and end his participation in the study without harm or penalty, and similarly the research can be terminated by the researcher at any time.

This decision of the respective Secretariats of Public Health has been adopted by the Teaching and Research Committees that govern that activity in our national and municipal hospitals.

Likewise, the State Secretariat for Public Health rules on the approval or reinscription of new drugs presented by the pharmaceutical companies, and the National Institute of Pharmacology and Dietetics is responsible for the evaluation of the information. First the preclinical studies including pharmacodynamics, pharmacocynetics, acute and prolonged preclinical toxicology, teratogenesis and embryotoxicity, must be accepted to get authorization to start the clinical pharmacology trials. These must be carried out by adequately authorized clinical researchers in recognized centres.

The participating pharmaceutical companies, the director of the organization where the research is carried out and the researchers themselves have to take into account the recommendations expressed by the World Health Organization, the Nuremberg Code and the Helsinki Declarations on ethical and legal aspects.

In May 1980 an intersectorial group was created in Argentina for the study of ethical aspects of research. It was organized and coordinated by the National Division of Institutes and Research of the Secretariat of Public Health and is made up of the State Secretariat of Science and Technology, Universities of Buenos Aires, Mar del Plata, La Plata, National Academy of Medicine, National Institute of Pharmacology and Dietetics, Pan American Health Organization, Archbishopric of the city of Buenos Aires and General Health Division of the Argentine Air Forces. During 1980 several meetings took place with the idea of preparing a document for publication.

So far, I have commented on the mechanisms of official organizations; I would also like to comment on our experience from the point of view of a clinical researcher involved in hematological studies for the last 14 years.

Argentina has had in the last 50 years an authentic school of basic and clinical research, of which the undoubted leader has been Dr Bernardo Houssay, professor of Physiology of the School of Medicine of Buenos Aires and winner of the Nobel Prize for

Medicine in 1947. From him several disciples have emerged, all of whom started and developed a love of research as students. Many of these have become well-known basic researchers, such as Dr L. Leloir, Nobel Prize winner in Chemistry in 1970, and are now heads of departments and very prominent in their own field.

In 1960 the Argentine Society for Clinical Research was organized, under the sponsorship of the Argentine journal Medicina (Buenos Aires). During the annual meeting research work carried out in the country is presented from both clinical and experimental aspects.

In 1957 the Argentine National Research Council was organized under the leadership of Prof. Houssay, and sponsors a number of full-time researchers, many of them working in medical departments or research institutes in direct contact with clinical researchers. However, the greater part of this medical research is focused on experimental physiology, physiopathology, immunology and endocrinology.

Preclinical and clinical papers on pharmacology and the study of new compounds are very scarce in our country. This is due to the fact that several Argentine pharmaceutical companies are branches of foreign companies that bring in their products after phases I and II of preclinical and clinical trials have been carried out abroad, or else they are national companies that purchase patents of drugs already commercialized abroad.

Phase I studies of the toxicology of a drug in human beings are very unusual in Argentina; there are more phase II studies, particularly for Chagas disease and Argentine hemorrhagic fever, since both are diseases of national importance, and recently studies have been started in patients with neoplastic diseases.

On the other hand, there are many phase III studies in different clinical fields. However, randomized phase III clinical trials are very uncommon and most of them are performed in the fields of oncology and oncohematology.

It is important to remember that Argentina is a Latin country, with all that this implies. Relatives almost always insist that patients should not be given information about lethal diseases, possibility of death, or the severe toxic risks of a drug. People reject the possibility of taking part in a research project, particularly if it is randomized, that is, if the therapeutic scheme is not decided by the physician in charge but in a random way.

In a recent experiment in our Institute, a new phase II drug 'Amsa', provided by the National Cancer Institute through a programme with the Pan American Health Organization, was tried in malignant hemopathies for patients resistant to known drugs. The relatives of the patients, most of them children, were told that it was an experimental drug with marked myelotoxicity; only 50% of them gave the necessary written authorization to carry out the study.

I think that there are few studies performed in which the clinical trial is adequately explained to the patients before they give their written consent. We think that in many cases ignorance of the disease or of the unavoidable possibility of death prevails.

It has not become general in Argentinian hospitals, except in a few devoted to research, to have an ethical committee which reviews the protocols not only from the scientific standpoint, but also from the ethical one. Due to this we believe that the effort made by the Secretariat of Public Health in organizing a national intersectorial group for the study of ethical aspects of research was very useful.

More precise rules should emerge about the informed and free consent of people who participate as patients or volunteers in a scientific experiment in health research, compensation problems, researches using people with limited legal capacity, curricular demands of researchers, teaching of the ethical problems to undergraduates and postgraduates, etc.

Undoubtedly, the bases are laid and the official organizations have adequate documentation to rule and teach the medical researcher about ethical rules in clinical research. However, we must try and avoid undue delays or hindrance of research arising from long and troublesome official controls, often in the hands of bureaucrats without much knowledge of clinical trials.

We think that the researchers and/or institutions should be authorized to carry out clinical trials on humans on the basis of their background, recognized prestige and moral values. Furthermore, these institutions must set up their own mechanisms of ethical control on the basis of medical ethics committees within the institution which will judge the scientific and ethical value of the experiment. Adequate information will have to be provided to the healthy persons or patients in whom the research will be

performed about the risks and responsibilities, with written consent authorizing the experiment.

We think that it is not practical in our country for each therapeutic protocol to be authorized by official organizations of the Secretariat of Public Health, because they will probably not be judged by persons competent in the subject and bureaucracy would tend to introduce delay.

Resumen

En la medicina argentina, dividida en varios sectores, coexisten hospitales de jurisdicción nacional, hospitales provinciales, hospitales comunales, hospitales que pertenecen a comunidades de diferente origen étnico, unidades de seguridad social que pertenecen a sindicatos, hospitales universitarios, privados, y pertenecientes a sociedades médicas.

La Secretaría de Estado para la Salud Pública reglamenta la aprobación o reinscripción de los nuevos fármacos presentados por las compañías manufactureras, y el Instituto Nacional de Farmacología y Dietética es responsable de la evaluación de la información suministrada.

En 1980, se creó un grupo intersectorial para el estudio de los aspectos éticos de la investigación, organizado y coordinado por la División Nacional de Institutos de Investigación de la Secretaría de Salud Pública, y del que forman parte diversos institutos, universidades y academias, así como el Arzobispado de la Ciudad de Buenos Aires.

En 1960 se fundó la Sociedad Argentina de Investigación Clínica poco después de que, en 1957, se creara el Consejo Nacional Argentino de Investigación. La mayor parte de las investigaciones de que se ocupa el Consejo versan sobre fisiología experimental, fisiopatología, inmunología y endocrinología.

Los trabajos clínicos y preclínicos sobre farmacología y el estudio de nuevas drogas son poco frecuentes en Argentina. Los estudios de fase 1 son muy poco frecuentes; son más numerosos, en cambio, los estudios de fase 2, especialmente sobre afecciones que, como la enfermedad de Chagas y la fiebre hemorrágica argentina, son problemas de importancia nacional. Por otra parte, se realizan numerosos estudios de fase 3 en las diferentes líneas clínicas, pero pocos de ellos son estudios al azar; éstos se realizan de preferencia en los campos de la oncología y la oncohematología.

A juicio del autor son pocos los estudios en los cuales los procedimientos clínicos se explican en forma adecuada a los pacientes antes de que éstos otorguen su consentimiento, y aún no se ha generalizado en los hospitales, exceptuando unos cuantos muy orientados hacia la investigación, la práctica de contar con un Comité de Revisión Etica que analice los protocolos de investigación no solamente desde el punto de vista científico sino también en sus aspectos éticos. Ante esta situación de hecho, la Secretaría de Salud Pública ha tratado de organizar correctamente estos sectores; pero el autor considera que con la multiplicación de los controles oficiales se corre el riesgo de burocratizar el procedimiento, y que en estas condiciones es mejor autorizar individualmente a los investigadores o las instituciones, sobre la base de sus trabajos anteriores, de su prestigio reconocido y de sus valores morales, para que puedan efectuar investigaciones en seres humanos, dejando que las instituciones organicen sus propios mecanismos de control ético a base de comités intrainstitucionales.

AN EXPERIENCE OF PROTECTION OF THE RESEARCH SUBJECT AND CLINICAL RESEARCH IN CHILE

Oscar Brunser *

In mid-1976 the research staff of the Institute of Nutrition and Food Technology of the University of Chile decided to systematize some activities that had been carried out in recent years and which were a prerequisite to the beginning of all research projects involving human subjects. The consequence of this process was the creation of an Ethics Committee that was to be responsible to the Director of the Institute and which was invested with ample powers to analyse by reference to the most strict ethical criteria all research projects already under way or in the planning stage. It was decided that no project could be started or presented to local or foreign institutions for support unless it had been previously studied and approved by the Ethics Committee.

The Chairman of the Ethics Committee is the Director of the Institute, the other members being three physicians with very high academic qualifications, a biochemist, a sociologist who represents the psycho-social sciences and a lay person who does not participate in the research activities of the Institute. At the present time this lay person is an educator. Among the first activities undertaken by the Committee were a request to the Library of the Institute to start collecting information on the subject and the elaboration of a set of rules of procedure to regulate its own activities. The latter have been revised recently and have been modified in accordance with experience gained in the past four years.

The Committee not only reviews the substance of the project itself in its ethical implications but also the consent forms, instruction sheets and other materials that will be used to explain to research subjects the reasons for and justifications of the study, the cooperation requested from them, the benefits and/or inconveniences they may experience as a consequence of their participation, compensations for time or expenses incurred during the study (for travel and lost income for example), the possibility of withdrawing at any time when they so desire, etc.

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* Professor Brunser was unable to attend the conference, but his paper was subsequently submitted.

The types and details of the information provided to research subjects are considered of the utmost importance because true voluntary participation is achieved only when the individuals have received complete information relevant to the project.

In an Institution such as ours, the provision of full information is especially important in long-term nutritional balance studies in which the diets may at times be monotonous and full cooperation by the subjects is necessary.

In the case of minors, all explanations are provided to their parents or guardians. In addition, the Director of the Institute appoints an advocate of the child. The advocate is a highly qualified physician whose name is proposed by the Committee. He is charged with reviewing and evaluating each procedure that the child may be subjected to. He may reject the participation of the child if he considers that there are any reasons that justify doing so, overruling even the consent provided by the parents or legal guardians. On the other hand, he cannot overrule the opinion of parents or guardians if they decide that they do not want the child to participate in an experience. It is the feeling of the Committee that in this way the interests of children are well protected.

The Committee is not a bureaucratic hurdle and strives not to hinder research. One of the guidelines that orients its operation is the need to consider 'probable risks versus potential benefits'. This requires that all projects submitted to the Committee have scientific merit and for this reason they must be first evaluated by the Research Committee. In this context, the Ethics Committee has established strict criteria of permissible risk and in this sense projects are evaluated not only for possible physical harm but also for potential psychologic disturbances that may result. For this reason all investigations in the psycho-social sciences are carefully scrutinized to avoid situations that may be interpreted as violations of privacy or overt or covert forms of psychological pressure.

To evaluate better all projects submitted to it, the Committee frequently requests the cooperation and opinion of specialists from other Institutions. The aim is to consult people whose experience far exceeds that available in certain fields at the Institute. Thus, the Committee has requested the opinion of psychiatrists, pharmacologists, experts from governmental institutions (such as the Chilean Food and Drug Administration, and the Chilean Atomic Energy Commission), religious

ministers of different denominations and people deemed to have high moral standards. All studies that include use of radioisotopes must be cleared in advance with the Chilean Atomic Energy Commission. To reduce to a minimum the potential risks derived from radioisotope use, the Committee is actively stimulating the study and application of techniques using stable isotopes. Within the same context, emphasis is being placed on the development and use of noninvasive techniques and of micro- and ultramicro-chemical analytical methods.

Up to now, the Committee has met 123 times and has evaluated 72 projects. Although it has been necessary to suggest modifications to some of them, none has been rejected because of ethical objections. The most controversial areas are those involving the use of radioisotopes and drug testing. The Committee believes that, because of the scope of the research carried out by the Institute, there is little justification for testing of new drugs except in very special circumstances, and the tendency is therefore to discourage all activities of this type. One of the main tasks of the Institute is the study and testing of nonconventional sources of protein and other nutrients. In this situation either the investigators or the institution contracting services for this purpose must make available all relevant chemical, nutritional and toxicological information. This is verified in our laboratories before tests in volunteers are authorized. Products from foreign countries must be accompanied by certification that they have been previously tested in the country of origin.

As far as we know all hospitals in Santiago have standing committees on ethics. However, their scope is somewhat different from that of our committee because they mainly deal with complaints about malpractice arising from the treatment of patients. These committees also regulate the conditions under which all drug tests are conducted and supervise the application of ethical standards during such tests. The Scientific and Technological Development Service of the University of Chile requests that all projects involving studies in humans and submitted to it for possible funding receive prior approval from institutional committees on ethics. The Chilean Medical Association, to which every physician practising in Chile must belong, also has an Ethics Committee concerned with all ethical aspects of medical practice.

Our Committee feels that one of its most important functions is to educate those who are in contact with research subjects. To this end some of the personnel of the Institute work part time in medical and research projects in other institutes in Santiago.

All projects in which Institute staff cooperate, even if these projects are not physically carried out at the Institute, must be reviewed by our Committee before authorization for their participation is granted. This has awakened considerable interest in our approaches to ethical matters in many institutions. Furthermore, the rules of procedure that regulate the operation of our Committee and some of the most important Declarations of Principles (Nuremberg, Helsinki, etc.) are being included in a booklet that will be widely distributed shortly.

The many discussions held during the analysis of research projects submitted for consideration to the Committee have made us conclude that the most obvious, but nevertheless the most important, safeguard of the research subject is the moral quality of the investigator. We think that this special quality is the basis on which the relationship between the subject and the investigator must stand. Ethical aspects must be stressed in the curricula of all schools that train health-related personnel. In this way, consideration of the ethical aspects of studies in humans will become a natural constituent of experimental designs of each investigator and of each research project.

Resumen

En 1976, los investigadores del Instituto de Nutrición y Tecnología de los Alimentos de la Universidad de Chile decidieron institucionalizar y sistematizar una serie de actividades que deberían desarrollarse como paso previo a la iniciación de todo proyecto de investigación en seres humanos. A raíz de esa decisión se creó un Comité de Etica directamente dependiente de la dirección del Instituto e integrado por tres médicos, un bioquímico, una socióloga y un lego que no participan en proyectos de investigación.

No se permite que se presente a las entidades interesadas en su financiación ningún proyecto de experimentación en seres humanos - incluidos los que versan sobre las ciencias sociales, la psicología y la tecnología de los alimentos -, si no cuenta con la aprobación del Comité. Este revisa el contenido del proyecto en sus aspectos éticos y analiza además los formularios mediante los cuales se explicará a los sujetos de la experimentación la razón y la justificación de la investigación, la colaboración que se les pide, los beneficios o inconvenientes que puedan resultar de su participación, la posible compensación por el tiempo que destinen al proyecto y la posibilidad que se les ofrece de retirarse libremente del mismo.

En el caso de los menores de edad, las explicaciones se proporcionarán a los padres o los responsables legales. Se asigna además al sujeto un 'defensor', que debe ser médico, encargado de revisar y evaluar cada uno de los procedimientos a que será sometido su pupilo, y que está facultado para negar su participación si estima que existen razones suficientes para ello, aun cuando los padres o el responsable legal hayan otorgado previamente su consentimiento.

El Comité de Etica ha fijado unos límites estrictos de riesgo tolerable. Para la mejor evaluación de los proyectos, el Comité solicita frecuentemente la cooperación de especialistas de otras instituciones.

Todas las experiencias que incluyen el uso de radioisótopos deben contar con el permiso correspondiente de la Comisión Chilena de Energía Nuclear.

Desde su creación, el Comité se ha reunido 123 veces y ha analizado 72 proyectos. Las áreas más conflictivas han sido las que se refieren al uso de radioisótopos y al ensayo de drogas o medicamentos.

Por lo que el autor ha podido saber, los hospitales de Santiago con función asistencial o docente-asistencial tienen sus propios comités de ética. Por otra parte, el servicio de desarrollo científico y tecnológico de la Universidad de Chile exige que todos los proyectos de investigación que se le presenten para su financiación obtengan la aprobación previa de un Comité de Etica institucional. El Colegio Médico, entidad gremial que agrupa a todos los médicos del país, mantiene un Comité de Etica que vigila el comportamiento de los profesionales en lo que se refiere a la relación médico-paciente.

ETICA DE LA INVESTIGACION EN PEDIATRIA

Jesús Kumate

La experimentación clínica o biomédica en niños se ha considerado como un tema sensible y delicado, porque es difícil de reglamentar y en muchas ocasiones imposible de realizar en razón de 3 factores, a saber:

1º) La imposibilidad del niño para consentir las intervenciones que implica el experimento;

2º) la extrema labilidad homeostática del ser humano en la edad pediátrica; y

3º) la gravedad de las secuelas irreversibles en virtud de las etapas del crecimiento y desarrollo afectadas.

Sin embargo, algunos conocimientos necesarios para el progreso médico debieron practicarse forzosamente en niños; v.gr.: ¿Cómo demostrar el efecto protector de vacunas como las del sarampión, la poliomielitis, la difteria y la tosferina? ¿Cómo evaluar la tolerancia y los efectos de los regímenes dietéticos especiales para niños? ¿De qué forma pueden conocerse los tratamientos eficaces en la artritis reumatoide juvenil?

Al parecer no se plantean graves problemas cuando se trata de autorizar investigaciones con fines terapéuticos o que han de redundar en beneficio de los pacientes, con tal de que se cumplan los requisitos mínimos de un consentimiento paterno o tutorial, previa información completa sobre los riesgos que entraña la investigación y con la garantía de poder suspender la maniobra experimental en cualquier momento.

Las dificultades aparecen cuando la investigación no ofrece ningún beneficio inmediato para el niño enfermo o cuando éste se encuentra sano.

Las recomendaciones y orientaciones señaladas en el Código de Nuremberg y en la Declaración de Helsinki (actualizada en Tokio, en 1975) no contienen ningún capítulo o artículo especial para las investigaciones en los niños. Las pautas de la AMA son explícitas para ciertas pesquisas en niños que padecen retraso mental.

En todos los reglamentos se incluyen como requisitos el consentimiento de los padres o tutores y la aprobación de un comité revisor institucional, independiente del grupo que tiene a su cargo la investigación. En la práctica, la mejor salvaguarda de los intereses del paciente o persona sujetos de estudio es el investigador principal. Es particularmente favorable que sea el médico responsable del cuidado directo del niño enfermo.

El respeto de los intereses o derechos de los niños es materia cambiante y en ocasiones inexistente o por lo menos descuidada. Afortunadamente, se observa una evolución hacia un mayor interés por parte de médicos y legisladores.

Los niños huérfanos, expósitos o retrasados mentales y los afectados por malformaciones congénitas han sido sujetos de experimentación médica con mayor frecuencia que los niños sin esos tipos de minusvalidez legal u orgánica. Lo anterior es aplicable en la época actual, lo que pone de relieve la inoperancia práctica del consentimiento y de los comités de revisión.

La posibilidad de realizar ciertas investigaciones en países con una legislación menos estricta agrega una dimensión incontrolable a toda generalización. En el Año Internacional del Niño (1979) no se presentó ninguna contribución al respecto.

Las pautas y recomendaciones vigentes actualmente en la investigación pediátrica son el producto de reflexiones, de una mayor conciencia del problema por parte del investigador, y, sobre todo, del respeto de la dignidad profesional y de la incapacidad de los niños para otorgar un consentimiento válido.

El camino recorrido desde el siglo XVIII hasta nuestros días ha sido muy largo. En 1721, en ocasión de una epidemia de viruela declarada en Londres, Jorge I, enterado del procedimiento de la variolación, observado en Turquía por la esposa del embajador inglés, ordenó que la preparación infectante fuera administrada a 7 criminales condenados y a 7 niños huérfanos, antes de aplicarla a sus nietos.

El experimento de Jenner, efectuado el 14 de mayo de 1796, que inició la era de la moderna inmunología, consistió en la inoculación del niño James Phipps, de 8 años de edad, con el líquido obtenido de un dedo de Sarah Melmes, quien padecía viruela de las vacas. El 1 de julio del mismo año fué inoculado con líquido infectante de vesículas de viruela; y el hecho de que no se infectara como habría ocurrido en un individuo no inmune tuvo

como resultado la popularización de la vacuna antivariolosa. Cabe preguntarse, sin embargo, qué hubiera sucedido si el niño Phipps no hubiera desarrollado inmunidad con la vacunación previa de la viruela bovina.

La expedición de Francisco Javier Balmis en 1804-1806 fue posible gracias al empleo de unos niños expósitos de la Coruña que permitieron preservar la linfa variolosa durante la travesía atlántica. El viaje de Acapulco a las Filipinas requirió la variolación de 26 niños mexicanos, que fueron embarcados en la Nao Fernando de Magallanes con el propósito de llevar linfa fresca, a través del Pacífico, a Filipinas y a Macao. No parece que se planteara entonces ninguna consideración de orden ético acerca del empleo de niños huérfanos con esos propósitos.

La primera aplicación de vacuna antirrábica fue efectuada por Pasteur, en julio de 1885, en un niño alsaciano de 8 años, llamado Joseph Meister, quien presentaba heridas múltiples en todo el cuerpo causadas por un perro rabioso. El hecho de que Joseph no contrajera la rabia marcó el inicio del empleo de esta vacuna e impidió realizar un estudio controlado que aclarara el mejor producto de la vacuna pastoriana.

La aplicación de suero de caballo con antitoxina diftérica se realizó la noche de Navidad de 1890 en el Hospital de Niños Enfermos de Berlín, sin que mediara otra experimentación más que la animal, practicada en caballos intoxicados, con preparados simples purificados de toxina diftérica.

En pleno siglo XX, en 1920, Weil-Hallé y Turpin administraron por vez primera la vacuna BCG a un niño muy expuesto a contraer la tuberculosis dada su estrecha convivencia con un abuelo enfermo. En este caso se menciona que hubo consentimiento por parte del padre.

La demostración de que el virus causante del herpes zóster y el de la varicela son idénticos fue llevada a cabo por dos dermatólogos: Kundratitz, en Hungría, y Bruusgard, en Noruega, en 1925 y 1932 respectivamente, al inocular líquido de las vesículas de enfermos con zóster en niños y provocar así en ellos el cuadro clínico típico de la varicela.

La demostración del efecto enteropatogénico de algunos colibacilos se logró mediante la administración oral de cultivos apropiados a niños lactantes con malformaciones congénitas. Los experimentos se realizaron en Estados Unidos y Japón en la década 1950-1959.

En nuestros tiempos, los trabajos de Krugman y sus colaboradores en el asilo de niños retrasados mentales de Willowbrook, N.Y., son probablemente un ejemplo de los peligros que la interpretación formal de los códigos éticos sobre investigación puede presentar en la práctica. Más de un centenar de niños recibieron por vía oral una preparación que contenía partículas infectantes del virus de la hepatitis A. La fuente del material fueron las evacuaciones de niños en la etapa ictérica inicial suspendidas a 20% en solución salina, centrifugadas por periodos de 30 minutos y una hora a 2000 y 8500 r.p.m. Los sobrenadantes se calentaron a 56°C durante media hora y se añadieron 1000 unidades de penicilina LG y 0.1 mg. de cloramfenicol por ml de la suspensión. El producto final demostró ser inocuo cuando se inyectó intracerebralmente en monos y carecer de efectos citopatogénicos en cultivos tisulares.

En todos los casos hubo consentimiento de los padres o tutores y el proyecto de investigación fué aprobado por un comité local.

Los experimentos descritos no son muy diferentes de la manera de pensar de un médico sueco citado en Catholic World (enero 1900): ...'Tal vez debiera haber escogido animales... pero los más apropiados, las terneras, eran muy costosas. Por otra parte, su mantenimiento resultaba muy caro, así que decidí realizar mis experimentos en los niños de la casa de huérfanos, para lo cual obtuve el amable permiso del médico encargado'...

Resulta difícil aceptar que un médico, en particular un pediatra, realice maniobras o prácticas tan agresivas como las descritas anteriormente. Es obvio que no hubo ninguna consideración previa respecto a consentimiento paterno o tutorial y que no se tomaron en cuenta en absoluto los derechos de los niños sujetos de investigación; sólo en algunos casos se menciona que los médicos encargados o jefes de servicio dieron permiso para llevar a cabo la investigación. En el caso de Willowbrook consta el consentimiento de los responsables legales y del comité de investigación local. Cabe preguntarse: ¿En qué medida fue 'informado' el consentimiento? ¿Es posible que un padre o madre den su autorización para que un hijo suyo - retrasado mental - reciba por vía oral una suspensión infectante de materia fecal? Se trata de una experimentación realizada entre 1957-1967!

La lista de los experimentos realizados en niños es extensa; en mayor o menor grado puede identificarse en todos ellos elementos suficientes para considerar tales experimentos como variantes del

'síndrome del niño maltratado', con la peculiaridad de que sus autores no fueron los padres sino médicos investigadores animados de la mejor intención de contribuir al progreso de la ciencia.

Propongo que se incluya en el estudio del síndrome del niño maltratado una sección permanente que identifique, recoja y dé a conocer los casos en los que se ha incurrido en faltas de consideración y respeto a la integridad física o emocional de niños hospitalizados y no-hospitalizados, que han sido tomados como 'testigos' con fines experimentales.

En todas las publicaciones médicas debe incluirse entre las recomendaciones a los autores de contribuciones escritas, la de que especifiquen los detalles relativos a la obtención del consentimiento; y propongo que, en los casos en que exista el permiso pero se incurrió en una violación flagrante, se deniegue la publicación de los resultados.

Es de prever que en el futuro inmediato la investigación en pediatría no sólo continúe sino que se acreciente. Nuestra ignorancia acerca de los mecanismos homeostáticos, la fisiopatología de muchas enfermedades de la edad pediátrica, las respuestas terapéuticas, tan diferentes en los niños de las de los adultos y las modalidades peculiares que imponen las etapas de crecimiento y desarrollo hacen indispensable conocer mejor las características biológicas de los niños para poder administrar, en la práctica médica, un tratamiento más racional.

Los desgraciados casos de fibroplasia retrolental, el síndrome gris del recién nacido, el kernicterus en la etapa neonatal y la muerte súbita de los lactantes son algunos de los muchos episodios de consecuencias fatales que han ocurrido como consecuencia de nuestra ignorancia, arropada en la mejor de las intenciones, acerca de cómo funciona y en qué condiciones de reactividad se encuentra el ser humano en las primeras etapas de su vida, y de nuestra tendencia a aplicar a los niños lo que sabemos respecto de los adultos.

A mi juicio, la mejor salvaguarda contra las agresiones de que se hace víctima a los niños es que los investigadores sean médicos con profunda raigambre clínica, responsables directos de sus pacientes objeto de pesquisa, interesados de manera permanente en el problema que se trata de investigar, y con experiencia suficiente en otros campos antes de hacer incursiones en el terreno pediátrico.

Considero imperativo que el tiempo de experiencia requerido para el investigador biomédico en pediatría sea más prolongado que el requerido en otras ramas de la Medicina, y que por convecimiento propio, fruto de la experiencia y la reflexión, acepte los consejos de Leake: ...'Recordemos siempre que cualquier información que podamos obtener acerca de nosotros y del ambiente en un estudio científico, siempre será relativa, tentativa, sujeta a cambio y a corrección, y que no hay respuestas definitivas...'

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Summary

Three factors make clinical research in children particularly sensitive and difficult to regulate:

1. Children cannot give informed consent.
2. Homeostasis is critical, especially in small infants.
3. Sequels can be irreversible because development processes may be affected.

However, some important medical knowledge can be derived only from children, such as the protective value of some vaccines, the utility of certain special diets, and the treatment of juvenile rheumatoid arthritis. There are really not serious ethical problems in therapeutic research on children as long as there is consent of parents or guardians after full information on risks and assurance of the freedom to stop the procedure at any time.

Difficulties arise in non-therapeutic research or in experiments in healthy children.

The Nuremberg code and the Helsinki-Tokyo declaration do not deal directly with children. The American Medical Association guidelines are quite explicit in regard to children with mental retardation. In all cases consent of parents or guardians is necessary, as well as approval by an institutional review committee independent of the research team. It appears, however, that the best safeguard of the child's welfare and interest, is the ethical quality of the head of the research team, especially if he or she should happen to be the physician responsible for the child's medical care.

Orphans, destitute, or mentally-retarded children, and those affected by congenital malformations, are subjected to medical research more often than less underprivileged children.

Some important medical discoveries have been made using children as subjects, without benefit of ethical guidelines: The first vaccine inoculation by Jenner in 1796; the bringing to America and later to the Philippines of variola vaccine, using destitute Spanish and Mexican children by Balmis in 1804-1806; the application of rabies vaccine by Pasteur in 1885; and many others.

These experiments show a similar attitude to that expressed by a Swedish physician in 1900, and published in the magazine 'Catholic World' who stated: 'It would have been better to use animals, but the appropriate ones, calves, were expensive to buy and to maintain, so I decided to use children of the orphanage. The physician in charge gave, most kindly, his permission'.

Such situations are in the same category as the 'battered baby syndrome', the doctors being responsible for the mistreatment. Recommendations of medical journals to authors, should include mandatory specifications of procedures for eliciting consent and other ethical considerations, and articles should be rejected if violation of human rights are detected.

ETHICAL ISSUES IN RESEARCH ON WOMEN

Hildegard Stolz

Introduction

The International Association of Medical Women, which I am representing here, as well as the Medical Women's Associations of Ibero-America as whose Vice-President at the International Association I am still acting, want to express the gratitude of our group for the fact that we ourselves have been called upon to discuss ethical issues in research on women.

As medical women we are members of a profession which is considered to be sexless. But we are not only professionally involved with these problems but are also women whose biological function is to be the sexual partner, to conceive and bear the next generation, trying to guarantee a worthy life to her breed. Medical problems of these functions will be discussed as research issues under ethical criteria.

Medical research on women means clinical and scientific research on the specific functions of her organs of generation with its social, economic, populational and psychological implications and the possibilities of convenient medical guidance and interference in these functions.

There may have been some changes in ideas about women's place in our communities: years ago any treatise on gynecology or obstetrics had as the first chapter: Genital Organs of the Female or Organs of Procreation and the Female Pelvis. One of the more modern treatises (published in 1965) begins with the chapter: The Position of Women in Modern Society.

It is only about one hundred years since the appearance of the women's rights movement and an increasing awareness in women of the need for conscious responsible participation in economic life, personal freedom and better health for her organism. Better health meant liberation from the excessive burden of childbearing and delivery every year which, in some cases, meant more than twenty children for a mother, many of whom would have no chance of survival under acceptable conditions.

In the USA the fight of Margaret Sanger, who defended personal liberty for women, reinforced by sanitary and economic arguments

resulted, only forty-five years ago, from 1936 to 1938, in the suspension of the so-called Comstock Law which declared contraception immoral, forbidding education or elucidation on correlated methods and procedures. Following her example, Family Planning and Planned Parenthood Federations are now internationally organized. The change in trends in medical ethics has been most striking in problems concerning family planning, which now represents one of the most challenging problems of ethical issues in research on women. Non-christian religions do not know any prohibition of contraception.

Ethical Issues of Research

Contraception. Once the principle of family planning is admitted, we must face ethical issues about the most convenient methods of contraception, the convenience of their universal acceptance, and the freedom to use them.

There is no longer any doubt that the method of Ogino-Knaus is not satisfactory because of the appearance of paracyclic ovulation and its inconvenience for the strongest impulse we know in our lives.

The simple medieval mechanical contraceptives such as sponges and tampons which may provide reasonable protection are now despised, other medical vaginal protection of little use, and the use of diaphragms with additional chemical protection is not very widespread. The Japanese prefer condoms for the male.

Recently, there was renewed curiosity about contraceptive herbs used in indigenous and primitive medicine. The only literature I found was about the Borraginacea Lithospermum ruderale used as a contraceptive infusion by American aborigines. It is known that this herb diminishes fertility in mice, but involution of sex organs and growth inhibition occurs simultaneously. These effects were also described by an indigenous native when we asked her about tribal contraception practice. This high toxicity precludes its general use.

With modern endocrinology research, the pharmacological industry and business are increasingly interested in hormone contraception. When we admit that more than fifty million women all over the world use this medication, we may say that hormonal contraception is one of the most generalized therapeutic procedures and worth our study. In many countries more than

one-third of the female population between 15 (or even before) and 44 years old actually use this contraceptive resource. In spite of this widespread use of endocrine contraceptives, it has not been possible to formulate a definite interpretation of complaints such as headaches, increase in weight, loss of libido and depression (which also appear with placebo-tablets, as clinical investigation has shown). We know still less about the possibile interdependency of intake of oral contraceptives for many years and gallstone troubles, hepatic tumours and uterine and breast carcinoma.

The risk of thromboembolism has been much discussed, and resulted in changes of the formula of contraceptive pills which now may contain only 50 microgrammes of estrogen. Another result was that in planning surgical intervention, oral contraception should be discontinued at least one month before the intervention, in order to prevent pill-dependent increase of postoperative thromboembolism.

Cerebral ischemias and cerebral hemorrhage may occur even without typic prodrome, such as migraine, vertigo, ocular disturbances and slight hemilateral symptoms. Generally the tendency of these accidents is complete regression, but in some cases invalidity may occur. Perhaps one-third of thrombotic cerebral attacks of women during sexual maturity and one-tenth of hemorrhagic strokes must be attributed to hormonal contraception. White skinned women are affected with four times the incidence of coloured women.

Incidence of myocardial infarctus increases 2.7 to 4.5 times, with higher occurrence among women over 40 years of age. This has resulted in the recommendation to check serumcholesterol values, blood pressure, over-weight and cigarette consumption in the group at risk.

Other vascular diseases such as Raynaud syndrome, ischemic colitis, thrombosis of the mesenteric artery and vein, the Budd-Chiari syndrome, occlusion of the retinal arteries and thrombosis of central veins apparently may have ovulation suppression as a determining cause.

As to breast tumours, information is still contradictory: the recommendation now is that women with a history of benign mamma-affection should not take oral contraceptives, while in the non-affected oral contraception may perhaps have a protective effect against tumours.

The occurrence of endometriumcarcinoma in young women observed between 1975 and 1976 was attributed to the fact that they took two-phase medication with too much ethinylestradiol and small dose of gestagen (this sequential substance was used in 40% to 70% of the sequential drugs in the USA). It is now recommended to have biopsy control of hemorrhage during sequenstherapy.

As to cervical carcinoma, there has been no additional contribution to the finding that even prolonged intake of oral contraception is harmless.

The occasionally appearing functional ovarian cysts disappear after cessation of oral contraception.

More than 100 cases of liver tumours have been published, most of them hepatomas or malignant hepatomas. Due to a tendency for spontaneous intra-abdominal hemorrhage benign hepatomas may also endanger life, so mortality amounts to about 25%. The real connection between oral contraception and these tumours is not yet definite, since other drugs have also been correlated with these very infrequent tumours.

The only contraindications persistent in other affections of the liver and gallbladder are in the seldom occurring affections such as Rotor and Dubin Johnson syndrome and family cholestase. Recently, an increase of gallbladder stone affection was reported, but this increase in cholelithiasis appears rarely and only after two years of pill use.

Increase in blood pressure may be slight under contraceptive medication, diastolic more than systolic, occurring generally only after two years, and not attaining pathological values. After suspension of contraceptive hormones, most cases return to normal blood pressure, with the exception of a few where is progression to malignant nephrosclerosis. Therefore, control of blood pressure should definitely be practised during a survey of contraceptive medication, and the method changed to non-hormonal contraception in these patients.

The over-suppression syndrome appears in 9.3% to 41.7% of pill-takers and must be correlated with the previous hormone medication in about half of the cases. The other half may have some other pathology coresponsible for this amenorrhea. Former failure of the menstruation cycle may be a contributing factor,

therefore women with irregular menstruation should be excluded from hormonal contraception. Not even former pregnancies may prevent the oversuppression syndrome, which is independent of the length of time of hormonal contraception as well as of the patients' gynecological age when beginning treatment and the kind of pills. Even two-phase drugs do not protect against oversuppression. In about half of the patients with post-contraceptive amenorrhea, of more than one year's duration, menstruation did not normalize, persisting even after pregnancy induction.

The pill-pause is useful for the early diagnosis of this tendency in women who wish more children, but in those who do not wish further children it is not only unnecessary but even of disadvantage.

Fertility and pregnancies reappear in most cases immediately after suspension of hormonal contraception except in patients with persistent contraceptive amenorrhea. In some statistics 43% recover fertility during the first month after treatment, and in up to 85% of the nulliparous and 95% of those who had already given birth it reappears within two years. Increase in fertility has not been proven up to now, and abortion and ectopic pregnancies are not of greater incidence after oral contraception. Increased malformations after the pill are not demonstrable, but whether coincidence of pill medication in an unnotice pregnancy may cause malformation of the fetus has still to be investigated.

Considering now intra-uterine contraception, it is asserted that intra-abdominal late complications of perforation by an IUD are extremely rare. Ascending infection, posterior fertility and danger for the conception product in the case of failure of an IUD may be a problem. Recent surveys indicate that infection risk is higher in nulliparous than in women who have had children. Some models of IUD such as the Dalcron shield in the USA had to be withdrawn from use because of the high incidence of serious septic abortions in case of failure. Consequently there is an urgent recommendation to remove the IUD immediately after diagnosis of pregnancy. Malformations have not been definitely asserted. Total mortality rate due to intra-uterine contra-ception even in cases of pregnancies is considerably lower than with the usual hormone contraception.

Another topic is sterilization: techniques have changed rapidly during recent years, and laparoscopic procedures with bipolar high frequency or endocoagulation and clipcolocation are now predominant.

It has not yet been possible to evaluate whether the somatic late sequels of traditional surgical sterilization methods, such as menstrual disorder, functional bleeding, hypermenorrhea, dysmenorrhea and amenorrhea also appear with modern laparoscopic procedures.

Experience has shown that up to 18% of sterilized patients, and about an average of 4% to 5% later regret the intervention. This may cause emotional problems and guilt complexes. Especially unfavourable cases are the patients with medical or eugenic indications for sterilization, those who were urged to agree to the operation in a situation of distress such as before a cesarean section or interruption of pregnancy, sometimes even by the imposition of others, and psychically unstable patients. The best emotional response was observed in patients who upon second thoughts and for socio-economic considerations opted for sterilization.

The mortality rate in these interventions is about 7 per 100,000, thus the method may be considered reasonably safe in comparison with reproductive mortality or the other contraceptive methods.

In conclusion, we may assert that the danger from modern contraceptive practice for women is so low, that we may assume there should be no ethical conflict in this practice. But, please consider that this minimization of perils is due to considerable investment of medical observation, skill, care, and investigation. Many complications may be prevented by better individualization of contraception which should not be allowed to be available on a 'self-service' system.

As a general rule, with regard to the age of the patient, oral contraception in young patients, and IUD during the reproductive phase.

It is sad to observe that lay information in the mass media sensationalizes the dangers of modern contraception, so that young girls may disregard instruction and refuse to ask for contraception counselling when necessary with the result of an increase in unwanted pregnancies and the practice of abortion. This means a waste of twenty years of scientific effort for progress.

Interruption of pregnancy. In gynecology one of the big problems is still interruption of pregnancy for medical-social indications. UN Committees have investigated the innocuity of these interventions, trying to establish legal justification as

well as socio-economic need for infringement of the divine commandment accepted by Christian religions: 'Thou shalt not kill'. We know that for other religious ethics this divine law does not exist. We know from history that even 'putting out' of children was practised for socio-economic, social or religious reasons - even the Vestal put out her twin sons Romulus and Remus for she was supposed to be a virgin.

After legal agreement about interruption for medico-social indications four items have to be considered:

1. which is the best procedure to terminate pregnancy?
2. who should perform this intervention?
3. late sequels for the patient.
4. patient's failure to use contraception.

1) As to the technical problem, we may affirm that elaborate instrumental devices, such as suction cannulas, which substitute for traditional dilatation and curettage of the uterus, as well as the use of antibiotics, have diminished the risks of traumatic and infectious accidents by surgical abortion. Medical induction by prostaglandins may be still less offensive, but the method is rejected by patients because of the prolonged discomfort of this procedure.

2) No law may oblige a gynecologist in charge of a hospital or in his office to perform 'legal' abortion if this will result in a personal ethical conflict. As some gynecologists may experience later psychological reactions, it is preferable that patients be sent to specialized clinics which agree with legalized abortion.

3) Late emotional reactions of these patients in temporary economical stress-situations are familiar to psychiatrists. Some patients tell us ten or even twenty years after wanted interruption that now they feel sorry about it and, reconsidering, they admit that there might have been a possibility for rearing one or two more children, which might have increased their happiness!

4) Clinics that undertake personal interviews with patients coming in for 'legal' interruption of pregnancy have asked why patients will fail to use contraception as offered by widespread family planning dispensaries with all facilities to prevent this undesired accident. There has been no satisfying answer yet.

Other ethical problems. Another less relevant problem with ethical implication concerns fertility treatments - test tube fecundation with implant of the incubated ovum in the uterus of a patient with oviduct impermeability. These operations are still problematic and therefore infrequent, but artificial heterologous insemination may be more frequent than we realize, being considered ethical with the agreement of all involved, and may contribute to the happiness of a couple. If practised in single women who have contact problems, this procedure must be rejected, for it may contribute to the birth of an underprivileged child in a society who identifies a human by descendency from the father and mother.

Trans-sexual individuals who ask for sex-changing surgery is not only an ethical problem but also a scientific one, but fortunately one that seldom arises.

Surprising as it may seem, there exist ethical problems in the field of early detection of cancer of the breast and uterus. Early cancer detection practice should begin with patients in their mid-twenties. The problem now is that cancer-phobia may pursuade physicians, as well as patients, to undertake 'preventive' mutilating surgery without competent indication. Hysterectomy with the combined intention of preventing pregnancy and cancer is inadmissible. Substitutive hormone therapy may be a facultative cancerogenic factor, and we know of tragic occurrences of vaginal cancer in young girls whose mother had taken estrogens during the pregnancy to prevent abortion.

Chemotherapy in advanced cancer may be another problem, where side affects are sometimes even more serious than the cancer pathology. Subjective feelings of personality change are the most striking complaints in this respect, and we should consider whether we may really demand the patient to suffer this.

With these rapidly delineated points I think that this exposition of the main ethical issues in research on women may be concluded.

Resumen

Por investigación médica en mujeres se entiende la investigación científica clínica sobre las funciones específicas de los órganos femeninos de la reproducción, con todas sus implicaciones sociales, económicas y de población. El cambio de dirección en

las orientaciones de la ética médica ha sido muy notable con respecto a los problemas concernientes a la planificación familiar, que actualmente constituye uno de los sectores más controvertidos, desde el punto de vista de la ética, en relación con las investigaciones practicadas en mujeres. El autor procede a hacer una sinopsis de las ventajas, los inconvenientes, los efectos secundarios, los peligros y otros aspectos de los diversos métodos de contracepción utilizados, y presenta sucintamente las consecuencias médicas y psicológicas de la esterilización femenina.

En este trabajo se señalan como sectores en los que se pueden plantear problemas éticos la interrupción del embarazo, los tratamientos de la infecundidad, la fecundación in vitro y la cirugía que pretende cambiar el sexo, así como los problemas que pudieran plantearse en relación con la detección temprana del cáncer mamario y uterino y con la quimioterapia aplicable en los casos avanzados.

PUNTOS DE VISTA DE LAS ACADEMIAS NACIONALES DE MEDICINA RESPECTO A LA REVISION ETICA DE LA INVESTIGACION CLINICA

Alberto Cárdenas Escovar

El tema de las normas éticas que deben regular la investigación en el campo de la salud del hombre es motivo de muchas controversias y de comportamientos distintos en los diversos países y grupos sociales.

Esto se debe a dos causas principales:

1. La confusión en las definiciones de algunos términos como 'la ética', 'la moral', 'el bien del hombre', su 'destino', etc.

2. El desarrollo acelerado de las ciencias, con la disponibilidad de nuevos recursos y nuevas técnicas, y una difusión cada vez más rápida de los conocimientos, gracias a los medios de comunicación.

En cuanto a lo primero, es evidente la evolución histórica del concepto de la ética, dentro de una escala en la que contrastan, por una parte, las concepciones espiritualistas, como la de Aristóteles, que define la ética como la búsqueda del 'más alto bien mediante la actividad espiritual conforme a razón', y la de Tomás de Aquino que establece como 'base primaria de la moral la relación de las acciones humanas con Dios como último fin y supremo bien del hombre'; y, por otra parte, el utilitarismo moderno (Bentham y J.S. Mill) que afirma que el fin del hombre es la mayor felicidad del mayor número, ética moderna basada en el valor material del fin de la acción. Dentro de esta ética moderna, junto a la ética individual aparece la ética social. Aquí es pertinente citar las palabras de Alfred Gellhorn en la 7a Conferencia del COICM (2): 'Reconociendo que hay muchas maneras de responder a esta cuestión (el progreso biomédico en relación con el beneficio del hombre), yo registraría como mi conclusión personal que la ciencia no puede substituir los conceptos altamente idealizados de comportamiento ético y de moralidad que han caracterizado las diversas religiones del mundo'.

En cuanto a lo segundo, o sea el perfeccionamiento de las técnicas, disponemos de extenso material para estudio, por ejemplo, las excelentes comunicaciones y discusiones que aparecen

en las memorias de las Conferencias del COICM, y especialmente las de las Conferencias 7a (1972) y 8a (1974), que nos han sido de gran utilidad para nuestra monografía.

La ALANAM ha celebrado dos reuniones para debatir el tema general de la 'Investigación en el área de la salud' (VI Reunión de Trabajo, Buenos Aires, 1978, y VI Reunión del Consejo Directivo, Caracas, 1979) (1). En la introducción de la primera, el Secretario Permanente recordó las palabras de Claude Bernard: 'La moral cristiana sólo prohíbe una cosa, a saber, hacer el mal al prójimo. Así pues, entre las experiencias que se pueden intentar en el hombre, están prohibidas las que pueden causar daño, se permiten las que son inocuas y son obligatorias las que pueden hacerle bien'. Este concepto, tan sencillamente expresado por el sabio, es a nuestro entender la clave del problema que nos ocupa. El conflicto surge en los casos en que un mismo procedimiento, vedado en principio porque 'puede causar daño', al mismo tiempo 'puede hacer bien', y por tanto 'es obligatorio'.

Sin embargo en este como en tantos otros dilemas que se plantean al hombre, es posible una elección basada en la razón, en la buena fe, en los elementos de juicio disponibles y en la comparación del riesgo que se corre con el beneficio obtenible, es decir, con el remedio de un mal cuya magnitud justifica que se corra ese peligro ('riesgo calculado'). Como ejemplo de esta situación cabe citar el empleo de fármacos en la embarazada.

Es además un principio establecido el del 'consentimiento informado, libre y válido' por parte del sujeto.

Por supuesto, para que la decisión se tome y se lleve a efecto dentro del marco de la ética es indispensable que los fines buscados sean, ante todo, el bien del hombre y/o el de la comunidad. Aquí aparece una segunda situación que, en ocasiones, plantea también un dilema que se puede resolver ateniéndose a los principios ya expuestos. Ejemplos: la esterilización y el aborto con fines eugénicos.

El Papa Juan Pablo II ha atacado recientemente la investigación médica 'irresponsable', señalando los peligros que entrañan los transplantes de órganos, la experimentación genética, la inseminación artificial, los métodos anticonceptivos y los nuevos medicamentos. En presencia de 2700 médicos el Papa dijo que 'hay voces de alarma' que denuncian los efectos perniciosos de 'una medicina que se ocupa más de sí misma que del hombre al

que debe servir'. También afirmó: 'Aún con la intención de curar, el médico puede, involuntariamente, lesionar el derecho de los individuos a su propia vida'. 'La ciencia no es el valor supremo al cual todos los demás deben subordinarse. Más elevado es el derecho de los individuos a su vida física y espiritual, y a su integridad psíquica y funcional'. 'Las normas éticas, fundadas sobre el respeto por la dignidad de la persona, deben iluminar y disciplinar la medicina en su aspecto de investigación así como en la aplicación de los resultados logrados'. 'Los médicos deben considerar el peligro implícito para el derecho a la vida del hombre (que encierran) descubrimientos tales como los que se realizan en las áreas de la inseminación artificial, el control de la natalidad, la fertilidad, la hibernación, la muerte retardada, la ingeniería genética, las drogas psíquicas y los transplantes de órganos'. 'Aun cuando el conocimiento científico tiene sus propias leyes que cumplir, debe reconocer por encima de todo el límite insuperable del respeto por la persona y de la protección de su derecho a vivir en forma digna como ser humano'. 'La verdad es que el desarrollo tecnológico padece de una profunda ambivalencia'.

En la introducción a las reuniones de la ALANAM ya mencionadas, se destacó también la importancia de establecer 'organismos directivos que se ocupen de estos asuntos (la aplicación de los progresos biomédicos) en un plano humanista y asuman la tarea de fijar criterios para el quehacer técnico-científico en función de los valores humanos'; y en las conclusionas se señaló la necesidad de 'promover la formación de investigadores de alta calidad, con acentuada orientación humanística y ética, conscientes de los problemas de su patria, de Latinoamérica y de la humanidad'.

Los capítulos que hoy se consideran prioritarios en el estudio del problema ético-científico pueden enumerarse así:

Genética, eugenismo

- Amniocentesis diagnóstica
- Aborto provocado en las embriopatías
- Inseminación artificial
- Reproducción clónica
- Manipulación de cromosomas ('ingeniería genética')

Biología de la reproducción

- Fecundación in vitro
- Métodos de control de la natalidad
- Esterilización

Definición de la muerte

Eutanasia
Donación de transplantes

Experimentación en el hombre

Investigación clínica combinada con el cuidado profesional
Investigación clínica no terapéutica

No es posible analizar todos los capítulos dentro de los límites de este trabajo, pero podemos señalar algunos aspectos que interesan especialmente, con referencia a Latinoamérica, en el campo de la investigación clínica.

Los códigos de ética médica de los diversos países que señalan las pautas esenciales se están actualizando para ajustarse, en lo posible, a los adelantos biomédicos recientes y a los principios reconocidos internacionalmente; este es el caso de los códigos de Nuremberg (1942), de la Asociación Médica Mundial (Declaración de Helsinki, 1964), de la OMS, basado en lo prescrito por la Asamblea General de las Naciones Unidas (1966), de la Declaración de Tokio (1975) y de la OPS (1978).

Los códigos de ética médica de Argentina, Brasil, Colombia, Chile, Guatemala, Perú, El Salvador y Venezuela, entre otros, concurren en las normas relativas al control de las autoridades científicas reconocidas y de las juntas asesoras, a la posibilidad de curación y al consentimiento expreso del paciente o de sus responsables.

Señalemos que esto último es especialmente importante en el caso de los menores de edad y de las personas cuya condición psíquica no les permite adoptar una decisión responsable.

Con respecto a las Comités o Juntas locales, deben constituirse de manera que tengan adecuada participación en ellos todos los estamentos de la realidad sociocultural de cada colectividad, tales como el científico, el jurídico, el religioso, el de la mujer, etc.

En Colombia, el Congreso Nacional tiene en estudio el proyecto de ley que dicta normas de ética médica. En las partes pertinentes de ese proyecto se declara:

'El hombre es una unidad psíquica y somática, sometido a variadas influencias externas. El método clínico puede explorarlo como tal, merced a sus propios recursos, a la aplicación del método

científico natural que le sirve de base y a los elementos que las ciencias y la técnica ponen a su disposición. En consecuencia, el médico debe considerar y estudiar al paciente como persona que es, en relación con su entorno, con el fin de diagnosticar la enfermedad y sus características individuales y ambientales, y adoptar las medidas curativas y de rehabilitación correspondientes. Si así procede a sabiendas podrá hacer contribuciones a la ciencia de la salud, a través de la práctica cotidiana de su profesión. Tanto en la sencilla investigación científica antes señalada como en la que se lleve a cabo con fines específicos y propósitos deliberados, por más compleja que ella sea, el médico se ajustará a los principios metodológicos y éticos que salvaguardan los intereses de la ciencia y los derechos de la persona, protegiéndola del sufrimiento y manteniendo incólume su integridad.

'Si en circunstancias excepcionalmente graves un procedimiento experimental se ofrece como la única posibilidad de salvación, éste podrá utilizarse con la autorización del paciente o sus familiares responsables y, si fuere posible, por acuerdo en junta médica.

'El médico se atendrá a las disposiciones legales vigentes en el país y a las recomendaciones de la Asociación Médica Mundial, con relación a los siguientes temas:

1. Investigación biomédica en general.
2. Investigación terapéutica en humanos; aplicación de nuevas tecnologías, con fines de diagnóstico, tales como biopsias cerebrales, o bien con fines terapéuticos, como es el caso de algunos tipos de cirugía cardiovascular y psicocirugía y experimentación en psiquiatría y psicología médica, y utilización de placebos.
3. Transplante de órganos; organización y funcionamiento de bancos de órganos y tejidos; producción, utilización y procesamiento de sangre, plasma y otros tejidos.
4. Diagnóstico de muerte y práctica de necropsias.
5. Planificación familiar.
6. Aborto.
7. Inseminación artificial.
8. Esterilización humana y cambio de sexo.
9. Los demás temas de que se ocupen las disposiciones legales vigentes sobre la materia o las recomendaciones de las Asambleas de la Asociación Médica Mundial.

'En caso de conflicto entre los principios o recomendaciones adoptadas por la Asociación Médica Mundial y las disposiciones legales vigentes, se aplicarán las de la legislación colombiana.

'Las personas que se encuentren privadas de la libertad no podrán ser utilizadas con propósitos de investigación científica en contra de su voluntad.'

En los problemas específicos se requieren legislaciones especiales, cuyos proyectos son objeto de estudios como el de Michèle Steuer sobre 'Los transplantes en el derecho comparado. Estudio y documentación para una nueva legislación colombiana, 1980'(3). La autora ha utilizado como fuentes legales las de cinco países latinoamericanos y nueve europeos, y presenta las siguientes conclusiones:

'1. La vida y la salud de todo ser humano y su protección deben defenderse con el mismo celo que los otros derechos de la persona humana.

2. El injerto o transplante de órganos o tejidos hace posible la conservación y prolongación de la vida humana.

3. El problema del injerto o transplante de órganos o tejidos comprende la utilización de órganos o tejidos de una persona y la utilización de órganos o tejidos de un muerto.

4. En ambos casos, la disposición de órganos o tejidos para la conservación y prolongación de la vida humana es jurídicamente posible.

5. El cuerpo humano es un bien jurídico, individual y extrapatrimonial, cuya disposición sólo corresponde a la persona que lo posee en forma natural mientras vive.

6. Después de la muerte del sujeto se puede disponer de todo o parte de su cuerpo para la prolongación y conservación de la vida humana, la investigación científica o el estudio anatomopatológico, siempre que su poseedor natural, en vida, no disponga lo contrario.

7. Toda persona que padezca de una lesión irreductible de un órgano o tejido tiene derecho al uso, para transplante, del órgano o tejido similar aprovechable de un muerto.

8. La donación, entre vivos, de órganos y tejidos, y el consentimiento para la utilización de los órganos o tejidos aprovechables de un muerto constituyen un acto de solidaridad humana y son una prueba de la elevación espiritual de las personas.

9. Los principios de deontología médica tienen importancia fundamental en todos los momentos que conforman el proceso de un injerto o transplante de órganos o tejidos, cualquiera que sea la forma que adopte su ejecución.'

Para concluir, debe esperarse que en el proceso dinámico de los conceptos normativos se tengan siempre en cuenta los principios de la moral natural, los factores socioculturales y religiosos de las diversas colectividades, y las directrices de una medicina eminentemente humanista.

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Summary

Ethical norms in health research are subject to controversies because of two main considerations:

1. Confusion between terms like 'ethics' 'moral' 'human welfare' 'human destiny', etc.

2. Accelerated development of medical sciences, new techniques, and faster dissemination of knowledge.

In regard to the first consideration, it is quite evident that rapid changes in the ethical concepts do occur, from the spiritual concepts of Aristotle, defining ethics as 'The highest well being through spiritual activity according to reason', through the religious conception of St. Thomas Aquinas as 'the relation of human actions with God' to the modern utilitarian view

as 'the greatest happiness to the largest number of people.'

The Latin American Association of National Academies of Medicine has organized two meetings on health research, in Buenos Aires in 1978 and in Caracas in 1979.

In the first one, it was considered that 'Christian morals forbid only one thing: To hurt a fellow human being'. This means that experiments are forbidden if they cause injury, are permitted if no harm is done and are mandatory if a benefit is obtained. However, this is a simplistic view, since it is always difficult to ascertain both risks and benefit in advance.

It is possible, however, to make a good decision if it is based on good faith, reason and a proper assessment of risk and benefit. It is also imperative to elicit free, informed consent from the subject.

The author cites some Roman Catholic considerations, to which Pope John Paul II has referred, enumerates several of the most controversial matters, such as eugenics, abortion, genetic engineering, in vitro fecundation, fecundity control, sterilization, the concept of death, and organ transplants. The author mentions the ethical codes of several Latin American countries, and presents the text of a regulatory project under consideration by the legislature in Columbia.

DISCUSSION - DISCUSION

Towers: First of all I want to congratulate the speakers for an extremely good series of presentations and discussions. This two-day conference is concerned with 'medical ethics and medical education'. Tomorrow we will be dealing specifically with education. Today we are looking at clinical-ethical issues and at guidelines concerning the ethics of medical experimentation and therapy. We have had references to major ethical codes and guidelines from the past, namely Nuremberg and Helsinki-Tokyo. Now we have proposed guidelines from WHO and CIOMS. I would like it to be noted that in none of the guidelines adopted to date, nor in those proposed at this session, is there any reference to educational requirements with regard to the ethics of the practice of medicine. We are very accustomed to requirements that schools of medicine throughout the world give adequate instruction in the basic medical sciences and in clinical science. The overall intention of such instruction is to ensure that students acquire sufficient knowledge and skill so that they can make sound clinical judgements in both diagnosis and treatment. It seems to me we should also have curricular requirements that would lead to the development of what one might call sound ethical judgement. I would like to suggest to WHO and to CIOMS that the proposed ethical guidelines should include a section, directed primarily to medical educators, on the necessity for instruction in these areas of concern. There are many ways of arranging such teaching, and different schools in the same and in different countries will use different methods. However, unless it is included as a formal requirement, some physicians will graduate without being aware of the fundamental need to exercise sound ethical judgement as part and parcel of sound clinical judgement.

What we are trying to do in the programme of the University of California, Los Angeles, is to raise the level of conscious awareness, throughout the medical school and beyond, concerning the need to take full account of ethical and legal matters in everything to do with patient investigation and patient care. Concentration on the purely scientific or technological in medicine tends to lead to poor ethical, and therefore poor clinical, judgement. I hope that when the new international ethical guidelines are revised, they will include a section on the teaching of human values as an integral part of the practice of medicine.

De Wachter: Regarding the guidelines under discussion I extend my warmest congratulations to your organization because of what I believe to be an historical step in the control and protection of human values in research. Their potential impact contrasts with the weakness of most previous guidelines. Indeed, any guideline which does not result in a change of attitude or a change of projects and design, is weak. Helsinki, Tokyo and many more suffer from this kind of weakness. One reason for such weakness is the absence of a mechanism which helps one to apply guidelines to the practical situation. The guidelines we have in front of us are already quite specific. Clinical situations of the type so brilliantly described by Professor Vilardell are within the actual reach of your guidelines. May I suggest, first, that the guidelines presented by Dr Dunne include the recommendation that research mechanisms be developed at international, national and regional levels. Second, I suggest that, should you decide to make this recommendation, mention be made of several such models explaining these mechanisms which bring guidelines of principle to the clinical research situation.

With your permission, Mr President, I would like to take just one moment to sketch a method in our Center for Bioethics, with which we try to be of help to researchers and doctors in clinical situations. We believe that biomedical ethics should always start from facts. Among the various levels in ethical discourse, pointed out so well by Professor Ladd, we choose to start from the one where they are, that is in the laboratory or clinic. As we try to identify possible value conflicts we often find that the groundwork has been laid by these doctors who perceive ethical issues in the clinic. Then, priorities must be set, making possible a medical decision. It is obvious that we believe in 1) experience as a basis for ethical decision-making; 2) dialogue as method in ethics; 3) biomedical decisions which allow, in Jean Fourastié's words, only for 'décisions-options' ever since we have left the time of 'décisions-solutions' behind us.

To the extent that such decision-making offers an answer or a perspective towards an answer, we think we contribute to creative medical ethics. I do not suggest this to be the model for your guidelines. Only, that this and similar mechanisms be considered in or with the presentation of the guidelines.

Finally, a small remark on the fifth of your 'Provisional Guidelines'. In my view, this guideline ought to state more clearly today's controversy over the control of human research.

As we all know, there is some doubt about your affirmation that 'the health professions are uniquely qualified to organize and implement ... a system of ethical assessment of research'. Perhaps the guideline is too reconciliatory and altogether optimistic. A correct assessment of research, according to a great many specialists, cannot be reached 'unless' committees are broadened to include non-scientists. Perhaps there is good reason for discussion and reconsideration.

Farber: Thank you for the privilege of the floor. I am speaking in my capacity as Chairman of the Ethics Committee of the World Medical Association and so no-one is going to wonder why I am also speaking in favour of the Helsinki Declaration.

What happened during the discussions leading to the adoption of the Helsinki and Tokyo declarations was in fact an effort to meet the criticism of those who were afraid at the unbounded enthusiasm of doctors or others involved in research on human beings.

Our main contribution is of course the introduction of independent bodies of experts whose terms of reference are to check the scientific and moral aspects of each experiment. I have been a member of one such body for 5 years and I would like to emphasize at this point that research can only be ethical if it rests on a sound scientific foundation.

If research is not performed by trained personnel and is not scientifically sound it is unethical per se. This consideration, however, has a practical consequence. The Medical Ethics Committee must have within its membership people with sufficient scientific expertise to be able to evaluate the experimentation on scientific grounds. That is, to evaluate whether the experimentation could produce something new in the field of knowledge, diagnosis or treatment, and that a reasonable degree of success may be expected.

The Committee also has to satisfy itself that the subject of the experiment would have access to full medical attention if and whenever a medical complication occurs.

So, and may I repeat, unscientific experimentation is unethical. And this evaluation has an absolute priority on the agenda of any Ethics Committee.

Lastly, I wish to comment on the programme on medical law and human values of the University of California, Los Angeles (UCLA). In all Western European medical schools the curriculum includes a mandatory course on medical ethics. But I am sorry to report that this means more often than not a course on legal medicine. Students are advised on the worst type of encounter, the one between a doctor and a medical law suit. This is of course very important but has nothing to do with medical ethics.

May I express the wish that all medical schools give the same importance as UCLA to moral problems.

Ladd: I really feel that I've talked too much already today, but I cannot resist jumping into the fray once more; that's part of my professional background! I would like to address my remarks indirectly to the statements of the speaker who represents the Vatican, but also to some of the other views that have been expressed here.

One of the things that I would like to warn you against, if I may be so presumptuous, is a certain misconception of the nature of ethics. Perhaps you will forgive me, since I have spent my life on ethics. In the last 35 years or so, I have studied all kinds of ethics and have even investigated the ethics of other cultures. On the basis of a lot of experience with ethics, I want to warn you against treating it as a closed subject. My view of ethics and that of people that I agree with, is that ethics must be approached as an open subject, an open field. Ethics is basically controversial in character and, in this regard, may be compared to politics or to law. You get into trouble handling arguments about ethical issues, if you don't understand that ethical issues cannot be closed by fiat. Now, one of the typical ways that certain parties have of closing an ethical issue in dispute is to appeal to authority. So-and-so said such-and-such and that closes the issue. We've had many years, centuries, millenia of attempts by institutions and individuals, states, political parties and religious sects - you know who they all are, we all know who they are - to close ethical issues by appealing to authority. When you appeal to authority you say: this is it, don't argue with me. Against this, I contend that when you are discussing ethical issues of one sort or another, it is often important to acknowledge them as controversial. I think these codes and plans that you all have are really great, but behind them often lurks a difficult ethical issue that cannot be written off. Population control

is a basic ethical issue which is not a medical issue at all. It is a political issue and it should not be regarded as a closed issue simply because we are told that it is closed by somebody. One thing, then, that I suggest that you keep in mind is that when you invoke authority you close the issue and make dialogue with other people who disagree with you impossible. So, I hope that you will reflect on the methods that you use implicitly in the drawing-up of your codes, and that you will not close the issues in such a way that you scare off a large number of important segments of mankind and people who disagree with you on very basic matters.

I would like very much to recommend the kind of approach that was just suggested by the gentleman from Montreal, Dr de Wachter, a procedure whereby you sit down and discuss the particularities and try to capture all the values involved and retain them in the way he suggested. This is a kind of open dialectical approach in which the answers are not predetermined at the outset, but are established as one goes along. It is what I would call an open approach to ethics in contract to the closed approach that I have been arguing against.

Siegler: Mr Chairman, I want to congratulate you and CIOMS speakers today for providing such illuminating answers to questions about the nature of ethical questions in human investigations. What I want to share with you and the audience is my perplexity in not quite knowing what the question was to which today's responses were the answers. Which is to say, it is not clear to me what the problem is that is being addressed by our speakers, or for that matter exactly what the problem is to which the WHO/CIOMS proposed guidelines are a solution. For example, one problem might be that the public, the public at large, is disenchanted with medical research. And, we as a profession think that it is terribly important to re-engage public sympathies for problems of investigations involving human subjects. And, therefore, the guidelines become a kind of public education in an effort to re-enlist support and cooperation. That is one possibility. Another one is, that the guidelines are being formulated to control and restrict the activities of the investigators. That recalls the Nuremberg Code as the forerunner for such guidelines. It may be that about 35 years later we are still concerned that the profession of investigators is not sufficiently ethical. Now, those are merely two aspects of the questions that are being raised. Others might be that we wish to define the limits of a subject in order to get the public and

the profession re-engaged in a dialogue in these questions. Another one is that we might want to control science in such a way. I am merely saying that none of the speakers, nor the guidelines proposed by WHO/CIOMS, seem to specify clearly what the major problem is that we are confronting in the next 15 or 20 years. So, in countries that are considering forming IRBs or developing guidelines for ethical research, it becomes terribly important to know what problems they ought to be looking forward to rather than merely adopting responses that have been developed in other countries earlier on.

Riis: We live in a world of existential pluralism, even if we in Northwestern Europe and the United States of America sometimes behave as if only a few sets of human values existed. On this background of pluralism, it has been almost astonishing that guidelines, stating the autonomy of the individual citizen, have gained widespread international acceptance.

Probably no-one here believes that we can change the world by just making guidelines, but still the voluntary acceptance of guidelines on scientific ethics is a small step forward. One thing, however, is a general acceptance of principles by nations of different cultures, political systems and religions. Quite different from this line would be the attempt to define, within such guidelines, how these principles should be implemented, and endorsed by educational programmes.

We have until now reached rather far by having principles accepted internationally, and I certainly would warn against trying to define in which way different countries, cultures and religions would have to implement the principles. We need to be patient, and we must accept that the principles are implemented in different ways by different countries. This fact does not prevent us from evaluating these different ways at a later stage.

In conclusion, I am at the present stage in favour of guidelines, supplementary description of models, and international discussions, but they should be formally kept apart, not integrated in one document.

Robbins: I was going to comment in much the same way as Dr Riis in that I was very taken aback when Dr Levine was unable to give any solid figures relating to what has happened over the more than 15 years that IRBs have been in use in the United States. Being somewhat research-oriented myself, I would suggest that we should be more active in our efforts to evaluate what we are doing. It is my undocumented impression that the IRBs in the United States have been a qualified success after a shaky start. At first they were resented. The medical investigators felt them to be legalistic and an imposition to be circumvented if possible. However, now this review process seems to be accepted as a useful part of our culture. There has been control of abuses and an unexpected benefit has been better research protocols in many institutions.

Levine: I started out this morning by saying that I was appalled by the fact that, since we have invested so much effort in our IRB system of 'prior restraint', we have made so little effort to see whether it does more good than harm. Put another way, does it do enough good in terms of protecting the rights and welfare of human research subjects to justify the enormous expenditure of dollars, human energy, and so on. I believe that IRBs do somewhat more good than harm; however, as a scientist, I would feel more comfortable if this belief were validated through the devices of science.

In the beginning, the balance of costs and benefits seemed rather good. Committees under various names started operating in our institution in the 1950s. The early committees were rather small, met informally and did not keep careful records of their activities. Thus, they did not cost very much. Those that developed formal guidelines seemed to be almost exclusively concerned with activities that we now call 'therapeutic innovation' or 'nonvalidated practices'. There did not seem to be very much concern with what some people still persist in calling 'non-therapeutic research' unless the procedures used seemed to be highly risky. This judgement of our predecessors has gained affirmation in the recent empirical studies showing that subjects of protocols involving exclusively procedures done in the interests of research almost never get injured. There is, of course, a small subset of this class of activities that presents a threat of physical or psychological injuries; this is what our predecessors meant when they spoke of 'risky research' which, in their view, merited peer review.

During the 1960s we began to see the development of complicated federal policies calling for civersification of committee membership (which has at least theoretical advantages); great increases in the documentation of the activities of the IRB (designed largely to protect the institutions rather than the subjects); and an increasing call for monitoring activities (unfortunately based upon presumptions that investigators are not to be trusted). All of these steps tended to greatly increase the costs of prior restraint and there is no evidence that they have brought about proportionate benefits.

I think it would be most difficult to prove that the IRB has a great effect on reducing the frequency of serious violations of human rights and welfare. One of the problems presented to those who would try to demonstrate such an effect is that there is not much of a base-line to begin with. If we consider the activities that created public pressure to develop our system of prior restraint, there are not many of them. There are the Tuskegee Syphilis studies, the Jewish Chronic Disease Hospital case, the Willowbrook studies (to this day we have no general agreement on whether this study was ethically justified); and we have, perhaps, a handfull of additional cases. Thus, given this as a base-line, it would be most difficult to show an effect of our IRB system in reducing the frequency of this type of violation. On the cost side, in the United States we have established at least one IRB (some universities have as many as 16) at every institution that conducts what the government has defined as research. Promulgation of regulations on intraocular lenses alone necessitated the establishment of 1200 new IRBs - essentially overnight. What do you suppose it costs to maintain this system? We have no reliable estimates but informally I have calculated that it must be over $ 100,000,000 each year.

Prior restraint is a very expensive way to reduce wrongdoing. Perhaps it is time to consider gradually moving toward the system we use to deal with most other forms of wrongdoing - e.g. murder, arson, embezzlement, and so on. We publish rules stating that such actions are forbidden and we prescribe suitable penalties for those who violate the rules.

I do not intend to suggest that I would abandon the entire IRB system. Rather, I would redesign the regulations to free the IRB up from its current obligations to spend most of its time doing very unimportant things. I would publish rules, for example, saying that certain sorts of behaviour on the part of investigators

are not acceptable. I would further state that those who violate these rules will be punished in some fitting way. Most major violations will become visible through publication of the results of the research. For those major violations that might not become visible in this way, prior restraint might be justified but only for those that present important detriments to persons' rights and welfare.

There are some other very important things the IRB does. I would revise the regulations so as to allow IRB members to concentrate on such things. Most investigators are not setting out deliberately to violate people's rights and welfare. But in this age of complexity and specialization, occasionally they need and appreciate getting guidance in ethical matters. I would revise the rules to allow the IRB to serve in the capacity of consultant to those investigators who want its help. I also think that the IRB serves an important educational function; it should continue this and it should continue to serve some of the public relations interests that Dr Gellhorn suggested. Bureaucratic oversight and cumbersome procedural protections should be employed only when necessary - not never, but also not for most research activities.

Gellhorn: I should like to comment on the remarks of Dr Robbins and Dr Siegler. Since I feel some modest sense of responsibility in regard to the organization of the conference, I think it is important that I try to restate the question that we have endeavoured to answer during our meetings. They have asked whether we believe that the public is disenchanted with us as a profession and that the activities of investigators should be controlled and restricted. I think that ethical considerations in medicine and medical investigation have fundamentally changed in the course of this century with the focus now being not so much on the medical profession and what we do and whether our actions are ethical, but rather what is the place of the individual, be he patient or subject. The individual is now recognized as being autonomous so that it becomes necessary, whether in straight therapy and diagnosis or in investigation, to recognize an individual's independence from us, and his ability to participate in decisions regarding his own body. Therefore, it seems to me that the purpose of this conference has been to accept that there has been a change in the ethical emphasis and to define how we are responding to this change. I think that a manifestation of the success of ethical review committees is that research in the USA

and elsewhere in the world is being encouraged and is continuing. That is not to say that our review procedures are entirely adequate. These will need to be further developed. In this way we are recognizing the individual's autonomy and independence without prejudicing the active support being given to research. Nevertheless we should not caution against too rigid guidelines but should rather state general principles to be followed, and at the same time stress the importance of the representation on ethical review committees of lay members of the public, as some of us here have mentioned.

THIRD SESSION

MEDICAL ETHICS IN MEDICAL EDUCATION

Moderator: Octavio Rivero-Serrano

LA ENSEÑANZA DE LA ETICA EN LAS ESCUELAS DE MEDICINA

Octavio Rivero Serrano

El tradicional juramento hipocrático sigue siendo válido. Sin embargo, como marco ético del ejercicio de la medicina actual, de la ética de la investigación científica, de la relativa a los problemas derivados de los grandes progresos actuales de la ciencia y la tecnología biomédicas y a los que se derivan de los cambios habidos en la forma de entender la vida en las sociedades actuales, consideramos que este decálogo no es suficiente para abarcar todos los problemas que plantean la medicina actual, su ejercicio y la investigación médica.

La ética, por otra partem,no es solamente una materia de enseñanza a partir de análisis teóricos y verbalización de conceptos en las aulas. Tanto la enseñanza de la ética para los estudiantes de pregrado o de posgrado o en las residencias médicas como el ejercicio ético de la medicina por los médicos, no consisten en un análisis de conceptos teóricos, sino en una materia ejemplar, es decir, una serie de conceptos, preceptos y normas que rigen el ejercicio de la medicina y cuya enseñanza se deriva de ese mismo ejercicio. Quiero decir con esto que no es posible enseñar conceptos éticos sobre problemas o aspectos de la medicina o de su ejercicio si no es la misma medicina en ejercicio la que enseña conceptos.

La ética médica se enseña ejerciéndola.

La ética médica la enseñan los grandes maestros orientadores de la medicina con su actitud en relación con los enfermos, con su actitud en relación con las enfermedades, con su actitud en relación con los problemas de salud de la comunidad y con los problemas derivados del ejercicio de la medicina.

La ética de la medicina es única; sin embargo, puede pensarse en diversos aspectos que han de regir la conducta de todos los que, de alguna manera, tienen que ver con el ejercicio de la medicina. Así, es ético que un aspirante a médico desee seguir esta carrera si tiene una auténtica vocación de servicio; no es ético, en cambio, que persiga como fin primordial su ascenso económicosocial.

En la escuela, la ética del trabajo del profesor y del alumno está inscrita en el máximo esfuerzo que ambos deben realizar; aunque al profesor, lógicamente, le preocupen sus problemas

profesionales y de estabilidad económica, su ética de profesor de medicina le obliga a realizar el máximo esfuerzo, más allá del que le exige su contrato de trabajo, para atender al alumno; en cuanto a éste, independientemente de sus inquietudes de otro orden, que pueden ser sanas y dignas de ser estimuladas, su obligación es hacer el máximo esfuerzo por aprender medicina, deber que está ligado a la ética del médico en ejercicio en que aspira a convertirse, y cuya obligación fundamental consistirá no sólo en adoptar una actitud humana o en adquirir y ejercer conocimientos biomédicos, sino también en mantenerlos y acrecentarlos mientras dure su ejercicio profesional.

La ética de las escuelas de medicina guarda cierta relación con la de los organizadores de los servicios médicos; ambas consisten en facilitar la organización y en conseguir los recursos logísticos, humanos y de equipo necesarios para poder, en el primer caso, enseñar realmente medicina, y en el otro caso, prestar atención médica. En este punto, es difícil llegar a componendas. En el caso de las escuelas, no es aceptable, bajo ningún pretexto, abrir escuelas y admitir alumnos sin contar con los recursos necesarios para poder ofrecer una enseñanza adecuada: esto significa disponer de locales, laboratorios, bibliotecas y personal preparado, contar con un presupuesto suficiente y mantener una relación adecuada entre estos recursos y el número de alumnos aceptados, ya que un desequilibrio en esta proporción no es ético.

La organización de los servicios médicos tropieza en la actualidad con problemas especiales.

La medicina actual, y el concepto mismo del médico, se han enriquecido. De ser un hombre preocupado por estudiar el problema de un paciente, por ayudarle a recuperar la salud, por sanarle, por aliviarle o, por lo menos, consolarle, el médico ha pasado a ser un hombre interesado en comprender mejor el fenómeno biopsicosocial, capaz de atender al enfermo como individuo o miembro de una comunidad; es decir, se ha pasado del concepto de la medicina individual, del concepto de relación médico-paciente, al concepto de la medicina social. No es que el médico actual no deba preocuparse del individuo enfermo y de cómo curarle. Pero debe interesarse, además, por comprender los fenómenos, no sólo biológicos, sino psicológicos y sociales de las comunidades.

En el futuro de los conocimientos biomédicos, habrá que revisar y analizar con cuidado muchos aspectos para definir las posiciones éticas de la medicina actual. Los grandes adelantos

de la ciencia y la tecnología y la evolución de la sociedad actual en que vivimos imponen la necesidad de revisar algunas ideas que tienen que ver con ciertos conceptos fundamentales, los que el hombre conserva para preservar la ética y la moral natural y aún para respetar la moral religiosa de las sociedades, en coexistencia con los adelantos de la ciencia y la tecnología, y con los nuevos planteamientos sociales que, en fin de cuentas, no deben contraponerse a los valores éticos que la humanidad ha considerado fundamentales.

En la vida del hombre hay valores que no deben ser modificados por los adelantos de la ciencia y la tecnología ni por otras concepciones de la organización de las sociedades.

En relación con los adelantos biomédicos que actualmente permiten resolver problemas médicos para los que antaño hubiera sido imposible imaginar siquiera una solución debe tenerse siempre presente el valor ético que les confiere el hecho de estar al servicio del hombre. En esto consiste el humanismo del conocimiento científico. Por ejemplo, los transplantes de órganos abren, sin duda, posibilidades biomédicas de extraordinaria importancia; se hallan en el origen del gran progreso de la inmunología moderna, esta ciencia que, nacida decenios atrás, cobró nuevo auge cuando fue necesario desentrañar el problema biológico de los transplantes de órganos y comprender el comportamiento de las infecciones en el ser humano; y que abre una perspectiva, quizá la definitiva, para explicar la aparición y la progresión - y tal vez algún día el control - de algunos tumores malignos en el hombre.

En la práctica, sin embargo, los transplantes de órganos entrañan un problema ético; lo que no significa forzosamente que la medicina esté en contra de la práctica de estos transplantes ni del progreso de la ciencia biomédica de los transplantes en sí, ni de otros progresos paralelos a este desarrollo. El hecho es, sin embargo, que entre los miles de pacientes que requieren un transplante renal, hay que decidir cuáles deben tener acceso a esta operación decisiva para su supervivencia; decidir quiénes pueden recibir el transplante de conformidad con las normas éticas; y todo ello sin incurrir en el error de erigirse en juez para decidir quiénes van a vivir y quiénes van a morir, puesto que no hay suficientes donadores para los receptores en espera. Sin embargo, la investigación biomédica al respecto debe continuar; y es posible que aquí esté la justificación. Quizá en el futuro esta investigación permita encontrar métodos más sencillos, aplicables a muchos más.

El ejemplo anterior permite plantear un problema ético de la organización de los servicios médicos: ¿Hasta qué punto los países pueden invertir en el desarrollo de una medicina de tercer nivel, altamente tecnificada, como la que he puesto como ejemplo, cuando no han resuelto todavía el problema de la extensión de la cobertura de atención de primer nivel: es decir, la que ofrece posibilidades, al fin y al cabo, al 100% de la población?

Seguramente también aquí el problema es de grado, y no de exclusión. Idealmente, un país debe poder conseguir la extensión total de la cobertura del primer nivel y mantener al mismo tiempo grupos de la más alta excelencia de investigación en el tercer nivel. En términos generales, la enseñanza de la ética de la medicina en las escuelas no puede estar desligada de la ética misma de la medicina del país en que viven esas escuelas. Así, si hay problemas éticos planteados en la medicina en ejercicio, las escuelas tienen la obligación de realizar una crítica constructiva de esos problemas y de coadyuvar a su solución.

Como el mencionado, se podrían señalar otros problemas derivados de los adelantos biomédicos en la ciencia y la tecnología: por ejemplo, el sostenimiento de la vida biológica mediante una serie de procedimientos que permiten mantener casi indefinidamente en vida a los enfermos, en ocasiones en condiciones terminales; o los problemas éticos derivados del control de la reproducción, incluido el aborto. En algunos medios ha surgido el problema de la eutanasia y del derecho a morir o el problema de la ingeniería genética, para mencionar sólo algunos de los problemas derivados del aumento de los conocimientos en ciencia y en tecnología biomédica. Como hombres de ciencia no podemos oponernos a estos adelantos, pero debemos, eso sí, aprestarnos a enmarcarlos dentro de las normas éticas que rigen la vida de la humanidad, para mantener, en todo momento, este progreso al servicio del hombre.

En las aulas, hay que enfrentar a los estudiantes de medicina con los problemas de ética de la medicina actual, del ejercicio de la medicina en la comunidad, en un sistema o en un país, y mostrarnos críticos en lo necesario. Hay que hablarles de la ética en relación con el ejercicio actual de la profesión, cuando el costo creciente de la atención médica la hace cada vez menos asequible a las grandes masas y sólo permite que tengan acceso a ella los económicamente privilegiados.

Hay que poner un tela de juicio una medicina que ha invertido casi exclusivamente en la atención de tercer nivel, es decir, que

resuelve los problemas graves de las minorías, mientras sigue sin resolverse el problema de la atención de primer nivel para la mayoría; esta situación, justo es decirlo, no es sólo un problema de organización de las instituciones de atención de salud; la crítica puede dirigirse igualmente contra los que no quieren entender por falta de auténtico sentido de servicio que su presencia y su ejercicio son necesarios en ese nivel.

He mencionado solamente algunos ejemplos de los problemas éticos que plantea el ejercicio de la medicina actual. No he pretendido ofrecer soluciones. Ojalá en el curso de este simposio los participantes encuentren respuesta a muchos de estos problemas; en todo caso, sigo considerando que la enseñanza de la ética para los estudiantes y para los jóvenes médicos en ejercicio se deriva del ejemplo de sus maestros.

Summary

Valid as the Hippocratic Oath still is, it no longer encompasses all the problems of an ethical nature that arise in today's clinical medicine or health research.

Medical Ethics is not a theoretical consideration to be taught in the classroom: it is, rather, a process of practical application that appears in the context of specific medical situations, and can best be taught by the example of the teacher, during the clinical training of the student.

There are many diverse ethical considerations that can be studied in regard to basic attitudes in medicine. For instance, it is ethical to become a physician if there is an authentic vocation to serve, but it is not ethical to use medicine only as means of social or economic advancement.

The ethical responsibility of the teacher of medicine is to use his utmost effort to convey the proper information and attitude to the student, disregarding any consideration of employee relations with the university, which can properly be discussed and acted upon in different context.

The ethical responsibility of the student is to use his or her utmost effort to assimilate the instruction that is offered. The medical school, per se, has ethical obligations; for instance, to acquire and organize the human resources and equipment that make the proper teaching of medicine possible. It is unethical to establish 'medical schools' that lack the

proper resources, including laboratories, libraries, and access to hospital facilities adequate to the number of students.

Other ethical dilemmas appear because the advancement of medical sciences and technology runs far faster than the increase in economic resources, making it impossible to offer certain expensive treatments to all the patients that could benefit from them. The classical example is renal transplant. The dilemma here is to design an ethical way to decide who gets the transplant and who does not.

Many ethical problems appear in regard to the planning of medical care by the State. For instance, how much of the resources can be destined to be used in high-level medical attention and in medical research, when there is not coverage of primary health care for 100% of the population?

Many problems arise in the context of individual relations between doctor and patient, such as the use of life machines, reproduction control, abortion, genetic engineering, etc. The physician must learn to weigh ethical considerations from the very beginning of his career in the medical school.

A CONCEPT OF PROFESSIONAL ETHICS IN MEDICAL EDUCATION *

Edmund D. Pellegrino

Medical education in the 1960s abounded in pedagogical panaceas, few of which survived the 1970s. One striking exception is the introduction of the teaching of ethics and human values. Just beginning a decade ago, such teaching is now offered in the majority of United States medical schools.

When a medical school comes to mind we turn quickly to familiar scenes -- cadaver dissection, lectures in many-tiered amphitheaters, and white-coated neophytes at their first autopsy or birth. Not at all familiar are images of medical students in class pondering the meanings of George Eliot's Middlemarch and Thomas Mann's The Magic Mountain or analysing moral dilemmas at the bedside.

Yet new and exciting humanities teaching has been occurring in more and more medical schools. Ethics, philosophy, literature, and other humanistic studies are taking a place alongside anatomy, biochemistry, and physiology in the doctor's training. We are witnessing that rare event -- a fundamental shift in the aims of medical education -- one as profound as the introduction of the laboratory sciences in the early years of this century. The new shift will survive because it is firmly rooted in the altered nature of medical care and the patient-physician relationship.

The Impact of Medicine on Society

Medical care has always been a value-laden enterprise. That is why every advanced medical system prescribes an ethical code to safeguard the good of the patient. That prescription is today more difficult to fulfill than ever before because both medicine and patients'expectations have been fundamentally changed in the last three decades.

For one thing, medicine now has unprecedented powers to modify the quality of individual and communal life. These powers have profoundly transformed medical care from an individual art to an institutionalized, specialized technology thoroughly infused with the scientific spirit. Medicine is, as a result, one of the most potent forces shaping human culture.

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* This paper was read in Dr Pellegrino's absence by Thomas K. McElhinney, Ph.D., Director of Programs, Institute on Human Values in Medicine, and is based on an earlier form which was published in Encyclopaedia Britannica Medical and Health Annual, 1980.

Simultaneously, patients have become better educated and more assertive about participating in the decisions that affect them. They recognize that illness is an assault on the whole person and that depersonalization is a constant threat in today's technologically oriented medical care. They understand too that in a morally pluralistic society the values of physicians, patients, and society may be in serious conflict.

Physicians now must confront the moral dilemmas of abortion, in vitro fertilization, prolongation of life, genetic counseling, patient consent, and patients' rights. Even more complex challenges to traditional values will come from future medical advances. To conduct their relationship with the patient in a morally responsible way, physicians now must re-examine and restructure professional ethics to accommodate problems their predecessors could not imagine.

That is why ethics, taught in only a handful of medical schools in the mid-1960s, is now found in medical schools around the world. The rise of this development in the United States has meant that virtually every one of the 120 plus medical schools has some instruction in ethics and that some 80 schools also teach one or more of the humanistic disciplines -- history, philosophy, literature, or even law and theology, or at least have two philosophers at work. Some of the work in other countries will be discussed by other participants in this conference.

The Teaching of Ethics and Human Values

As with so many new ideas, interest in this kind of teaching germinated slowly in the minds of a few before coalescing into a national movement. A small group of campus ministers and medical deans began meeting in the 1960s. They formed the Society for Health and Human Values to advance their interests. Today that Society numbers 1,500 and includes health professionals of every kind as well as humanists and social scientists. The Society has served as an essential forum and as a stimulus for reinforcing an interest in the teaching of medical ethics and bioethics that was obviously widespread but latent.

In 1970 the Society founded the Institute on Human Values in Medicine, which for the past decade has been funded by the National Endowment for the Humanities. The Institute has been a major force in encouraging the establishment of teaching programmes through its faculty seminars, fellowships, and inter-

disciplinary dialogues, bringing together medical faculties with humanists, social scientists, and theologians. Through these activities the Institute has reached 350 different health care institutions and some 15,000 health professionals. Many thousands more have had access to the publications of the Institute which now number 13 in print, 3 presently in various stages of editing, and two others being written.

The greatest impetus came, of course, with the establishment of the first actual teaching programmes at such places as the Milson S. Hershey Medical Center in Pennsylvania (1967), the State University of New York at Stony Brook (1968), and the University of Texas Medical Branch at Galveston (1970). Since then, the teaching of ethics and values has burgeoned in every part of the nation. New schools as well as the oldest and the most prestigious, the most practice-oriented as well as the most research-minded, have incorporated such teaching into their curricula.

As befits an emergent field, there is a rich variety in what is taught: how, when, by whom, and for what purpose. The unifying themes are the centrality of values and ethics in medical care and the importance of the humanities for dealing with them responsively and responsibly.

If there is a 'core' discipline to these curricula, it is medical ethics and bioethics, offered in every school. Most frequently added is philosophy as it pertains to medicine and the health sciences. After that, varying combinations are found depending upon the school and its educational aims. In some schools, such as Southern Illinois University, the behavioural sciences predominate; in others, such as Hershey, the humanities.

No one place in the curriculum is best for the introduction of human values topics. Arguments may be made for the inclusion of systematic material in the basic science years, for re-enforcement when clinical teaching is done, and for review with house officers and hospital staff. In introductory courses general issues arising from common moral dilemmas -- abortion, care of the dying, patient confidentiality, etc., are introduced along with models of decision making and brief reviews of ethical theories. At least two schools -- the Medical College of Pennsylvania and State University of New York, Buffalo -- give students certificates in bioethics.

Teaching is most successful when professional ethicists or philosophers and physician-teachers cooperate. Ethicists may be

employed full time by the medical school or 'on loan' from other university departments. The aim is not to make professional ethicists of physicians but to acquaint them with the systematic study of right and wrong medical acts, the theories of ethics underlying them, ethical reasoning, and how to resolve conflicts of obligations. Although discussions begin with emphasis on clinical cases, some grounding in didactic principles is afforded as well.

Ethics may be readily accepted in a medical curriculum, but literature seems a bit distant. Yet at least 12 medical schools as diverse as Harvard, the University of Illinois, and Morehouse teach literature as well as ethics. The aim here is to use the evocative power of the creative writer to probe the nature of empathy and to call upon the novelist's imaginative powers that are not inherent in scientific studies. Works as varied as Tolstoy's The Death of Ivan Illich, Solzhenitsyn's Cancer Ward, Eleanor Clark's Eyes, etc., Joyce Carol Oates's Wonderland, and Balzac's The Country Doctor are used to communicate the experience of illness, of being a doctor or a patient, in ways that didactic lectures can never equal.

Other branches of the humanities have their contributions to make too. Philosophy is necessary for understanding the logic of medical diagnosis, the concept of health and disease, or meanings of illness. In some schools law plays a prominent role in the curriculum, as at the University of California at Los Angeles, the University of Connecticut, and Boston University; at others it is religion, as at St. Louis University, and Creighton University in Omaha, Nebraska; and at still others history is strongly represented, as at Yale, Washington University, Johns Hopkins, and Duke. History imparts a sense of continuity of human ideas and experiences, which serves to locate the student, and without which an age is rootless. The programmes at Southern Illinois, the University of Florida, and Wright State University, in Fairborn, Ohio, teach the affective components of medical humanism through anthropology, sociology, and psychology.

Humanistic studies in medical school cannot substitute for an undergraduate liberal arts education. When such is present it is reinforced; when uncertain or lacking, the importance of humanistic studies in medical care can at least be shown. It should be clear in both cases that humanism and science converge at the moment of decision making for individual patients. It is unfortunately, often true that undergraduate liberal arts courses are poorly taught and therefore present negative images that students carry into medical school.

Acceptance of the teaching of human values is variable. It is best received among students in family practice, community medicine, and psychiatry departments and least well received in the basic sciences and those schools whose aim is to prepare investigators and specialists. Those who object to such teaching worry about competition for the student's limited time or are convinced that ethics cannot be taught in the first place. Others feel that the medical school should not be expected to do the work of the liberal arts college. For some students the humanities seem out-of-place in medical school. However an even larger number of students find these disciplines refreshing in that the meaning of medicine and medical practice is clarified and their own humanity is integrated into the professional role that they are assuming.

Wherever teaching is well planned and executed, the humanities are fast becoming integral parts of the entire medical curriculum. They are taught, for example, in all four years at Georgetown, Tennessee, and East Carolina and in at least two years in most schools. Full-time teachers are being employed in increasing numbers. Medical schools are one of the few 'job markets' still open to ethicists, philosophers, and teachers of literature.

In some 80 medical schools teaching extends well beyond medical ethics to include at least one and usually two or three of the other humanistic disciplines. These programmes in the 'medical humanities' offer a broad view of the physician's role in contemporary society and culture. They also stimulate interest in the humanities as sources of enrichment of the physician's own life as well as essential tools for dealing with value and moral questions of medical practice.

Emphasis on human values is extending beyond undergraduate medical school and house officers. On the one hand, quite a few of the medical schools and the Institute on Human Values in Medicine are extending the continuum of human values teaching to include the practising physician. On the other hand, the burgeoning of such courses in colleges and universities unassociated with medical school promises to bring students to medical schools far better prepared than ever before. This means that medical schools in the future will be challenged to adopt a more sophisticated treatment of ethical and moral issues than is now the case.

For effective teaching, humanists need to familiarize themselves with the special character of medical education. They must

learn to teach by the medical case method, rather than in their accustomed didactic fashion. Cases are generally different for physicians, lawyers, and philosophers. Thus, some familiarity with the language of the clinicians is mandatory as is a grasp of the authority structure of medical care and its institutions. This is accomplished in most programmes by a preparatory year or more, working and planning with medical faculties prior to active teaching. At the University of Tennessee all graduate students in philosophy who concentrate in bioethics serve a 'residency' period full time for several months in the medical centre hospitals.

Ethics and humanistic attitudes of mind are as essential to nurses and other health professionals as to physicians. In the last five years schools of nursing have also initiated programmes in bioethics, analagous in method and aim to those described for medical schools. Emphasis, however, is on the special problems of nursing practice and research. Teaching is done by nurses as well as professional ethicists and philosophers. An Institute for Nursing Ethics has recently been established. Very slowly -- but steadily -- the quality of the teaching of human values in allied programmes is improving.

Teaching programmes rarely survive unless a substantial intellectual base is constantly added through research. The vitality of medical ethics and medical humanities is attested by the cascade of books and articles appearing in recent years. Several journals devoted entirely to medical ethics have been founded, such as Ethics in Science and Medicine *, The Journal of Medical Ethics, Philosophy and Public Actions. Two are dedicated specifically to the philosophy of medicine: The Journal of Medicine and Philosophy in the United States and Metamedicine in Germany.

A dozen or more institutes and centres dedicated to research in human values and bioethics have come into existence. Most notable are The Hastings Center Institute of Society, Ethics, and the Life Sciences, The Kennedy Institute of Ethics Center for Bioethics at Georgetown University, and the Institute for Medical Humanities at the University of Texas Medical Branch at Galveston. Multi-volume publications like the Encyclopedia of Bioethics and the Bibliography of Bioethics have appeared, enabling professionals to keep up with the research in this field.

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* The title of this journal has been changed to Social Science and Medicine.

Teaching human values and ethics seems assured of survival well into the 21st century. The forces responsible for today's intense interest will surely generate new moral dilemmas. The need to protect the humanity of the ill person will deepen as medicine becomes even more technologically oriented and physicians more narrowly educated in the specialities.

As with the basic medical sciences, a few physicians are being educated with both an M.D. and a Ph.D. in one of the humanistic disciplines. Teaching will continue, however, to be a cooperative effort between bona fide humanists and clinicians. Students will take more electives and continuing education will expand as today's students become practitioners and appreciate that keeping up with new ethical problems is as essential as keeping up with new treatments.

Final Comments

The gravest danger in an expanded medical education is of over-expectation. Ethics and the humanities can heighten sensitivities to the human and personal dimension of medical care. They can provide intellectual skills necessary for morally responsible decision making. They cannot be expected to make all students humane or sensitive human beings. They cannot correct personality disorders, improper motivations, or plain rudeness. Nor can they satisfy the swelling demand for 'medical humanism', which has such complex origins and divergent definitions. Some call for medical schools to teach esoteric non-Western medical practices; others call for sensitivity training; others see the answer in religious training or self-care. To expect the humanities to satisfy or provide a 'quick fix' for these special interests is to foreordain defeat.

The humanities in medicine are neither pedagogical panaceas nor mere arabesques around the central core of a scientific education. They comprise essential cognitive skills required by the changing nature of medicine and society to safeguard the person of the patient and his agency as a moral being. Medicine is a shaper of human values and culture. Health professionals make value decisions daily. They should be educated to make them as well as possible. The same is true of the other professions -- engineering, law, the ministry, and business. There are evidences of a parallel renaissance in the teaching of humanities in these fields for which the experience in medicine can be a model.

Medicine and the humanities have always been closely associated. In early Greek times medicine was indistinguishable from philosophy. In the Hippocratic era it was separated as a distinct discipline. Until the fifth century AD, medicine was even included among the humanities. Because it deals with so personal an experience as illness and health, medicine must ground itself in both the sciences and humanities.

The innovation of teaching human values and ethics is not simply a transient pedagogical fashion. It is a recognition that the physician as scientist and the physician as humanist must converge if medicine is to be a boon and not a threat to individuals and society.

Resumen

La enseñanza de la ética y de los valores humanos era prácticamente inexistente hace 10 años, en tanto que actualmente se realiza en la mayoría de las Escuelas de Medicina de los Estados Unidos.

En los últimos años, muchos estudios humanísticos, tales como la ética, la filosofía y la literatura, han adquirido importancia, junto con la anatomía, la bioquímica y la fisiología, en el adiestramiento de los médicos.

El tratamiento médico siempre ha entrañado un juicio de valores. Esa es la razón por la cual todos los sistemas médicos avanzados establecen un Código Etico para proteger el bienestar del paciente. Esta función es actualmente más difícil de desempeñar debido a que tanto la medicina como lo que de ella esperan los pacientes han cambiado fundamentalmente en los últimos decenios. La medicina moderna, en efecto, tiene el poder de modificar la calidad de la vida individual y comunitaria, lo que ha transformado el tratamiento médico de un arte individual en una tecnología institucionalizada.

Simultáneamente, los pacientes tienen más conocimientos sobre las cuestiones y desean participar más en las decisiones que los afectan.

Los médicos deben actualmente resolver los dilemas morales del aborto, la fecundación in vitro, la prolongación de la vida, el consejo genético, el consentimiento de los pacientes y los derechos de los enfermos. Para mantener la relación con sus enfermos de manera responsable, los médicos deben examinar y

reestructurar su ética profesional con el fin de adaptarla a problemas que sus predecesores ni siquiera imaginaron.

En los Estados Unidos, la enseñanza de la ética y de los valores humanos se inició gracias a un pequeño grupo de sacerdotes universitarios y decanos de escuela de medicina, que fundaron la Sociedad para la Salud y los Valores Humanos. En 1970, la Sociedad creó el Instituto de Valores Humanos en Medicina. Este Instituto ha constituido una fuerza importante en la elaboración de programas de enseñanza, por medio de la celebración de seminarios, el establecimiento del diálogo interdisciplinario y la organización de estudios en los que participan conjuntamente médicos, humanistas, especialistas en ciencias sociales y teólogos.

El paso más importante fue el establecimiento de los primeros programas de enseñanza de la ética médica en diversos centros. Como es lógico que ocurra en un campo de reciente creación, existen grandes variaciones en el contenido de esas nuevas enseñanzas. Pero los temas generales son la importancia fundamental de la ética y de los valores en la atención médica y la necesidad del humanismo para tratar esas cuestiones de manera sensible y responsable.

La enseñanza es más fructífera cuando cooperan en ella médicos, profesores de ética y filósofos. El objetivo no es hacer de los médicos eticistas profesionales sino familiarizarles con el estudio sistemático de lo correcto y lo erróneo en los actos médicos, con las teorías éticas que apoyan esos actos, con el razonamiento ético y con la forma de resolver los conflictos de la ética con el deber.

Junto con las cátedras de ética, se instauran en algunas escuelas de medicina otras sobre materias tan diversas como la literatura, que utiliza la creatividad del escritor para explorar la naturaleza de las relaciones interhumanas.

Otras ramas de las humanidades aportan también su contribución. La filosofía es necesaria para comprender la lógica del diagnóstico médico, y la historia para captar la corriente de continuidad que enlaza las experiencias y las ideas humanas.

En el plan de estudios de algunas escuelas, ocupa un lugar importante el estudio de los aspectos jurídicos.

Los estudios humanísticos en la escuela de medicina no pueden substituir, sin embargo, una educación sólida en la esfera de las artes liberales, que debe adquirirse en la fase de pregrado.

El grado de aceptación de las enseñanzas sobre los valores humanos es muy variable. Estas enseñanzas gozan de más aceptación, por ejemplo, entre los estudiantes de medicina de la familia, de medicina de la comunidad y de psiquiatría. Algunas escuelas de medicina y el Instituto de Valores Humanos en Medicina han extendido las enseñanzas sobre valores humanos para incluir entre sus beneficiarios al médico en ejercicio.

Las actitudes mentales éticas y humanísticas son igualmente importantes para las enfermeras y otros profesionales de la salud. En estos casos, la enseñanza corre a cargo tanto de enfermeras como de eticistas profesionales y filósofos. Recientemente ha sido establecido un Instituto de Etica en Enfermería.

Los programas de enseñanza raramente logran sobrevivir a menos que su base intelectual se enriquezca constantemente mediante la investigación. Hay varias publicaciones periódicas consagradas exclusivamente a la ética médica, tales como la Etica en Ciencia y Medicina, o la Revista de Etica Médica, Filosofía y Acción Pública. Otras dos están dedicadas específicamente a la filosofía de la medicina: La Revista de Medicina y Filosofía publicada en los Estados Unidos, y Metamedicina, que se publica en Alemania. Por otra parte, han sido creados más de una docena de institutos y centros dedicados a las investigaciones sobre los valores humanos y la bioética.

Sin embargo, la educación humanística tiene sus límites. Sería sumamente peligroso esperar demasiado de ella. Los estudios de ética y de humanidades pueden aumentar la sensibilidad con respecto a las dimensiones humanas y personales de la atención médica; pueden también facilitar la capacitación intelectual necesaria para poder adoptar decisiones con un mayor sentido de la responsabilidad moral; pero no puede esperarse de esos estudios que hagan de todos los estudiantes seres humanos dotados de sensibilidad exquisita, puesto que no pueden corregir, por ejemplo, los trastornos de la personalidad, las motivaciones inadecuadas o simplemente la grosería.

Los estudios humanísticos en medicina no son ni una panacea pedagógica ni simples arabescos decorativos alrededor de un núcleo central de educación científica. Permiten adquirir, eso sí, la formación intelectual indispensable que requiere la naturaleza cambiante de la medicina y de la sociedad, para la protección de la persona del paciente y de su integridad como ser moral.

ENSEÑANZA DE LA ETICA MEDICA EN VENEZUELA

Augusto León

La enseñanza de la ética médica en las escuelas de medicina de Venezuela es similar, a grandes rasgos, a la impartida en los restantes países de la América Latina. Ello justifica un análisis breve del estado actual de la enseñanza en esta última, con carácter general, precediendo la información específica referente a Venezuela.

Situación actual en la América Latina

Tres elementos de juicio permiten poner de relieve la situación de la ética médica en la América Latina: el análisis de las encuestas realizadas con tal fin, la evaluación crítica de la educación médica y el estudio de la enseñanza de esta disciplina (1).

En 1966 se publicó la 'Primera encuesta continental sobre temas éticos en la América Latina' (2), realizada mediante el interrogatorio de los médicos de 17 naciones latinoamericanas seleccionados por su dedicación al estudio de estos problemas, por la notoriedad que les conferían sus cargos, o por el valor representativo de sus opiniones como muestra de los puntos de vista más generalizados en sus respectivos países. Se resumen a continuación algunos de los resultados obtenidos.

1. La falta de un código de ética fue señalada por el 55% de los profesionales sometidos a la encuesta.

2. Para el 40%, no se publica casi nada acerca de normas éticas destinadas a regular el ejercicio de la profesión médica.

3. Una minoría expresó que no creía en la necesidad de un código escrito y que bastaría con seguir los preceptos del juramento hipocrático de 'atender al enfermo como si fuera uno mismo'.

4. En casi todos los países latinoamericanos son los Colegios de Médicos y las Federaciones respectivas los organismos que gozan de autonomía para juzgar las contravenciones al código de ética. La justicia ordinaria sólo interviene en los casos de graves desviaciones contra la moral y que pueden

calificarse como delitos públicos. Las asociaciones profesionales no son órganos de justicia, de modo que en caso de comprobarse un delito lo único que pueden hacer es someter el problema a los tribunales. Las sanciones consisten habitualmente en amonestaciones verbales o escritas y pueden llegar a la propuesta de la suspensión del ejercicio profesional. En algunos casos las autoridades judiciales han aplicado sanciones por faltas contra la ética profesional.

5. La mayoría emitió observaciones críticas sobre los códigos de ética. El 51,5% de los médicos consultados respondió que los códigos actuales están parcial o totalmente obsoletos, ya que ningún código puede mantenerse vigente en una ciencia tan sometida a mutaciones como lo es la medicina moderna, en la que todos los días surgen nuevos problemas no contemplados lógicamente en los códigos respectivos.

6. Al analizar las relaciones entre los códigos de ética y las leyes que rigen el ejercicio de la medicina muchos son del parecer que las reglas abstractas generales y rígidas de la justicia no pueden, de manera alguna, ser aplicadas a un arte tan personal a la vez que complejo como el acto médico. Los juristas, a su vez, insisten en que los médicos deben someterse, si no a las reglas de derecho común, por lo menos a las de un derecho médico establecido por otra instancia ajena a la de los propios médicos, y que la medicina moderna no es cuestión de simple ejercicio personal, ya que su repercusión sobre la colectividad justifica la intervención de la misma, en su funcionamiento, por medio de los organismos legales.

Consideramos íntimamente relacionados el tipo de educación médica impartida en un país y el comportamiento ético de sus médicos. Por ello concedemos importancia al estudio publicado en 1972, sobre la 'Educación médica en la América Latina' (3), el cual abarca el modo actual de formación de los médicos en las escuelas de medicina correspondientes.

Para obtener el título de médico en la América Latina, incluyendo los ciclos escolares previos, se requiere un tiempo mínimo de 16 a 20 años de estudio. El objetivo de la educación se resume así: 'La formación de médicos que sirvan a las necesidades del país y que tengan preparación científica, técnica y social que los capaciten para ejercer y desarrollar su profesión'. Ninguna de las escuelas de medicina presentó objetivos más específicos que los citados, ni tampoco se hace mención de los requerimientos de orden ético.

El promedio de horas por alumno de los estudios médicos propiamente dichos es de 5367 en las escuelas latinoamericanas con curso completo. La asignatura medicina tiene un promedio de 1308 horas de enseñanza por alumno y por escuela y un 67% de horas prácticas. En la asignatura medicina se incluye la cátedra de 'Medicina legal y deontología' sólo en las escuelas donde se programa algo en relación con esta última materia.

La enseñanza de la ética ha sido ignorada tradicionalmente por las escuelas de medicina de la América Latina, y prácticamente, con excepciones notables, no se programa ningún tipo de adiestramiento en este sentido en el plan de estudios de las mismas.

Tres factores son muy obvios: 1) el cúmulo de conocimientos exigidos para la obtención del título desplaza a un plano subalterno la consideración de los aspectos morales; 2) el recién graduado tiende, casi sin excepción, a la especialización precoz, y en los programas de los cursos de especialidades tampoco se incluye la consideración de los problemas de naturaleza ética; 3) los profesores muestran mayor dedicación en transmitir los conocimientos y el dominio de las técnicas relativas a su especialidad y muy pocos muestran interés por los problemas humanitarios de la profesión médica; o, si tienen interés, no siempre tienen capacidad para el análisis de los mismos porque no figuró la consideración de éstos en su etapa formativa. Se cierra así un círculo vicioso.

Durante años hemos efectuado una encuesta que abarca Venezuela y otros países latinoamericanos, mediante el contacto personal y la correspondencia con personas calificadas de los respectivos países (4). Las respuestas obtenidas fueron muy similares:

1. La mayoría de los médicos muestra poco entusiasmo por el enfoque directo, formal, de los problemas de la ética en medicina, por considerar que el análisis de los mismos es cuestión de filosofía moral, para lo cual no disponen de sólidas bases.

2. La interpretación de la naturaleza de las reglas morales y su aplicación a situaciones particulares, según algunos, deben quedar al arbitrio o buen juicio del médico, y es improbable que unas pautas generales puedan resultar de alguna utilidad.

3. Muchos se refieren al planteamiento formal de los problemas éticos durante la etapa de formación del futuro médico con la frase de 'argumentaciones tortuosas', sin aplicación práctica un última instancia, y se resisten a incluir la

consideración de dichas situaciones, de manera sistematizada, en los programas de enseñanza, porque habría que hacerlo a expensas del tiempo dedicado a las disciplinas técnicas que más directamente les conciernen y acerca de las cuales creen poder opinar con plena autoridad.

4. La moral de los médicos sería, en última instancia, un 'subproducto' de las creencias morales de la sociedad donde éstos ejercen y - necesariamente - tendrán que acogerse a los criterios que prevalecen en la misma.

La mayoría de los códigos de ética vigentes en la América Latina dan la impresión de manuales de etiqueta y cortesía profesional, donde se nos señala nuestros deberes hacia los otros colegas, las responsabilidades que nos atan a determinados mandatos gremiales y lo que debemos hacer de acuerdo con lo que nuestras 'asociaciones profesionales' decidan pensar por nosotros. Ello ha conducido a determinados médicos a la actitud irrazonable de considerar que mientras no violen determinadas normas de etiqueta - las expresamente transcritas en el código -, mientras se conduzcan como buenos escolares domesticados, se hallarán libres de toda reconvención.

Situación actual en Venezuela

La enseñanza de la ética se incluye en Venezuela en el programa de la disciplina 'Medicina legal y deontología', y durante todas las etapas de los estudios médicos se dictan 7 (siete) horas concernientes a temas relacionados con la ética. El porcentaje dedicado a esta materia es irrisorio si se compara con el promedio de horas por alumno durante la totalidad de los estudios médicos: 0,00132.

Tengo la plena convicción de que muchos docentes de las escuelas de medicina de nuestro país consideran los problemas morales lejanos e irrelevantes, ignorando en forma pedestre que a medida que el conocimiento médico se ensancha merced a la contribución de las múltiples especialidades, se crean nuevos problemas que suscitan el juicio moral de la sociedad al mismo tiempo que de la profesión (5).

En mi Facultad, el tiempo de las autoridades y de las diversas 'comisiones de trabajo' se consume, año tras año, en el loable esfuerzo de introducir valiosas reformas en el plan educativo; pero la cuestión ética no ocupa siquiera un lugar subalterno; simplemente, no se menciona. Los representantes de cada cátedra discuten apasionadamente, exigiendo mayor atención y 'mayor número

de semanas' para la asignatura correspondiente a su campo de acción. El fruto de ello lo recoge el estudiante: se le exige asimilar una cantidad formidable de conocimientos, muchos de ellos inútiles, inaplicables y destinados al saludable olvido inmediato.

La enseñanza de 'su materia' ocupa todo el tiempo de profesores dedicados a cumplir como mejor puedan el deber que les impone la facultad: formar buenos técnicos en el campo médico, quirúrgico o lo que sea, pero nunca profesionales de sólida formación moral. No hay tiempo para perderlo enjuiciando materias de ese tipo. Algunos me han dicho que no dejan de reconocer su importancia, pero, ¿cómo 'ocuparnos de eso' cuando apenas disponemos de tan escaso tiempo para cumplir con nuestra responsabilidad primaria?

El objetivo mayor, o para mejor decirlo, el 'blanco' hacia el cual apuntan con orgullo sus esfuerzos nuestras escuelas de medicina es la alta calidad de la preparación científica suministrada a sus egresados; e históricamente han demostrado una tremenda debilidad en cuanto a su capacidad e interés por relacionar medicina y valores humanos.

Estos hechos me llevaron a proponer en 1975 a la Academia Nacional de Medicina, nuestra máxima institución científica, un 'Programa de investigación y aprendizaje de la ética en medicina' (6). Este programa fue aprobado y exigida su adopción por las escuelas de medicina de todas las universidades del país.

Describiré, en el mismo orden, las dificultades que se oponen al logro de los objetivos de cualquier plan de formación ética en Medicina, las alternativas posibles y, finalmente, mi proposición.

Dificultades

- El plan de estudios de nuestras escuelas de medicina se halla sobrecargado. Parece obvio, luego de un examen superficial, que ya no disponemos de espacio ni tiempo para la incorporación de otra disciplina.

- Se dice que el estudiante emitirá reservas ante la simple mención de una 'nueva materia', preocupado en forma tradicional por capacitarse lo más pronto posible en la adquisición de destrezas técnicas, las únicas exigidas para culminar con éxito sus estudios e ingresar en la vida profesional.

- La ausencia - inexcusable para el país donde nació Razetti - de una tradición formal en la enseñanza de la ética, la cual ha figurado durante largos años como algo muy secundario dentro del programa de estudio de otra materia.

- La escasez de personas interesadas en patrocinar y/o colaborar en la realización de un programa de adoctrinamiento en este campo. Dentro de este sector, un grupo numeroso de docentes conduce su actuación profesional en forma irreprochable desde un punto de vista moral y les satisface la creencia de que basta el simple ejemplo de su conducta para influir en el ánimo de sus discípulos. Algunos, con gran énfasis, defienden la tesis de que la ética se transmite con el ejemplo, sin necesidad de recurrir a otras vías de acción; sólo que el costado débil de esta argumentación consiste en dejar al instinto, o al mal llamado sentido común, los criterios de elección ante determinadas situaciones. Y estos médicos, honestos a no dudarlo, toman en múltiples oportunidades decisiones erróneas por no haber sido expuestos, durante su etapa formativa, al enfoque racional de las diversas actitudes que cabe adoptar ante el 'hecho ético'.

- La ausencia de interés por parte de las autoridades de la Facultad de Medicina. No han mostrado la menor preocupación por abordar en forma decidida lo que en las conversaciones informales tanto les alarma: la crisis de los valores éticos. Es explicable tan irracional comportamiento, ya que pueden alcanzar el rango de autoridades universitarias profesores que, durante el ejercicio de la docencia, no tuvieron interés en meditar sobre estos problemas, porque tampoco hubo quien se preocupara por los mismos cuando eran simples estudiantes. Se cierra así un círculo vicioso, que hemos intentado vanamente romper a lo largo de varios años, utilizando todos los mecanismos lícitos dentro de nuestra maltratada institución universitaria.

Alternativas

1. Mantener la situación actual, o sea la de incluir la 'deontología médica' en forma tan accesoria dentro del programa correspondiente a la asignatura de Medicina Legal.

2. Crear la Cátedra, con un programa determinado basado en exposiciones teóricas, incorporándola al plan de estudios en la etapa del pregrado, mediante su ubicación en alguno de los años finales de la carrera.

3. Aceptar la enseñanza de la ética en forma de transmisión informal de conocimientos, analizando las diversas situaciones habituales en el ejercicio de la relación médico-paciente. Los partidarios de esta tesis se oponen a la estructuración sistematizada de la enseñanza de la ética.

4. Someter su aprendizaje a un programa de adoctrinamiento mediante conferencias teóricas, destinadas al análisis de las situaciones habituales en la práctica hospitalaria, realizado específicamente durante la etapa de estudios clínicos.

5. Organizar un curso formal de aprendizaje e investigación, a todo lo largo de la carrera médica, sometido a un programa definido, con la intervención de otras Escuelas de las diversas Facultades de la Universidad, seleccionando con carácter prioritario las disciplinas de orden humanístico.

Proposición

Hemos seleccionado la última de las posibilidades descritas, dividiendo el programa en tres etapas.

La primera etapa consistiría en la realización de un Seminario Nacional sobre Etica en Medicina, con la participación de diversas instituciones (Academia Nacional de Medicina, Federación Médica Venezolana, Consejo Nacional de Universidades, Asociación de Facultades de Medicina y Ministerio de Sanidad y Asistencia Social), destinado a la adopción de procedimientos uniformes para la formación de los futuros egresados y para diseñar normas de supervisión del estricto cumplimiento de los principios deontológicos requeridos para el cabal ejercicio de la profesión médica. Durante dicho Seminario se discutirían las pautas que a continuación proponemos, para la realización de las dos etapas siguientes.

La segunda etapa comprende la elaboración de un programa multidisciplinario de investigación sobre los problemas morales en medicina, exigiendo la participación de personas con demostrada competencia en el campo de la ética y de las disciplinas humanísticas. Hemos demostrado la razón obvia del carácter multidisciplinario del programa. Durante esta etapa, de variable duración, se realizaría el adoctrinamiento de los profesores de la Facultad de

Medecina, de todas las materias - incluyendo las ciencias básicas - en los fundamentos éticos de la práctica médica y en el análisis de los correspondientos aspectos filosóficos.

La tercera etapa, o de realización propiamente dicha, consistiría en la libre discusión por parte de los estudiantes - con el asesoramiento de los preceptores respectivos - de situaciones concretas, evitando los planteamientos abstractos; enfrentando los alumnos a los dilemas éticos habituales en el ejercicio de la profesión médica, previo suministro de la información requerida para el análisis de las diferentes perspectivas morales.

El objetivo de nuestro programa se dirige a despertar inquietudes y clarificar situaciones, más que a exigir 'respuestas concretas'. Ya que no siempre existe para cada situación la solución correcta, debe evitarse la imposición dogmática de cualquier punto de vista.

Los planteamientos no partirán de la premisa: ¿Se halla esto justificado?, sino de otra muy diferente: ¿Se justifica esta decisión en esta situación en particular?

La discusión de un caso específico debe ser precedida de un análisis general realizado por el preceptor. A continuación se suministra al grupo de alumnos el material de referencia, y posteriormente se analiza el tipo de solución propuesta. La recolección de las conclusiones obtenidas, para su confrontación con experiencias similares en momentos posteriores, constituirá un documento valioso para evaluar la utilidad del programa y señalar el tipo de modificaciones que deben emprenderse.

Hay que hacer comprender al alumno que el problema tiene importancia práctica no sólo para el individuo sino, por su repercusión, para la sociedad en general. Hay que enseñarle la forma de apreciar la pertinencia de los hechos y la forma de aplicar las posibles soluciones.

El estudiante aprenderá que las formulaciones contenidas en los códigos de ética no cubren todas las posibilidades ni prevén las situaciones particulares. También debe enseñarse, y de ahí la importancia del carácter multidisciplinario del programa, que el punto de vista 'no médico' debe conocerse, debe solicitarse en múltiples ocasiones, puesto que a veces es más objetivo que el punto de vista 'puramente médico'.

No ignoramos que nuestra proposición suscitará críticas, y que se alegará, por ejemplo, que las virtudes morales no pueden - en opinión de algunos - ser objeto o materia de enseñanza. Sin embargo, el humanitarismo, la compasión y el espíritu de crítica pueden y deben ser, si no enseñados, formalmente aprendidos por todos los médicos durante su formación. Probablemente este objetivo ideal sólo puede alcanzarse mediante el ejemplo; pero, en todo caso, es evidente que la formación ética del médico no puede iniciarse al abandonar éste la Escuela de Medicina.

Summary

The teaching of medical ethics in the medical schools of Venezuela, is basically similar to the teaching imparted in other Latin American countries. Three elements make possible the assessment of the situation of medical ethics in Latin America; the analysis of polls, the critical evaluation of medical education, and the study of teaching on this subject. In 1966 the 'First continental poll on ethical subjects in Latin America' was published; the following results were obtained:

1. 55% of professionals did not follow a specific ethical code.

2. 40% stated that almost no publications existed on ethical norms destined to regulate medical practice.

3. A minority found no need for a written code, and believed that following the precepts of the Hippocratic Oath in helping the sick would be enough.

4. In most Latin American countries, medical schools and associations are autonomous in judging contraventions of medical ethics.

5. Most were critical towards ethical codes, 51.5% finding them partially or totally obsolete.

6. On analysing the relations between ethical codes and legal codes dealing with medical practice, many believe that rigid laws and regulations cannot be applied to such a personal and complex art as medical practice, whereas jurists insist on the submission of medical personnel to the rules of an established medical law.

We consider that the type of medical education and the ethical behaviour of a nation's doctors are intimately related.

A study published in 1972 on 'Medical education in Latin America' does not mention ethical requirements. The teaching of ethics has been traditionally ignored by Latin American Medical Schools. Three factors are evident; the needs of assimilating knowledge for obtaining a medical degree takes priority over the considerations of moral aspects. The recent graduate tends quickly to enter specialization programmes in which consideration of problems of an ethical nature are also not included. Teachers prefer to transmit technical knowledge and abilities. Few show interest in the humanitarian problems of the medical profession.

During some years we have undertaken a poll which covers Venezuela and other Latin American countries, by personal contact and correspondence with qualified personnel of each nation. The results obtained have been similar; 1. Most physicians show little enthusiasm for direct focussing on problems of medical ethics. 2. Some feel that the interpretation of the nature of moral rules must be left to the arbitrary judgement of the physician. 3. Formal analysis of ethical problems during the education of the future physician is referred to by some as 'tortuous argumentations' lacking practical applicability. 4. Medical morals are ultimately a product of the morals of the society in which physicians practise, and follow prevalent criteria.

Most standing ethical codes in Latin America refer basically to professional courtesy, duty towards other colleagues, responsibility to unions, and what is expected from physicians by their respective professional associations.

The teaching of medical ethics in Venezuela is included in the programme of a discipline named 'Legal Medicine and Deontology', in which there are seven hours of lectures on subjects concerning ethics. I am quite convinced that many teachers of our countries' medical schools consider moral problems as unrelated and irrelevant. These facts led me to propose in 1975 a 'Programme of research and learning of ethics in Medicine' to the National Academy of Medicine, our highest scientific institution.

Proposals

In a first stage, the holding of a national seminar on medical ethics, destined to adopt uniform procedures for the formation of future physicians. A second stage contemplated the elaboration of an interdisciplinary programme of research on moral problems in medicine. The third stage would consist of free discussion by the students of concrete situations involving habitual ethical dilemmas in medical practice.

THE TEACHING OF MEDICAL ETHICS IN BRAZIL

Murillo Belchior

The teaching of medical ethics started many years ago in Brazilian medical schools. However, it was presented in the course of legal medicine and only recently was it considered as a separate discipline in some medical schools.

The subject has received special attention in Brazil during the last few years, and the Councils of Medicine played a very important role in this. I must explain first that in Brazil the supervision of medical ethics is by the Federal Council of Medicine and the Regional Councils. They are the only organizations with the legal responsibility for taking care of all cases pertaining to medical ethics. When there is a suspicion or indication of ethical misconduct, the case has to be taken by the Regional Council in the area in which it happened. This Regional Council studies the case in the form of a judicial process, giving the defendant every chance to defend himself. The Federal Council acts as a Court of Appeal, to which the doctor can appeal in cases where he is considered guilty.

The Federal Council, conscious of its responsibility, a few years ago started a programme of sponsoring courses on medical ethics in cooperation with the medical schools and organizations of medical students. In 1975 it issued a Resolution stating:

(1) Medical education should have as a special goal the service of society.

(2) Medical education should be closely related with the prospect of better medical care.

(3) Medical schools should have the responsibility for the education and training of a health team conscious of their duties to the community in which they live.

(4) It is of the utmost importance to have an effective and harmonious relationship between medical education and medical care.

(5) It is necessary to teach medical ethics to medical students during the whole medical course.

(6) It is absolutely necessary for medical students to possess a perfect and clear idea about ethical principles and their interpretation concerning medical care and future professional obligations.

In this Resolution the Council recommended to the Regional Councils the organization of programmes designed to teach medical ethics during school time, as far as possible in cooperation with the medical schools in their area as well as with student organizations. Brazil now has 75 medical schools and 37 of them the teaching of medical ethics is already included in the curriculum.

We consider it essential that medical students realize that medical ethics is based on the idea of rights and responsibilities right from the beginning of their course.

The doctor has an unquestionable responsibility to society, to patients and to himself. However, these responsibilities should be the basis of the teaching of medical ethics. In the courses we sponsor, we try to make it very well understood that no nation can survive without social and moral values; moreover, medical ethics is a consequence of personal moral principles.

The subjects of the courses we are giving are as follows:

(1) Present status of medical ethics.
(2) Ethics and medical specializations.
(3) Religion and ethics.
(4) Medical contracts.
(5) Ethics and different medical institutions and organizations.
(6) Medical secrecy.
(7) Medical legislation - The doctor and the law.
(8) Doctors and the media - Advertising and publicity.
(9) Medical malpractice and negligence.
(10) Mercantilism and medicine - Commercial enterprises and connections.
(11) Incompetent and unqualified doctors.
(12) Methods of payment.
(13) Codes of medical ethics and ethical responsibility.
(14) Ethics and clinical investigation.
(15) Professional responsibility.
(16) Medical ethics and technological progress.
(17) Ethical violations.
(18) Medical ethics and conformity to law.
(19) The social role of the Councils of Medicine.
(20) Unethical medical procedures.

(21) Medical responsibility in the practice of surgery.
(22) Doctors and paramedical professions and professions supplementary to medicine.
(23) Ethical dilemmas.

As you can see these subjects cover some of the most important problems the doctor faces during his professional life.

CIOMS is at present engaged in a study on clinical investigation. A group of well-known experts in the field met in July 1980 in Geneva and developed a very good report about this subject. The conclusion of this work will be of great value in the teaching of medical ethics.

In only a few medical schools in Brazil is the teaching of medical ethics developed in a separate and independent department. In the great majority, the teaching is given in the Departments of Legal Medicine and Social Medicine, and all the courses for a Master's degree have medical ethics included in the curriculum. Some medical schools have already established a discipline of medical ethics as a compulsory field of study in the curriculum and there is a tendency to extend this to all medical schools.

The Federal and Regional Councils of Medicine are working in a close cooperation with the medical schools, the university hospitals and all kind of clinics and hospitals to develop programmes concerned with medical ethics, because we are very aware of the importance of this field in the medical profession. This past year, for example, we offered ten courses which were open to both students and doctors. These were supplementary courses to the ones offered by medical schools and had been specifically requested as a part of continuing education. We look forward to extending our system to all the professional bodies interested.

This in a few words is what is being done in Brazil about the teaching of medical ethics.

Resumen

La enseñanza de la ética médica se inició hace largo tiempo en las escuelas de medicina de Brasil, donde, sin embargo, se incluía en la asignatura de la Medicina Legal; sólo recientemente se la considera como disciplina separada en algunas escuelas de medicina.

En Brasil, la supervisión de la ética médica corre a cargo del Consejo Federal de Medicina o de los Consejos Regionales. Cuando se sospecha una falta de comportamiento ético, estudia el caso el Consejo Regional Local, y el Consejo Federal actúa como tribunal de apelación.

Desde hace varios años el Consejo Federal organiza cursos de ética médica en cooperación con las escuelas de medicina. En 1975 publicó la siguiente resolución:

1. La educación médica debe tender al mejoramiento de la atención médica.

2. Incumbirá a las escuelas de medicina la responsabilidad de educar y adiestrar al equipo de salud, y de hacerle conciente de sus obligaciones hacia la comunidad donde radica.

3. Es de vital importancia una relación efectiva y armoniosa entre la educación médica y la atención médica.

4. Es necesario instruir en la ética médica a los estudiantes de medicina durante todo el curso de sus estudios.

5. Es absolutamente necesario que los estudiantes de medicina tengan un conocimiento perfecto de los principios éticos y de su aplicación en relación con la atención médica y con sus obligaciones profesionales futuras.

En el plan de estudios de 37 de las 75 escuelas de medicina que hay actualmente en Brasil se incluye la enseñanza de la ética médica.

El autor presenta una lista de los temas que habitualmente se estudian en los cursos de ética médica ofrecidos en las escuelas de medicina de Brasil.

MEDICAL ETHICS INSTRUCTION FOR MEDICAL STUDENTS IN THE CLINICAL YEARS

Mark Siegler

Introduction

I wish to describe the programme we have developed at the University of Chicago for teaching ethics to clinical students. Our programme should be regarded as just one possible solution among many for teaching this difficult subject. Nevertheless, in addressing the problems of medical ethics instruction, it is often better to begin not by describing a hypothetical or planned curriculum, but rather by describing a functioning programme whose strengths and weaknesses have become apparent over a period of years. Before I describe our programme in detail, let me define 'clinical ethics' and indicate why I prefer it to the term 'biomedical ethics'.

Biomedical ethics (BME). This is concerned with the analysis and formulation of broad public policy options in medicine and science, such as the issues of abortion, just distribution and allocation of health resources, and societal concerns regarding the protection of human subjects in medical research. Indeed, some of the leaders of the BME movement have actually expressed their disdain for traditional, Hippocratic, bedside medical ethics which has always been both patient- and physician-oriented. The BME movement in the United States has largely been created and led by non-physicians, initially theologians and in more recent years, philosophers. Physicians, scientists, and other health professionals have had only limited involvement in its development. It has been suggested that many bioethicists have a frankly anti-scientific, anti-medicine bias; at the least, they represent interests quite different from those of the medical-scientific community. The proliferation of bioethics teachers and their virtual dominance in the field of teaching ethics to medical students is disturbing. Most of the programmes in BME are taught to medical students in their preclinical years. The courses tend to be theoretical and abstract; for many reasons, including the students' lack of clinical experience and bioethics teachers' lack of medical knowledge, such programmes are oriented more toward policy matters than toward patient-centered issues.

Clinical ethics. In contrast to BME, clinical ethics focuses on issues that confront the physician in his/her daily interactions with patients and is inextricably bound to the physician's central

task; the act of clinical decision. Clinical ethics can be defined as that branch of medical reasoning devoted to the identification, analysis, and resolution of medical-moral concerns that arise regularly between patients and physicians, between physicians, or between physicians and other health professionals. The development of the field of clinical ethics demands the involvement of clinicians. Only clinicians can identify practical problems which non-clinicians may not perceive. Further, only clinicians can understand these medical-moral problems as problems within the context of the clinical situation and not simply as isolated philosophical or ethical discourses unrelated to clinical activity. Therefore, by virtue of their clinical competence, involvement, and responsibility for patients, clinicians must serve as the principal teachers of clinical ethics to clinical medical students.

The distinction I have drawn here between biomedical ethicists and clinical ethicists is one between theoreticians and involved participants. Soren Kierkegaard captured this distinction perfectly in his response to the question: 'Is knowledge changed when it is applied?' Kierkegaard's response crystallizes the distinction I am drawing between non-physician theorists and physicians, or between biomedical ethicists and clinical ethicists:

> 'Let us imagine a pilot, and assume that he has passed every examination with distinction, but that he had not as yet been at sea. Imagine him in a storm; he knows everything he ought to do, but he has not known before how terror grips the seafarer when the stars are lost in the blackness of night; he has not known the sense of impotence that comes when the pilot sees the wheel in his hand become a plaything for the waves; he has not known how the blood rushes into the head when one tries to make calculations at such a moment; in short, he has had no conception of the change that takes place in the knower when he has to apply his knowledge.' (1)

The physician who is a clinical ethicist is never a mere observer. He/she is rather involved professionally in the patient's problem. The clinician ethicist cannot rely on the counterfeit courage of non-combatants. A physician who is a clinical ethicist is therefore in the best position to teach the subject to medical students during their clinical training.

With this distinction between biomedical ethicists and clinical ethicists firmly in mind, five years ago my colleague and I at the University of Chicago set out to design and evaluate a teaching programme in clinical ethics for medical students during their clinical years of training. Let me describe to you some of the assumptions behind our course in clinical ethics and the methods we used to implement them.

Assumptions in Teaching Clinical Ethics

The following assumptions directed the development of our course in clinical ethics.

(1) It is appropriate to teach clinical ethics to medical students, because the practice of medicine itself is a moral enterprise, because technological advances in medicine have increased the range of ethical issues confronting the physician, and because good clinical medicine is ethical medicine, i.e., good clinical medicine involves more than mere technical skill. Plato's reflection on this issue 2,500 years ago can be read in Book IV of The Laws. Here he noted the inadequacy of a cold, sterile, merely technically proper medicine practiced on slaves. He contrasted this with the elegant medicine practiced on freemen which combined technical-scientific knowledge with ethically sensitive, humane, personal care. In regard to slave medicine, Plato wrote:

> A physician who treats a slave never gives him any account of his complaints, nor asks for any; he gives him some empiric injunction with an air of finished knowledge in the brusque fashion of a dictator, and then is off in hot haste to the next ailing slave ... (2)

Plato contrasted this mechanical approach toward slaves with the kind of ethical accommodation achieved between the true physician and freemen:

> (The physician to a freeman) treats his disease by going into things thoroughly from the beginning in a scientific way and takes the patient and his family into confidence. Thus he learns something from the sufferers, and at the same time instructs the invalid to the best of his powers. He does not give prescriptions until he has won the patient's support, and when he has done so, he steadily aims at producing

> complete restoration to health by persuading the sufferer into complete compliance ... (3)

Since the practice of good medicine involves the patient and physician in a mutual effort to help the patient in the cause of health, and since clinical ethics explores this interaction, we believe our first assumption is correct: viz., it is appropriate, perhaps essential, to teach clinical ethics to medical students in their clinical years of training.

(2) If teaching programmes in clinical ethics are to succeed with busy medical students, these programmes must be integrated into the medical curriculum in such a way that they are explicitly related to what Dr. Pellegrino describes as the physician's central enterprise: the act of clinical decision aimed at providing optimal health care for patients. (4)

(3) Given the constraints of our first two assumptions, it is imperative that clinical ethics teachers specify and delimit their objectives. Here are some of the objectives that have evolved out of our own five years of experience in teaching clinical ethics.

(a) It is not our objective to teach medical students to be ethical. To do so would be not only unfeasible but also unethical.

(b) To sensitize students to value questions which arise frequently - I am tempted to say, invariably - in clinical situations and to their relevance in clinical ethical decision-making.

(c) To alert students to the importance of making justifiable decisions - not simply intuitive judgements - in situations that may have several possible resolutions.

(d) To demonstrate that in the face of medical uncertainty, there is rarely a single, uniquely correct decision either in clinical ethics or in clinical medicine. However, in ethical as well as in clinical decisions, some decisions are better than others. In fact, some decisions are simply wrong, and, in medicine, that sometimes means, 'dead wrong'. The rightness or wrongness of a decision - clinical or ethical - has little to do with the sincerity of the decision-maker;

one can be both sincere and wrong.

(e) To treat explicitly several common clinical-ethical issues: e.g., the management of terminal illness, decisions regarding whether or not to do cardiopulmonary resuscitation, obligations to care for comatose and senile patients, truth-telling and confidentiality in medical practice, disagreements between physicians and patients in both elective and emergency situations, and the effect of external factors on the physician's care of the individual patient.

(f) To overcome an almost universal belief among physicians that all ethical dilemmas can be solved by recourse to the law.

(g) Finally, to make students aware of the wide range of values, attitudes, and opinions among everyone involved in health care.

Methods Employed in a Course of Clinical Ethics

We arrange a one-month programme in clinical ethics for third-year medical students to run concurrently with a one-month rotation on the acute care General Internal Medicine Unit, the students' most intense medical experience. The ten medical students assigned to the General Internal Medicine Unit participate in each one-month cycle of the clinical ethics programme. During the month clinical ethics classes meet three times a week in a conference room adjacent to the medical unit for one and one-half hour sessions. In the course of a month we have approximately 12-14 separate class meetings.

Our programme is designed to be interdisciplinary. Faculty and students are drawn from many health-related disciplines in additional to clinical medicine: nursing, hospital social service, hospital chaplaincy, legal affairs, and occasionally, theology or philosophy. The majority of students are medical students, because the programme is weighted heavily towards clinical medicine. The principal faculty member is a physician, a factor we believe to be crucial to the success of any programme in clinical ethics.

The cases on which we focus for discussion arise directly from the clinical experiences of the third-year medical students. The cases presented are real, actively evolving, and 'alive' in at least two senses:

(1) The patients are not dead! We have learned from experience that discussions concerning patients who have died differ in tone, in demeanor, but most importantly, in the decision the students say they would have made in contrast to the discussion involving live patients.

(2) The cases themselves are 'alive' in the obvious sense that the issues are both pressing and of immediate concern to the medical service and to the student. Our classes don't work well when the case presented is hypothetical or describes either a dilemma which has been resolved or a patient who has been discharged.

Our classes proceed as follows: a medical student is asked to prepare a case for the next class meeting. Students elect any case from among the cases they are currently following in the hospital. Adhering to the highest standards of medical case presentation, the student presents the case to the clinical ethics class. At the conclusion of the clinical details of the case, the student will explain why this case was chosen for presentation to the ethics class, i.e. what value or ethical issues did the case raise which were of central concern to the medical student or to the medical service. The student is encouraged to describe the ethical concerns and to indicate his/her own feelings about the problem and the way the medical service was currently dealing with it. The discussion then proceeds informally, as medical details are clarified and as other students address the various ethical issues they see to be raised by the case.

After the initial presentation and remarks by the student, other medical students are encouraged to agree or to disagree with the presenter. Students are always urged to justify the positions they articulate and defend. Initially, the faculty help to clarify students' positions and to moderate the discussion. At some point midway through the class one faculty member will structure the class discussion by attempting to place the topic of this case in a broader perspective and by indicating the conceptual, philosophical, and policy issues raised. Students are then urged to explore the affective, conceptual, and philosophical implications of their respective positions on this clinical matter.

The discussion never strays very far from the immediacy of the case presented; it invariably ends with an assessment of whether or not we were successful in resolving the clinical-ethical dilemma to our satisfaction - and if not, how we might be

able to achieve such resolution: e.g., by seeking a medical consultation, by learning more about patient's wishes in the matter, by more detailed conversations with the family or with the physicians, etc. The student who presented the case is urged to report our class's conclusions to the medical service caring for the patient and to report to the class at our next meeting on whether or not the service agreed with our conclusion and what action, if any, was taken as a result of our deliberations. Our course is not intended to fulfill a consultative function, but we are often surprised at how a medical service will welcome and sometimes act upon suggestions which have emerged from our classroom discussions.

By the end of a month's cycle, each medical student will have presented one or two cases to the class and will have participated in the discussion of twelve different cases. Although we have no formal curriculum for the programme, we do make an effort to deal with cases relating to at least four different kinds of questions during each one-month cycle. These are: (1) confidentiality and truth-telling in clinical medicine; (2) decision-making and patient-physician conflicts; (3) issues relating to the prolongation of life (including decisions not to resuscitate patients); and (4) the allocation of limited clinical resources, such as physicians' and nurses' time, intensive-care unit beds, blood transfusions, and CT scanning.

We do not assign much reading in this course. Initially, we attempted to direct students to a small portion of the medical ethics literature (especially that appearing with increasing frequency in standard medical journals such as The New England Journal of Medicine and The Annals of Internal Medicine) when we could find literature clearly directed to the issues being discussed. After four years, however, we have discovered that there is surprisingly little relevant literature in clinical ethics that is useful to medical students or physicians. As a result of that discovery, and at the urging of some members of the American Board of Internal Medicine and the National Board of Medical Examiners, two co-authors and I are now completing a book which will be entitled A Physician's Guide to Clinical Ethics. (5) This short volume - and I promise it will be short - will be extremely practical and is addressed to clinicians and medical students who encounter ethical problems in their daily care of patients.

Evaluation of the Clinical Ethics Programme

Many schools have established courses and seminars in ethics for students in professions concerned with health care, e.g., medicine, nursing, social work, and others. Although more than 90% of American medical schools have some form of instruction in clinical ethics, none has developed techniques for evaluating the efficiency and effectiveness of these new and rapidly expanding teaching programmes. If developed and disseminated, such techniques would assist other institutions in improving their teaching techniques in ethics and in evaluating the effectiveness of their programmes. From the outset we have been deeply committed to creating evaluation methodologies to determine the effectiveness of our efforts in developing the curriculum in clinical ethics. Early in the preparation of our course, we attempted to design a comprehensive evaluation scheme to determine the success or failure in achieving our varied programme goals. We tried several approaches in developing this scheme.

A skilled participant-observer was employed who prepared a daily log of classroom discussions, including a description of the clinical case, an analysis of the ethical considerations raised by the case, comments on the direction and quality of the classroom discussion, and the observer's conclusions concerning the adequacy of the teaching methods and the results of that particular classroom session.

The participant-observer also collected attendance data. This was particularly revealing. In the first semester in which we taught the course, our attendance hovered around 60%. Since then, for the past four years, we have maintained an average attendance of over 90%. The initial attendance of 60% might be explained by the faculty's inexperience and frankly, our relative incompetence at our task. It also indicates that clinical medical students can always find perfectly reasonable excuses to absent themselves from classes which they consider neither useful nor helpful. Thus, I am gratified that in recent years our programme has been very well received and well attended by busy medical students.

We have also accumulated data on the kinds and frequency of issues raised in the clinical ethics forum on a General Internal Medicine Unit. I will be organizing that material for publication in the next few months.

We undertook several more ambitious evaluation efforts. These included developing a test instrument for clinical-ethical cases, which was designed to assess students' clinical decision-making. I do not have time today to describe this process in detail. All students entering a junior medicine clerkship were given a pre-test on clinical-ethical problems, and all students were given a post-test at the end of the quarter. Our control group consisted of 25% of the class who took their medicine clerkship at a hospital other than the University of Chicago, and who therefore did not participate in the clinical-ethics programme. All students were required to answer clinical-ethical questions which had two components. First, the students were asked to make a decision that involved certain ethical or value choices. Second, the students were asked to provide reasons to justify their decisions. A scoring procedure was developed that could be taught to scorers who were not involved in the course and who were not physicians or medical students. We obtained consistency from two independent scorers. Some of our preliminary results from these studies using clinical-ethical cases are:

(1) The students in the University of Chicago group who took the clinical ethics course were simply more likely to answer the questions. 25% of the control group did not write any answers to these difficult ethical questions. None of the students who participated in the course failed to write an answer.

(2) A comparison of the average scores of the University of Chicago and control groups showed a significantly higher mean score for the University of Chicago group.

(3) There was considerable variation in both groups as to type and quality of answer.

(4) The University of Chicago students' higher mean score was due largely to the fact that they provided multiple reasons to justify a particular decision, rather than giving only single and often medical reasons, as in the control group.

(5) Students were quite consistent regarding the types of reasons they gave for their decisions in a variety of clinical-ethical cases.

(6) After participation in this course, medical students more frequently included specifically moral considerations (e.g., truthfulness, promise-keeping, patient autonomy) rather than only medical factors (e.g., prognosis) in reasoning about cases.

Conclusion

I have described a programme in clinical ethics which has provided instruction in ethics to five years' of clinical students and which has been well received and well atended by these busy students. Nevertheless, I remain unsatisfied and regard our programme in clinical ethics as just a beginning of a more general effort in medical education.

In order to be complete, clinical ethics should be taught in all clinical departments, not just in the Department of Medicine. Teaching should include regularly scheduled clinical ethics rounds for students and house-staff, departmental grand rounds (in each clinical department) devoted once or twice each quarter to issues in clinical ethics, and ad hoc clinical ethics conferences which may be convened to discuss those pressing issues that may arise at any time in the clinical setting.

Clinical ethics will survive only if it can convince physicians and teachers of its value in patient care and accordingly be incorporated into the routine rounding practices of physicians. Elsewhere (6) I have considered the advantages of teaching clinical ethics at the bedside: dealing with actual cases in order to maximize the physician's personal accountability for decisions, involving the entire health-care team in these matters, decreasing the resistance of some in the medical profession to these issues and reinforcing the inseparable relationship between technical and ethical decisions. Several years ago, the great Spanish physician-humanist, P. Lain-Entralgo wrote concerning this last issue: 'The doctor's friendship for the patient should consist above all in a desire to give effective technical help ... benevolence conceived and realized in technical terms.' (7)

If this situation were to develop, ethical and biomedical ethics might be regarded as humanistic disciplines basic to the practice of clinical ethics. Clinical ethics, the applied skill, would be taught at the bedside, in the Oslerian tradition of clinican education, and the instruction would be done by clinician-teachers. The beneficiaries of this system would be our students and, even more importantly, our patients.

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Resumen

El autor describe el programa desarrollado en la Universidad de Chicago que tiene por fin el adiestramiento ético de los estudiantes a nivel clínico.

La ética biomédica trata del análisis y la formulación de las opciones públicas generales en la esfera de la medicina y la ciencia, como por ejemplo, los problemas del aborto, la distribución equitativa de los recursos de salud y la preocupación de la sociedad por la protección de los seres humanos sujetos a investigación médica. En los Estados Unidos, el interés por la ética biomédica ha sido cultivado principalmente por personas ajenas a la medicina, inicialmente teólogos y más recientemente filósofos. Muchos bioeticistas muestran una tendencia francamente anti-científica y antimédica, y la proliferación de maestros de bioética y su predominio en la enseñanza de la ética para los

estudiantes de medicina suscita inquietudes. Los cursos que ofrecen tienden a ser teóricos y abstractos y sus programas están más orientados hacia asuntos de política general que hacia los problemas que se plantean en relación con los pacientes.

En contraste con la ética biomédica, la ética clínica aborda los problemas que el médico debe resolver en su interacción diaria con los pacientes y está inseparablemente ligada a la labor central de los médicos; a saber, el acto de la decisión clínica.

El desarrollo y la enseñanza de la ética clínica requieren la participación de los clínicos. Unicamente ellos pueden identificar los problemas prácticos que quienes no son clínicos ni siquiera perciben.

La diferencia entre los eticistas biomédicos y los eticistas clínicos es la misma que existe entre los teóricos y los prácticos.

El eticista clínico, si es médico, nunca corre el riesgo de convertirse en un mero observador, puesto que está inmerso profesionalmente en los problemas de los pacientes y, por consiguiente, está en la mejor posición para enseñar la materia a los estudiantes de medicina durante su adiestramiento clínico.

Sobre la base de esta distinción entre el eticista biomédico y el eticista clínico, firmemente establecida, hace 5 años se fundó en la Universidad de Chicago un programa de ética clínica destinado a la formación de los estudiantes de medicina durante los años de sus estudios clínicos.

El autor describe algunos de los objetivos del curso y los métodos usados para alcanzarlos. Las principales premisas son las siguientes:

1. Es apropiado enseñar ética clínica a los estudiantes de medicina.

2. Para que los programas de ética clínica sean eficaces, deben estar integrados en el plan de estudios de medicina, de tal manera que estén explícitamente relacionados con el acto de decisión clínica y orientados a mejorar la atención de salud para los pacientes.

3. Es imperativo que los profesores de ética clínica especifiquen y delimiten sus objetivos. En los últimos 5 años se han identificado, entre otros, los siguientes:

1. El primero es un objetivo negativo: no se trata de hacer del estudiante de medicina un eticista, lo que no solamente sería irrealizable sino también antiético.

Los demás objetivos son positivos y consisten en:

2. Sensibilizar a los estudiantes a las cuestiones de valores, que frecuentemente se plantean en situaciones clínicas.

3. Hacer comprender al estudiante la importancia de adoptar decisiones justificables.

4. Demostrar que, dado el margen de incertidumbre inherente a la medicina, rara vez existe una sola decisión correcta, tanto en ética clínica como en medicina clínica. Sin embargo, en ambas esferas algunas decisiones son mejores que otras.

5. Tratar explícitamente algunos problemas clínico-éticos comunes.

6. Corregir la tendencia casi universal entre los médicos a creer que los dilemas éticos pueden resolverse recurriendo a la legislación.

7. Finalmente, familiarizar al estudiante con la gran diversidad de valores, aptitudes y opiniones que guardan relación con el cuidado de la salud.

La enseñanza se basa en un programa de clínica ética para los estudiantes del tercer año de medicina, de un mes de duración total, que se distribuye en tres sesiones de hora y media por semana y se imparte en una sala de conferencias contigua a la unidad médica. El programa está diseñado con un criterio interdisciplinario.

Los casos que se discuten se originan directamente de la experiencia clínica de los estudiantes; son casos reales que se están desarrollando activamente y están vivos en por lo menos dos sentidos:

1. Los pacientes no están muertos.

2. Los asuntos son urgentes y de importancia inmediata para el servicio médico y para el estudiante.

En el transcurso de la clase, un estudiante presenta un caso preparado previamente. Después de exponer los detalles clínicos, el ponente debe explicar la razón de la selección del caso para su presentación en la clase de ética. La discusión se desarrolla espontáneamente; a medida que se puntualizan los detalles médicos, los estudiantes exploran los puntos éticos que se van identificando.

La discusión nunca debe alejarse demasiado del caso presentado, e invariablemente termina con una valoración de la solución de los dilemas éticos clínicos encontrada, y, si no se les encontró solución, con una exposición de la manera en que se hubiera podido hallarla. El estudiante que presenta el caso debe comunicar las conclusiones a que se llegó en clase al servicio médico bajo cuyo cuidado se encuentra el paciente, y debe comunicar a la clase, en la siguiente ocasión, si el servicio aceptó o no esa conclusión, y qué acción fue emprendida como resultado de las deliberaciones.

A pesar de que no existe un plan oficial para el programa, se procura discutir casos que se relacionen por lo menos con cuatro diferentes tipos de cuestiones durante cada mes; a saber:

1. Confidencialidad y veracidad en la medicina clínica.
2. Conflictos respecto a la toma de decisiones y a la relación médico-paciente.
3. Temas relacionados con la prolongación de la vida, incluyendo decisiones de no reanimar a los pacientes.
4. Distribución de los recursos clínicos limitados, como por ejemplo el tiempo de las enfermeras y de los médicos, las camas en las unidades de cuidados intensivos, las transfusiones sanguíneas y otros medios.

Un aspecto importante es la evaluación del propio programa de ética clínica. Muchas escuelas han organizado cursos y seminarios de ética, pero ninguna ha establecido una técnica para evaluar la eficacia y la eficiencia de estos programas nuevos y en rápida expansión.

En la preparación de los cursos, se intentó desde el comienzo diseñar un procedimiento de evaluación para determinar el éxito o el fracaso respecto de las diversas metas fijadas. Se intentaron varios enfoques; por ejemplo, la designación de un observador entre los participantes encargado de preparar un

resumen diario de las discusiones de la clase y de los resultados de cada sesión en particular. El participante-observador tomaba nota asimismo de la asistencia. Los datos recogidos sobre asistencia fueron muy reveladores, ya que en el primer semestre en que se dió el curso el promedio de asistencia fue de cerca de un 50%, en tanto que en los últimos 4 años se ha mantenido un promedio de asistencia de más del 90%.

También se intentaron evaluaciones más ambiciosas, incluido el diseño de un instrumento para verificar la capacidad de los estudiantes en la toma de decisiones clínicas. Se ideó además un procedimiento de calificación que podía ser aplicado por personas que no hubiesen participado en el curso y que no fueran médicos ni estudiantes de medicina.

Algunos de los resultados preliminares de estos estudios mostraron que los cursos eran útiles. El dato más revelador era el hecho de que los estudiantes de medicina que habían participado en estos cursos incluían más frecuentemente aspectos morales en la discusión y presentación de sus casos clínicos.

CRUCIAL POINTS OF ETHICAL CONCERN IN PSYCHIATRY

Peter Berner *

Introduction

The subject of medical ethics is primarily to find a reply to the question as to how general ethical principles can be reformulated to relate to the special problems connected with medical practice. This should be followed by an investigation into methods likely to provide the physician engaged in treatment, research or teaching, with practical guidelines, enabling him to deal with the actual problems confronting him in his work. Such problems are most prominent in the personal encounter between physician and patient.

During past centuries, philosophers as well as physicians had repeatedly attempted to construct an ethical framework for this encounter and these attempts resulted in the formulation of oaths and resolutions, the most prominent of which became the Oath of Hippocrates. Up to very recent times, it was generally accepted that, in accordance with a 'Confucian-like' virtue automatically ascribed to members of the medical profession, all stipulations of that oath would undisputably be complied with. Two sets of circumstances have finally led to a reassessment of the situation with regard to the ethical problems inherent in medical practice. The immaculate virtue, supposedly inherent in every member of the medical profession, became a matter of speculation and doubt. Whether this resulted from an actual deterioration of moral behaviour, or from a loss of naivity on the part of the general public, can be left to conjecture. Therefore, changes in value systems as well as rapid new developments in treatment methods, must be held responsible for raising entirely new and complex problems in medical ethics.

For these reasons, the previously generally accepted ethical framework within which the physician-patient encounter took place has become inadequate, and it is imperative that it should be newly formulated in a joint effort by philosophers, physicians, theologists, social scientists and lawyers. It would be advisable to base such efforts on the old and accepted ethical rules, requiring non-maleficience, maximal benefit for the

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* In the absence of Professor Berner, this paper was presented by Dr. A. Escobar Izquierdo.

patient, confidentiality, justice and equality of treatment, veracity and respect for the patient's autonomy.

In the following, the various aspects of these principles with specific regard to the medical discipline of psychiatry will be discussed and investigated from the viewpoint of both the physician-patient encounter and the considerably increased specific and complex problems connected with new treatment and research methods.

Non-maleficience and Maximal Benefit

In psychiatry today, this problem becomes accute, above all in the choice of the treatment strategy and in the scientific evaluation of new treatment methods.

Choice of treatment strategy. Ethical deliberations in this respect are frequently swayed more by prejudice than by an exact risk/benefit analysis. Drug therapy, for instance, is often considered as being more dangerous than psychotherapy - hospital care, as being more risky, in the long run, than extramural facilities. Quite apart from the fact that in the case of certain disturbances, such as endogenous depression, where medication, or even ECT, has proved extremely efficacious, while psychotherapeutic treatment does not achieve satisfactory results, thus increasing the risk ratio (i.e., attempts at suicide), attention should here be paid to a statement by Blomquist (1) which asserts:

> 'Years ago we spoke of hospitalization as a risk with the old custodial type of hospital care. The patients got used to the hospital world and became unable to live outside its walls. This risk has returned in a quite different setting today. Milieu therapy, therapeutic communities, modern, lavishly fitted out hospitals, together with today's tendency to take away all responsibility from people, create the same problem as did the old authoritarian care and psychotherapy and psychoanalysis tend to be more addictional than most drugs.'

Medical ethics should therefore be primarily concerned with compiling, for standard therapeutic strategies, clear and easily understandable data on risk/benefit ratios, in order that this information might be made available to students, physicians, paramedical personnel and, in addition, to the general public.

Wherever such data are not available at present, they should be scientifically researched. This need, however, leads us to the follow-up problem connected with such research.

Testing the efficacy of treatment methods. As already demonstrated in detail by Helmchen and Müller-Örlinghausen [2], clinical trials in psychiatry today are characterized by the following, inherent paradox:

> 'First, it is unethical to use treatment, the efficacy of which has not been examined scientifically; second it is also unethical to examine the efficacy of treatment scientifically.'

Whereas the first part of this statement is relatively easily understood, the second demands detailed explanation: scientific examination of efficacy means to eliminate unspecific influences during the trial by suitable methods, especially by randomization and blind-technique. A distortion of randomization might however occur, when ethical considerations lead to the exclusion from the trial of certain groups of patients. If, for instance, within the framework of a study on a new anti-depressant suicidal patients were excluded, this measure may lead, in consequence, to a neglect of severe depressions, so that a critical evaluation of the efficacy of the drug in severely depressed cases becomes impossible. In consideration of this dilemma, Wing [3] points out that the question as to how far a risk, entered into in the case of one individual patient, should be accepted, in anticipation of the benefit to a great number of patients yet to be treated, should be left to the physician dealing with the individual case:

> 'No matter what society thinks about the necessity or otherwise for clinical trials, the freedom of individual clinicians to decide whether or not to allow his own patients to be included in a trial, must be preserved.'

In spite of the view hereby defended, the problem as to how to provide each individual case with the best available treatment, while at the same time attaining a clear, controlled trial situation, has not yet been solved.

Confidentiality

Psychiatrists, much more frequently than is the case in other medical disciplines, are confronted, directly or indirectly, by their patients, with fact which might endanger the patient's own person, or his surroundings. Whenever there exists the slightest doubt as to whether the psychiatrist can depend upon the prescribed medication or upon his own personal influence on the patient to retain control of this imminent danger, the complex question as to whether it remains within his rights, or indeed within his ethical responsibility, to waive the principle of confidentiality in favour of the patient's own safety, or that of the community he is a part of, will assume eminent importance. Whereas in the eventuality of danger to the patient by himself, divergent views may be taken (we shall return to this question when treating the subject of patient's autonomy). My opinion, which is shared by many colleagues, is that the psychiatrist is confronted with the absolute obligation to take action whenever danger to others appears evident and imminent. In this connection we draw attention to paranoic patients who are liable to attack an imagined pursuer, or to patients led by the delusion of their life-partner's unfaithfulness to entertaining homicidal thoughts. We are of the opinion that the involvement of third parties (such as official authorities able to arrange for involuntary confinement), should only be undertaken in observance of the principle of absolute veracity, meaning that the patient is fully informed of the steps about to be instigated and has been provided with the reasons for that decision. Such action, of course, has frequently to be accompanied by a number of complicated supporting measures, because the announcement of the physician's renunciation of the principle of confidentiality is likely to trigger the patient's immediate acting out of the intention forced upon him by his delusion, before he can be prevented from so doing.

However, the question raised by this example namely, whether certain circumstances justify a relaxation of confidentiality in the interests of the patient, or other persons or of society at large, cannot be answered without reference to the ethical considerations inherent in the specific situation.

The matter of confidentiality in the so-called 'double-agent' problem raised by Frazier [4], will have to be considered from another viewpoint entirely. In such cases, the confidence is of the kind passed by the patient to the forensic psychiatrist,

the prison psychiatrist, or perhaps to the psychiatric evaluator employed by insurance companies and other agencies. The ethical guidelines for these branches of psychiatric activity which touch upon the problem of who the psychiatrist in question identifies himself with - the patient, the state, the authority of the employing agency, etc. - have not even roughly been dealt with, whereas abuse of confidentiality for political reasons or for the personal advantage of the physician attending the case, has undisputably been classified as a violation of the principles of medical ethics.

A very critical problem concerning the principle of confidentiality is posed by the partner-, family-, or group-therapy sessions universally carried out today, because even though the physician in charge of the group is bound by the confidentiality principle, the remaining participants are not obliged to adhere to it. It should be an absolute obligation for the psychiatrist involved in such therapeutic techniques to draw the attention of all participants to this extremely important fact.

One more aspect, frequently not given the necessary consideration, but particularly relevant in the medical discipline of psychiatry, is the demand that cases dealt with in scientific publications are not described in a manner which enables identification of the individual patient.

Justice and Equal Treatment

The right to sound mental health as well as to universally equal quality of treatment is an ideal, the demand for which has only recently become an ethical requirement. Since the implementation of this demand depends to a very great extent upon economic resources, its fulfilment on an international level varies considerably. Certain priorities within the public health systems, which frequently do not devote the necessary attention to mental disturbances or refrain from offering to the general public treatment facilities which are likely to prove expensive, must be held responsible for this circumstance. It is customary, for instance, that financially affluent patients are given the benefit of individual psychotherapy, while less well-endowed cases are treated with behaviour therapy which is more frequently funded by social security services, although that circumstance might even be an advantage for the persons benefitting from such discrimination (1). On the other hand,

the poorer patient's psychogenic disturbance will generally be treated by medication, instead of by the time-consuming behaviour or psychotherapy methods reserved for his prosperous counterpart. Although these problems concern above all the national governments or health authorities of a given area, the demand for equal quality of treatment will not be adequately fulfilled simply by the provision of a financial basis enabling the poorer members of the population to benefit from all treatment methods available today. It would be of equal importance to address an ethical appeal to individual psychiatrists, not to remain in developed countries or cities which represent an appealing location, but to venture into the underdeveloped countries, or into the rural areas of the developed ones, which frequently lack adequate psychiatric facilities; or to refrain from clinging to the financially gratifying private practice and to accept, at least for part of their professional activity, the treatment of cases within institutions which serve the poorer sections of the population.

Veracity

The problem of veracity in psychiatry is essentially the same as in other medical disciplines and it is characterized by a lack of recommendations as to how much of the truth, with regard to diagnosis and prognosis of his ailment, the patient should be confronted with.

The Jewish physician Amatus, who asserted that to lie to a patient would bring upon himself the wrath of God and his angel Gabriel, was one of the few ancient professionals who provided an opinion on this subject. Plato, however, stated that the lies a physician needs to resort to are to be forgiven, since they are spoken in consideration of the patient's welfare. These two strictly divergent opinions show that the problem of veracity remains situation dependent in its ethical aspects and that all medical disciplines are similarly confronted by it.

The questions that have been raised concerning this subject during the last century find their source in the diminishing confidence the general public bears towards the members of the medical profession. Increased and easily available information on the risks connected with incorrect diagnosis, prognosis and treatment, have also served to raise the veracity problem to a much more prominent level within the subject of medical ethics. It has reached even more topicality with the introduction of the 'examination and treatment consent' which stipulates that

infringing methods of examination and treatment may not be employed by the physician unless the patient has supplied his 'informed consent'. Here again, it is necessary to point out that full information is an ideal demand which can only be approximately complied with, mainly because as Wing stated:

> 'It is difficult enough to gauge how far the patient can understand the advantages or disadvantages of the available alternatives exposed by the clinician.' (3)

This is a question which, especially in psychiatry, can become most problematic, since the patient's judgement is likely to be impaired by the disturbance he is suffering from. It could, on the contrary, be absolutely 'unethical' to inform the patient in detail of the risks inherent in some special treatment, which however promises decisive improvement, because this may result in flat refusal (i.e., refusal of antidepressive medication because of the possibility of agranulocytosis, as a result of which the patient remains in a state of high suicidal risk). We shall touch this problem again when discussing the matter of patient autonomy.

In the case of patient consent to therapeutical trial, psychiatry once more faces a paradoxical situation, as it is unethical to perform the therapeutic trial without informed consent, but equally unethical to perform it when such consent has been provided. (2) Here again, the first statement is easily understandable whereas the second has to be explained in detail, which Helmchen and Müller Örlinghausen have done as follows:

> 'Little is known about the influence of fully or partially informing the patient on the validity of blind trials. 'Full information' includes not only information of the expected effects and risks of the drug to be tested, but also the fact that the patient will be subjected to an experiment which is based on randomization and the blind technique. A serious problem can arise if the reference drug in a double-blind trial is a placebo, since many patients might refuse to consent to the trial. In addition, those patients who do consent to the trial represent a biased sample, and the results obtained from them will not be representative of the entire group of patients with the particular illness under investigation, but only of those patients who will consent to a

> therapeutic trial. As long as the influence of the information remains obscure and its scientific relevance doubtful, fully informing the patient may be of doubtful importance from an ethical point of view. Here it is to be noted that ever since the first edition of Martini's Methodology in 1947, it has been regarded as a necessary prerequisite to a controlled therapeutic trial that the patient be unaware of the experimental character of that therapy.' (2)

These authors have further raised the question as to whether it might not be more justified to burden the investigator with the responsibility for the risk inherent in any trial, than to obtain the 'informed consent' of the patient. A too legalistic and bureaucratic approach to the 'informed consent problem' may lead to a loss of interest on the part of the physician engaged in research on new therapeutic methods on one hand, and reluctance on the part of certain patients to participate in such a trial on the other, which would invariably lead to a selective process resulting in a distortion of the results. Both these possibilities might have the very 'unethical' effect of slowing down, if not completely arresting, the development of promising new treatment methods.

Autonomy

Psychiatry is confronted with the problems connected with this ethical demand in two different ways, depending upon whether the administrated treatment is applied on a voluntary or involuntary basis.

Problems arising in voluntary treatment. Value fidelity already enters the picture when the first decision as to the most suitable method of treatment has to be reached. Should a somatic therapy method)i.e., medication, ECT, or neurosurgery) be advocated, or a therapeutic programme, efficient only through psychological influences)i.e., psychotherapy, behaviour therapy), be recommended? The psychiatrist in charge of a case and deliberating upon such a range of therapeutic methods is already exposed, even before treatment begins, to an ethical conflict. Is he justified in influencing a patient to accept exactly the type of treatment he considers of greatest value for the patient's welfare, or would it be more 'ethical' to expose the possibilities and leave the patient free to make his own choice. Those individuals, expecting advice from the physician, would undoubtedly be frustrated by the difficulties they are obliged to face in reaching a well-founded decision.

Some of them may even make this decision in accordance with inappropriate information, previously gathered from various agencies such as newspapers, magazines, political or ideological trends, or even circulating rumours. With regard to the method of revealing psychotherapy, which is fashionable at present and in many places is considered the only effective and ethically justifiable method of treatment for mental disturbances, Blomquist (1) deliberated upon the following considerations:

> 'Insight and knowledge are surely values but sometimes they can be reached only at the cost of happiness, health or even life and sometimes other procedures - drugs, behaviour modification, surgery, etc. - give faster and cheaper relief from suffering. Is then insight therapy always better than other therapies and if so, better to whom?'

Even in cases in which psychotherapy is the only psychiatrically indicated choice of treatment, this method in itself if not without serious ethical implications because it deals inevitably with values and because the patient more or less identifies himself with the person applying this kind of treatment. This fact could enable the latter - either at will, or without realizing it - to influence the patient and to sway his attitudes and opinions. This danger is accentuated by the change of style in today's practice of psychotherapy. During the time of development and first broad application of classic psychotherapy, it was unthinkable for the therapist to offer his personal opinions to the patient during treatment. That attitude, however, has suffered considerable changes during the last ten years, as Blomquist (1) has vividly described:

> 'Large groups of doctors and others have come to see it a duty for the therapist to preach and try to convert their patients to certain political or religious belief systems. And certainly a strong case can be made for this view. But how can I know that my faith serves the common good? If we stick to the old view and try to avoid that political and religious ideologies influence the therapy, there will still remain value conflicts. What ought to be the highest value for psychiatric work: life, health, autonomy, self-knowledge or what?'

Ethical evaluation of the varied types of therapeutic method- at the disposal of psychiatry today, therefore, will largely depend on a satisfactory reply to all these questions.

Involuntary treatment. The most spectacular and certainly the gravest ethical problems become acute whenever it appears necessary to initiate measures resulting in involuntary detention of a patient within a psychiatric institution. How far is it 'ethical' to respect a patient's autonomy? Is he within his ethical rights if he demands to live his own life, even if in so doing, he becomes a danger to himself or to the community? Is danger to himself - especially inclination to end his own life - an act that should be respected by his fellow men and is it therefore only the existence of danger to others that justifies a precautionary detention? Does the abuse of nicotine, or the disagreement or non-compliance with a political ideology sanctioned and advanced by the pertinent national authorities, already fall into one of these two categories? And even if the matter of involuntary confinement has been considered as justified because the fact of an existing danger to the patient himself or to the community has been proven beyond doubt, will it be ethical under such circumstances to apply treatment without the patient's consent?

The supposition that involuntary confinement is permissible under the preposition of self-destruction or attack upon others, but not justifying the application of treatment without the patient's consent, is undoubtedly not as yet universally accepted. Enforced treatment is generally considered justified when the lack of it constitutes a danger to the patient's life. This will be the case especially when an 'illness', in the narrowest sense, has been diagnosed. With this statement, however, we have already touched upon a subject which represents the second question complex with regard to involuntary confinement.

Which states may be considered as 'mental illness' and when do they justifiably imply loss of patient autonomy? What, in particular, are the rights that the patient stands to lose under such circumstances; which of his rights as a human being does he retain, and what new rights must be attributed to him in view of his changed personal situation? Who, moreover, is to accept responsibility for the maintenance of the rights he is entitled to, in view of such loss of autonomy? Should it be the state, the relatives, or the physician, and so on.

These problems also require a solution in cases where 'illness', in the factual sense of the word, does not apply. For instance in the enforced treatment of juveniles, not necessary suffering from mental illness in the narrowest sense, whereby it will have to be decided from which point the juvenile is to be considered able to exercise autonomy. The question of abortion or genetic engineering also belongs in this context and poses problems for all fields of the medical profession.

Conclusion

We have attempted to provide an overview of the most relevant ethical problems with which medicine, and especially psychiatry, finds itself confronted today. It has not been possible to achieve more than a listing of requirements, since the formulation of the reply these questions call for will constitute an important task for the future. In view of the appearance of ever more topical problems, and the shifts and changes in the old and seemingly firmly established scale of values, the accomplishment of this task should perhaps be attempted along the following guidelines:

In cooperation with members of all medical disciplines, with theologists, social scientists and jurists, a new framework for ethical considerations within the medical discipline of psychiatry should be formulated. The regulations constituting the basis for this structure should be made known to the general public and they should be fully taken into account in student lecture and post-graduate training courses, so that the practising psychiatrist can draw upon the knowledge so gained when confronted with decisions involving ethical aspects. It will never be possible to provide more than the aforementioned framework for the ethical encounter between patient and physician, because - and here most authors find themselves in agreement - every individual case will eventually call for decisions that arise out of the pertinent situation itself. But whether the decision finally arrived at by the psychiatrist faced with such a situation will be an 'ethical' one in the best sense of the word will depend upon the training he has received and the efficacy of the framework that has been constructed.

An innovation, and perhaps one of considerable assistance in the reaching of concrete decisions in this respect, might be the involvement of 'peer-committees', the participants of which should be endowed with the necessary psychiatric training and experience.

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Resumen

El objeto de la ética médica es encontrar solución al problema de formular los principios éticos generales de manera que guarden relación con los problemas especiales de la práctica médica. Esto se intenta lograr investigando métodos y, en algunos casos, ofreciendo al médico en ejercicio o dedicado a la investigación o la enseñanza pautas éticas que le ayuden a resolver sus problemas cotidianos de índole profesional.

En el pasado, filósofos y médicos trataron de elaborar un marco ético, en forma de juramentos y resoluciones, siendo el más prominente de ellos el juramento hipocrático. Hasta hace poco se aceptaba generalmente que se cumplían todas las estipulaciones de ese juramento, cosa que no ocurre ahora.

La conducta intachable, que se suponía inherente a cada miembro de la profesión médica, vino a ser objeto de duda y de controversia. Cabe preguntarse si esta desconfianza surgió como resultado de un deterioro real del comportamiento moral o simplemente de una pérdida de la inocencia por parte del público.

En todo caso, el marco ético aceptado previamente, dentro del cual interactuaban el médico y su paciente, se considera ahora inadecuado y debe ser formulado de nuevo.

Es recomendable basar estos esfuerzos de renovación en las reglas éticas aceptadas desde tiempo atrás, que requieren la

ausencia de daño, el beneficio máximo para el paciente, la confidencialidad, la justicia e igualdad en el tratamiento, la veracidad y el respeto de la autonomía del paciente.

A continuación se examinarán los aspectos de estos principios que se relacionan específicamente con la disciplina médica de la psiquiatría.

Ausencia de daño y beneficio máximo

En psiquiatría actual este problema es particularmente agudo, sobre todo en la estrategia del tratamiento: hospitalaria, convulsivante, medicamentosa, quirúrgica, etc.; así como en la evaluación científica de los nuevos métodos de tratamiento. Al evaluar la eficacia de los métodos de tratamiento se tropieza con una paradoja: es antiético aplicar tratamientos cuya eficacia no haya sido examinada científicamente; y por otra parte, es antiético examinar científicamente la eficacia de los tratamientos.

Mientras que la primera parte de esta paradoja es fácil de entender, la segunda requiere una explicación: la valoración científica de la eficacia obliga a prescindir de toda influencia ajena a la investigación, especialmente mediante estudios al azar y técnicas ciegas; pero las técnicas al azar pueden ser distorsionadas cuando, por consideraciones éticas, se excluye de la prueba a cierto grupo de pacientes.

El problema es grave, ya que se trata de aplicar a cada individuo el mejor tratamiento posible y al mismo tiempo de formular un juicio claro, controlado y científico. Este dilema no se ha podido resolver aún.

Confidencialidad

Sobre la base de la información suministrada por sus pacientes, a veces los psiquiatras descubren hechos que hacen sospechar la existencia de peligros para el propio paciente o para los que lo rodean.

Es muy complejo el problema de si el psiquiatra tiene derecho a violar el principio de la confidencialidad, en aras a la seguridad del paciente o de la comunidad de la que éste forma parte. En mi opinión, el psiquiatra tiene la obligación absoluta de actuar siempre que advierta un peligro inminente, como en el caso de los pacientes paranoicos que pueden atacar a un enemigo imaginario, o de los pacientes que, falsamente persuadidos de la

infidelidad de su cónyuge, pueden albergar intenciones homicidas.

El problema de la confidencialidad respecto al llamado problema del doble agente debe ser considerado desde otro punto de vista. En estos casos, la confidencialidad se refiere a la información suministrada por el paciente al psiquiatra penal, al evaluador psiquiátrico empleado por una compañía de seguros, etc. Las pautas éticas para estas ramas de la actividad psiquiátrica deben señalar a quién ha de considerar el psiquiatra como objeto de su obligación principal, es decir, al paciente, al Estado, a la autoridad de la agencia que lo emplea, etc.

Las sesiones de terapia de grupo plantean un problema crítico respecto al principio de la confidencialidad, ya que, aun cuando el médico está sujeto al principio de la confidencialidad, el resto de los participantes no están obligados por este principio.

No debe olvidarse que los casos que se comentan en las publicaciones científicas no deben describirse de manera que se pueda identificar a los pacientes.

Justicia y tratamiento iguales

El derecho a la salud mental y al tratamiento igualitario para todos es un ideal cuya demanda sólo recientemente ha constituido un requisito ético. La aplicación práctica de este ideal depende de los recursos económicos, que no siempre permiten alcanzarlo. Existen prioridades en los sistemas de salud pública, que frecuentemente no dedican la atención necesaria a los trastornos mentales o no ofrecen al público general facilidades de tratamiento que pueden ser costosas a largo plazo.

Veracidad

El problema de la veracidad en psiquiatría presenta esencialmente los mismos aspectos que en otras disciplinas médicas.

No suele haber bases que permitan determinar qué parte de la verdad respecto al diagnóstico y al pronóstico debe decirse al paciente.

El médico judío Amatus afirmó que el hecho de mentir a un paciente atrae hacia el médico la ira de Dios y de su ángel

Gabriel. Platón, en cambio, señaló que las mentiras de un médico son excusables, puesto que el médico las dice en consideración al bienestar del paciente. Estas dos opiniones, tan divergentes, muestran que el problema de la veracidad, en sus aspectos éticos, depende de la situación en que se plantea.

Respecto a la información que se debe a los pacientes sobre las distintas posibilidades de tratamiento, se ha dicho que es muy difícil determinar hasta qué punto puede evaluar el paciente las ventajas o los inconvenientes de las opciones propuestas por el clínico. En psiquiatría esto es particularmente problemático, ya que el paciente suele tener el juicio más o menos afectado por los trastornos que padece. Por otra parte, podría ser absolutamente antiético informar en detalle al paciente sobre los riesgos inherentes a ciertos tratamientos que por otro lado prometen una mejoría decisiva, porque podría inducírseles a rechazarlos. Un ejemplo de ello es la posibilidad de agranulocitosis causada por los medicamentos antidepresivos, cuyo rechazo puede colocar al paciente en situación de alto riesgo suicida.

Autonomía

La psiquiatría aborda este problema de dos maneras diferentes, según si el tratamiento se aplica al paciente con su voluntad o sin ella. El psiquiatra ha de resolver ya un conflicto ético aun antes de iniciar el tratamiento. ¿Debe influir en el paciente para que éste acepte el tipo de tratamiento que considera de mayor valor, o será más ético simplemente exponerle las posibilidades y dejar que el paciente haga su elección libremente? En el segundo caso, algunos pacientes pueden decidir sobre la base de una información inadecuada, obtenida de varias fuentes como periódicos, revistas, etc.

Respecto a la actitud del psiquiatra en la psicoterapia, el médico se encuentra de nuevo ante una serie de dilemas. Muchos médicos consideran que es deber del terapeuta tratar de modificar ciertas creencias del paciente, incluidas sus creencias políticas o religiosas. No faltan argumentos convincentes en este sentido, pero, ¿cómo se puede tener la certeza de que las creencias del psiquiatra han de servir mejor los intereses de su paciente o el bien común?

El tratamiento impuesto contra la voluntad del paciente plantea los problemas éticos más graves. ¿Hasta qué punto obliga la ética a respetar la autonomía del paciente, cuando éste

exige que se le permita vivir su propia vida aun cuando, al hacerlo, se convierta en un peligro para sí mismo o para la comunidad? Si el peligro es tan sólo para el mismo paciente, especialmente la inclinación al suicidio, ¿debe respetarse su voluntad? Cuando el paciente, por su manera de vivir, representa un peligro para la existencia de otros, ¿está justificada su detención preventiva? ¿Hasta dónde se puede llevar este razonamiento?

El abuso de la nicotina o la oposición a la ideología política sostenida por las autoridades nacionales, ¿deben considerarse peligrosos para el interesado o para la sociedad?

Por otra parte, cuando el confinamiento involuntario se ha considerado justificado, ¿hasta qué punto es ético, en estas circunstancias, aplicar tratamiento sin el consentimiento del paciente?

Conclusión

En cooperación con miembros de todas las disciplinas médicas y con teólogos, especialistas en ciencias sociales y juristas, es preciso formular un nuevo marco para la consideración de las cuestiones éticas dentro de la disciplina médica de la psiquiatría. Las reglamentaciones que constituyan la base de esta estructura deben darse a conocer al público en general y deben ser tomadas en cuenta en la formación de los estudiantes y en los cursos de adiestramiento de post-grado, de manera que el psiquiatra en ejercicio pueda aplicar los conocimientos adquiridos en la materia cuando deba formar decisiones que afecten a la ética.

DISCUSSION - DISCUSION

OPENING COMMENTS - COMENTARIA INICIAL

Rubén Vasconcelos

Es contraria a la ética médica la participación del personal de salud para obligar a alimentarse a un prisionero, mientras la negativa de éste a aceptar alimentos esté fundada en un juicio racional.

En los países donde las leyes mantienen todavía los castigos corporales, las organizaciones médicas deben propugnar la abolición de tales castigos.

El postulado del párrafo 19 es aplicable también al confinamiento en espacios reducidos y a la limitación o privación de alimentos; estas prácticas y la sujeción corporal dentro de la prisión violan claramente los derechos humanos; el personal de salud no podrá justificarlas ni aceptarlas sin faltar a los principios éticos.

Toda forma de interrogatorio compulsivo y la administración de drogas que reduzcan la capacidad de razonar o de ejercer la voluntad están basadas en la inflicción de tortura mental; por ello, toda participación directa o indirecta del personal de salud en estas técnicas es contraria a la ética médica.

El drogadicto es víctima de una sociopatología que incluye el tráfico de drogas. El tratamiento y la rehabilitación de las víctimas de dicha patología incumben al médico, quien debe participar, por lo tanto, en el establecimiento de leyes efectivas y claramente orientadas a la rehabilitación de los enfermos y a la reducción de la patología.

La cirugía en el tratamiento de las anomalías sexuales productoras de conductas antisociales puede ser considerada como una actividad terapéutica útil y ética si en el caso tratado concurren los principios universales de la moral médica de no hacer daño y de respetar en todos los casos la dignidad y la libertad del paciente; dentro de este criterio, es recomendable que las organizaciones médicas insistan en la necesidad de evitar la morbosidad publicitaria, tan frecuente en estos asuntos.

La investigación biomédica no debe aceptar la existencia de diferencias entre un hombre libre y un prisionero en cuanto a la posibilidad o probabilidad de consecuencias iatrógenas de la experimentación. En consecuencia, es contrario a la ética médica el hecho de exponer a riesgos desconocidos a un ser humano, libre o prisionero.

Kimura: I would like to express my thanks for Dr Siegler's provocative presentation. However, in his introductory statement there are some points which I think might cause misleading interpretations of 'biomedical ethics' and its development in the USA. Since my own experience has been so different from his, I would very much appreciate specific references and data which would verify his strong criticism of the BME (Biomedical Ethics Movement).

Although his analysis of bioethics teaching might be applied, I am sure, to some courses, I know that in many cases bioethics courses are taught by interdisciplinary faculty teams, not only by theologians and philosophers, as you mentioned, but also by experienced clinical specialists, including doctors and lawyers. With such teams, courses are not abstract or merely theoretical, but they deal, quite concretely, with actual cases and professional practice. In my own experience I have not found BME leaders and many bioethicists to be at all anti-science or anti-medicine.

Zetterström: In Sweden, medical ethics has been taught in medical schools for about 15 years. A few months ago in the department of pediatrics of the Karolinska Institute in Stockholm we tried to evaluate the knowledge of the students within that particular field. When they are in pediatrics they are in the last year of their curriculum, which means that they have passed most of the undergraduate clinical teaching programme. It has been rather disappointing to find that the knowledge of the students in medical ethics is rather poor. For instance, they have been quite unable to define medical ethics. They have also given rather poor answers to questions about the most important issues in medical ethics. The only one they could list was that research projects involving experiments on human volunteers or patients should be reviewed by ethical committees. But since most of the students were planning to become general practitioners, this particular issue was not really related to their future professional work.

One important question is to find out the reason why our evaluation has given such a poor result. When considering the curriculum of our school we find that medical ethics is taught during the first preclinical year when the students do not yet have any clinical experience or knowledge. According to our experience, medical ethics should be part of the ordinary clinical curriculum. Aspects on ethics should be included in the teaching programme in the various clinical fields such as internal medicine, surgery, psychiatry, obstetrics-gynecology and pediatrics. During their training in pediatrics the students should have to consider the ethical aspects which are of relevance within that field. First of all, they have to learn how to show that they respect the integrity of every child, and that a child also has the right of being informed about diagnostic and therapeutic procedures. It is also obvious that there are a great number of other ethical issues which can be elucidated in connection with the training in pediatrics. Among those are the decision-making in cases of myelo-meningocele and other conditions when a newborn baby is defective, and when to stop intensive care treatment of newborn infants with severe brain damage following perinatal asphyxia. A discussion on the issue of who has to decide what sex should be given to a newborn child with ambiguous genitals gives rise to a number of aspects. Other issues with many ethical facets are artificial insemination and prenatal diagnostic procedures.

In summary, I completely agree with the statement made by Dr Siegler that medical ethics should be part of the ordinary clinical teaching. According to our experience the students tend to show a great interest in questions related to medical ethics, if they are introduced to them in connection with relevant clinical cases. It is, however, quite obvious that the Swedish medical students do not have a background that enables them to understand the more philosophical aspects of medical ethics. Such an ability may not develop until they have had their post-graduate clinical training.

Riis: To elucidate the size of the problem for medical students and doctors, I report the results of a prospective study dealing with clinical decision-making in the department. By prospectively analysing ethical aspects of everyday clinical decisions, it was shown that 25% of the cases in a department of internal medicine represented situations that could not be solved by just applying textbook knowledge, but that clinical weighting was necessary.

My experience with postgraduate courses in Denmark teaching medical ethics has involved 500 to 1000 doctors. Sometimes the ethical curriculum has been part of courses in clinical methodology, scientific methodology, or there have been direct courses in medical ethics. Based on this experience I certainly support what we have heard this morning from the United States, that one should start and end with the patient. Consequently such education has to be integrated into the curriculum when students see patients. My second comment is that one must strengthen the ethical analysis and never try to tell students that the teacher has a sort of ethical superiority. And, thirdly, such courses should be based on a number of real clinical situations, if necessary, condensed into synopses. If this is done, even the middle-aged surgeon who happens to attend such a course sometimes behaves like an old regimental horse. Hearing the trumpet sound, he starts to move and is activated in an extraordinary manner.

McCarthy: I want to establish a connection between the splendid papers we have heard today concerning the teaching of ethical values to students of medicine and science and the papers we heard yesterday concerning Institutional Review Boards (IRBs). Dr Levine alluded to this connection, but I would like to stress the point because I believe it is so important. One of the central functions of an IRB is that of pedagogy. By requiring investigators, whether they be students or professionals, to submit their scientific ideas and their ethical procedures to a jury of competent reviewers, IRBs make a significant contribution to the ethics of research. Dr Siegler's programme develops similar experiental learning. Although the contribution of IRBs to ethical education may be difficult or impossible to evaluate in numerical terms, my experience leads me to conclude that IRBs make an extremely important contribution to ethics education. IRBs add to the teaching of ethics a concrete and practical dimension which may not be obtained in any other way.

Levine: I would like to make some comments on the role of the clinician in the teaching of medical ethics. I agree with a lot of what I have heard - not only with what Dr Siegler said but also with what several others said during the ensuing discussion. I think it is very important to involve the clinician in the teaching of medical ethics. I have several reasons for that. The first is that the clinician tends to identify very different problems from those identified by the ethicist. In the

clinical context, the ethicist is more likely to define more general problems and then to provide an ethical analysis of the generic situation. The clinician, on the other hand, is much more likely to focus on the immediate problem of the particular patient. I suspect that this accounts - at least in part - for the success of Dr Siegler's clinical ethics programme and for the fact that it seems very attractive to medical students. I also think that a consideration of various types of publications of case studies will be instructive. We see very different sorts of cases presented for analysis when they are offered by ethicists than when they are offered by people who are actually practising medicine or conducting research. Consider, for example, the case studies that are published in the Hastings Center Report; these cases are assembled by Dr Robert Veatch, an ethicist; these are the cases to which Dr Siegler referred. For contrast purposes, consider the cases that have been published in the journal, Clinical Research as part of the Nellie Westerman Prize Programme; these cases are, in general, originated by researchers who have encountered actual problems in the course of planning or conducting their research involving human subjects. For another contrast, consider the case studies published in IRB: A Review of Human Subjects Research. These report on actual decisions made by actual IRBs. The analyses tend to be very different from those published in the Hastings Center Report even if one called upon an ethicist to contribute to the analysis. They focus on very different facets of the problems.

Another important reason to involve clinicians in the teaching of medical ethics - at least in the United States - is the tendency of our medical students to take very seriously the interests of the clinical faculty. The students are most interested in what respected members of the clinical faculties invest their time and energies in. For example, we have found that a lecture on carbohydrate metabolism can be given either by a member of our Biochemistry Department or by a member of our Department of Medicine. The content and the style of delivery can be virtually identical. The only difference is that the students - in this case, first-year students - observe that one of these lecturers shows up with a stethoscope in his or her pocket. They are not likely to see the relevance of carbohydrate metabolism to anything that they went to medical school to do. However, if the person who is talking about it has a stethoscope, they will take it on faith that two years later they will see the relevance.

Another very important issue, I think, is that in the United States, there is a very deep respect for technical and specialized authority. We find in our departmental conferences - for example, within our Department of Medicine - that you are very unlikely to see a gastroenterologist challenge what a cardiologist says about a cardiac problem. They are even less likely to challenge an ethicist. The presumption that there must be some mysterious technical expertise underlying the ethicist's views intimates student and physician alike. They fear that they will look very foolish if they were to challenge the ethicist.

Now with all I have said supporting my notion that the clinician should be involved in the teaching of ethics, I don't mean at all to say that there is no place for ethicists and various other humanists teaching in medical schools. The ethicist certainly has an expertise and a point of view that is worthy of respect. The ethicist certainly should be teaching not only in his or her own classes but also in combination with clinicians just as we now have collaborations in the teaching of pathophysiology, clinico-pathological conferences, and so on.

Towers: Following on what Dr Levine just said I want to say that I too agree with Dr Siegler on the importance of having clinicians actively involved in the teaching of clinical ethics. I don't want to suggest a polarization or adversarial relationship between the two groups, clinicians and bioethicists. It should not be an either-or but rather a both-and situation. The Medicine and Society Forum of the University of California, Los Angeles, demonstrates, in the list of some 65 topics and 150 panelists, how we try to achieve this in a very practical way. Virtually every panel includes at least one clinician, and the debate usually starts with an actual clinical case-history, presented by the clinician. Nearly half the panels have included a philosopher. We have not called on some one person to be a kind of 'resident ethicist', because his or her mode of analysis and philosophical biases in the field of human values might then become predictable and lose some interest. Instead we have spread the contributions amongst many philosophers. They have been most valuable in showing physicians how to set about logically analysing the ethical conclusions that clinicians so often derive more from intuition than from logic. Similarly, almost half of our panels contain a legal consultant, and they too have been drawn from a large legal faculty on campus. Psychiatrists and psychologists, too, have been very prominent in the discussions.

The benefits of all this seem to be that the philosophers have found it most refreshing to have a real clinical situation to analyse - one prepared and presented by the attending physician. That is different from the hypothetical case or 'analogy' which philosophers are so adept at inventing. They tend to structure hypotheticals in a way that will best allow for the analysis and conclusion they wish to pursue. Such cases often ring false to the clinician, who knows it 'doesn't quite work that way' and promptly loses interest.

It is very important to have genuine clinical input first, followed by analysis by the expert philosopher and expert lawyer, and then to return to the case under discussion. In this way one can really attract the interest of both students and faculty in the medical school. Clinicians who have engaged in these panel-discussions (all of which are recorded in videotape) have numbered more than sixty, and have come from a wide range of departments. They have put their minds to the task, knowing that the recording will be used for future classes. When they find that the discussion is stimulating and enjoyable they tend to spread the word around the school. That is all part of our endeavour, which can be summarized as an attempt to raise the conscious-awareness of the importance of ethical and legal aspects of clinical medicine at all levels in the school. A clinical analysis on the wards should always include consideration in depth of possible legal and ethical implications.

Gomaa: If medical ethics is taught to under-graduates or post-graduates as a special discipline, this may guarantee that we will develop knowledge of medical ethics but not that we will change attitudes and aptitudes during the practice of all the specialties. So, I would say that teaching medical ethics ought to be incorporated in all the medical disciplines, and this would require training the trainers or teachers of all the disciplines according to the adjusted ethics of each particular discipline. And there we come to the problem of the evaluation of the students. Again, evaluation should be not only of knowledge but also of attitude and aptitude. If we are going to submit students to a written or oral exam, then we are evaluating his knowledge, but how about evaluating changes in his attitudes and in his practice? I believe that the evaluation of these two factors needs to be postponed until after the year of internship, when we can assess how far the student has been influenced by the medical ethics he has been taught and if this influence is reflected in his practice.

De Wachter: I consider myself to be a full-time ethicist. Yet, I happen to spend half of my time in bioethics and the other half in clinical ethics. According to Dr Siegler's intimation I must, therefore, suffer from incurable schizophrenia. Anyway, I want to say that I share his belief about very few bioethicists being clinical ethicists. I also agree with Dr Siegler's view on clinical ethics, as well as with his method in teaching medical ethics. I probably don't feel very strong about bioethics and clinical ethics being mutually exclusive.

The point I want to make has to do with the implications of clinical ethics. Indeed, different presentations and a great many commentaries of this morning's session imply a fundamental change in the method of ethics. The French economist-philosopher, Jean Fourastié, made this very clear by saying that we have developed a method of decision-making which does not lead any longer to the traditional 'décision-solution' but only to a 'décision-option'. He means that, in the past, you could consult and seek advice, or go to the authorities, or decide on your own. Whatever the approach, you would always get a 'décision-solution', that is an answer which does away with the whole question. Nowadays such decisions hardly exist and, in medicine or in bio-medical issues, they don't apply at all. Instead, the 'décision-option' only sets the stage, i.e. a perspective for action. In other words, the 'option' creates an 'optique' allowing for a few of the next steps which will bring you closer to a solution. I believe that Fourastié's 'décision-option' is an adequate model for medical decision-making. Consequently, this is a model we ought to teach our students in medical schools.

Now, if this model offers a fair presentation of current medical ethics, we cannot but register this as a fundamental change in method. Thus, one basic concern of our Center for Bioethics is to call for dialogue as method in ethics. Also our courses in medical ethics both at McGill University and at the Université Laval in Québec city reflect this change in method. The facts of clinical situations are presented by doctors, nurses and social workers. The ethical and, where necessary, legal implications of deciding in such situations are then inventorized and debated by panelists and students alike. It is amazing to see how many ethical issues are already being perceived and dealt with by health professionals before the explicit debate on ethics. The Socratic method, then, easily joins dialogue as method in ethics.

For these reasons I feel somewhat ill at east with Dr Sielger's first negative objective, viz. 'it is not our objective to teach

medical students to be ethical'. I am aware of the controversy around this statement. Danner K. Clauser raised the same problem by saying: 'The ethicist should not be a reformer but only an adviser'. I would suggest that we do try and teach them to be ethical, that is consistent with the norms of their own conscience, their profession, and society. Moreover, dialogue as method is not just a technique of communication but equally an exchange of convictions on values. When different convictions lead to different priorities, these convictions must be openly confessed. To admit that we don't always live up to our convictions is one thing, to say that we give up to stress the value of living up to our convictions is quite another thing. Perhaps Dr Siegler's negative objective was meant to cover only the former.

Siegler: Thank you very much for your comments and criticisms. They were valuable and constructive. My response shall be brief because, in general, I concur with the points that have been made. I wish to emphasize my agreement with Professor Bernard Towers, from the University of California, Los Angeles, that the optimal occasion for the ethicist to interact with medical students is during their pre-medical years or their pre-clinical years. In this regard, ethics or medical philosophy might be regarded as a pre-clinical discipline. However, this educational experience should not be seen as an end in itself, just as for physicians the knowledge of anatomy is not an end in itself, but rather is meaningful preparation in an important discipline basic to the practice of clinical medicine. Medical ethics then would become the humanistic discipline basic to the practice of clinical ethics. Clinical ethics, the applied skill, must be taught at the bedside and this instruction should be done primarily by clinicians.

Regarding Institutional Review Boards (IRBs), I found the remarks by Drs McCarthy and Levine to be very interesting. I am intrigued by the idea that the IRB might serve as an educational device for physicians and investigators who prepare and submit them. I would urge Drs McCarthy and Levine to use the IRB as a teaching device, not only for those who submit protocols, but also for students and clinicians interested in medical practice and in clinical investigation. I think the IRB may prove to be a valuable educational resource that is being under-utilized in institutions that train future physicians and clinical investigators.

I agree with those who note that clinical ethics is premised upon the particularities of clinical medicine. Thus, although one might be able to develop several general principles to guide clinical decision-making, principles such as 'do no harm', the application of these principles would vary in different clinical circumstances. I believe that clinical ethical issues which arise, for example, in obstetrics and gynecology (a subject which Dr Stoltz discussed so eloquently at this conference) differ from issues encountered in, for example, pediatric neonatalogy or geriatric medicine or psychiatry. Clinical ethics is intimately related to the specificities of clinical medicine.

I was criticized at this meeting by one respondent for ignoring social, economic, and political issues while concentrating on clinical ethics and clinical medicine. Of course, medicine has never been an autonomous profession. Its practice has always been regulated and scrutinized by the prevailing social and political system. Further, clinicians engaged in medical practice are never oblivious to these political realities. Nevertheless, I believe the principal task of physicians should be to practice medicine and not to engage in social reforms. Of course, the physician as citizen may be a political or social activist, but the physician as physician should not be.

There is an unfortunate tendency among ethicists to be reformers. On the other hand, clinical ethics is not devoted to reforming the medical system. Medicine is imperfect. Its problems include: high cost, variable quality of care, inadequate access to health services, maldistribution of specialists, etc. If ethicists want to reform medicine, however, they should do so through the political process and not on the wards. Physicians should be conscious of the danger of programmes which, under the guise of 'medical ethics', embark on a course of moral reform of medical students, health professionals, or the particular institutional practices within which the programme is located. One can work for reform in the future, but decisions and actions must be taken by clinicians who work in the imperfect world of the present. I repeat: the proper concern of clinical ethicists should be the analysis and resolution of difficult clinical-ethical issues and not moral exhortation.

McElhinney: I would like to respond to a couple of questions about Dr Pellegrino's paper. One criticism was that we are too optimistic about human values developments. Our optimism has its limits, but we are hopeful because of the growth

in the number of human values programmes and in the number of faculty concerned with these matters. In the past ten years there has been a great increase in the attention given to human values problems. While the field is but a minor theme in the total scope of medical training it has achieved some distinct recognition. A second source of hope is the move away from discussion of dated issues (those important now but likely to be less controversial in the future); e.g., abortion, in vitro fertilization, etc. These are significant concerns, but ethical problems arising in day-to-day clinical medicine are more important for training medical students. Students are oriented to questions relating to individual care of their patients. They relate less well to more abstract discussions and therefore medical ethics must be clinically oriented. I teach in a clerkship in internal medicine. Our course is built upon the cases that the students bring from their immediate ward experience.

I would emphasize in passing general points about the strategy of teaching medical ethics: (1) When humanists teach in the clinic they need the validation of the physician. (2) As medical ethics moved into the clinical area it also moved into the 'major' departments - medicine and surgery. (3) Some evaluation is possible especially when medical ethics is taught as education in skills. Some attention has been given to longitudinal studies of human values education but humanistic education may not be amenable to evaluation either by present measures or by any foreseeable criteria. We face similar limits both in admission to medical education and in licensure. Some American specialty boards are examining the evaluation of humanistic traits, but there is much debate about the usefullness and the morality of these tests.

Dr Siegler addressed the question of when in the curriculum medical ethics should be taught. If medical ethics is taught as a skill it should be introduced systematically both in premedical and basic science years and then re-enforced in clerkships and residencies. Any one point is too little.

FOURTH SESSION

MEDICAL EDUCATION AND GOVERNMENT

Moderator: Carlos Campillo Sainz

EDUCACION MEDICA Y GOBIERNO

Carlos Campillo Sainz

El título de esta sesión lleva implícito el supuesto de que la educación médica corresponde por derecho propio a las instituciones docentes, las cuales guardan frente al gobierno un grado de independencia que les permite asumir su cometido con plena responsabilidad.

En los países como el nuestro, las escuelas de medicina dependen en su mayoría de universidades que gozan de autonomía para elaborar sus programas educativos y disponen de recursos propios para realizarlos. El gobierno, por su parte, tiene la misión de velar por la salud de la población, ya sea directamente con el concurso de las instituciones destinadas a este propósito, o bien reglamentando el funcionamiento de otras que con carácter privado laboran en el campo de la salud.

Las escuelas de medicina cuidan de que la preparación de sus estudiantes se rija por los cánones universitarios, tenga un sello científico y adopte los métodos pedagógicos aconsejables.

El gobierno, a su vez, formula el plan de salud conforme a las necesidades de la comunidad, traza las políticas, señala las estrategias y utiliza los recursos humanos que se requieren para tal fin.

Se trata, por tanto, de dos sistemas, el docente y el gubernamental, que, con una organización y unas responsabilidades distintas, son complementarios en sus funciones, al coincidir en el objetivo común de lograr tanto la salud individual como la colectiva.

Si las instituciones docentes forman al personal de salud, en las gubernamentales, que prestan servicios de esta índole, ese personal pone en práctica los conocimientos y habilidades adquiridos. Así, pues, la tarea de las instituciones docentes culmina en las de servicio, las cuales sólo pueden desempeñar su cometido merced a los recursos humanos que aquéllas les proporcionan. La labor de unas quedaría incompleta sin el concurso de las otras, porque unas y otras se necesitan mutuamente para realizar sus fines respectivos. Por consiguiente, las escuelas de medicina y el gobierno, a través de sus instituciones de salud, no son dos estructuras paralelas colocadas frente a frente

sin relación alguna. Por el contrario, establecen entre sí y a todo lo largo del proceso educativo, constantes intercambios en beneficio mutuo.

Cabe mencionar en primer término que toca al gobierno definir cuántas y cuáles son las necesidades de salud de la población e indicar prioridades para que, sobre la base de esta información, puedan las escuelas de medicina modelar al profesional adecuado a la realidad concreta en que vaya a actuar. De esta manera la educación médica se orienta en función de su finalidad, es decir, del servicio que el profesional está llamado a cumplir.

La consideración anterior pone de manifiesto el nexo estrecho que liga la docencia con el servicio, vale decir el medio con el fin, nexo que se manifiesta desde el arranque mismo del proceso educativo para acompañarlo en todas sus partes. Se habla ahora del binomio docencia-servicio, subrayando con tal expresión que, además de avanzar juntos, esos dos elementos mantienen entre sí una relación dialéctica en virtud de la cual se generan recíprocamente: la docencia engendra el servicio y éste deviene en enseñanza.

Este concepto, que en la actualidad goza de general aceptación, fue abriéndose paso entre nosotros no sin dificultades hasta modificar en poco más de diez años las antiguas ideas, tan rígidamente establecidas. Resulta en extremo satisfactorio, por consiguiente, comprobar que hoy en día las instituciones gubernamentales de salud abren sus puertas a la noble empresa de la educación médica. Su participación es tanto más necesaria cuanto que las escuelas de medicina universitarias apenas cuentan con sus propios servicios de atención médica.

El consabido binomio docencia-servicio reviste aún mayor solidez en la enseñanza de postgrado, etapa que para su buen desempeño demanda una mayor participación de las instituciones gubernamentales. Aquí no se trata ya de estudiantes sino de médicos, cuya formación profesional habrá de orientarse conciliando sus intereses personales con los de la institución que remunera sus servicios.

Me refiero en particular a las llamadas residencias médicas, que con tanta claridad ponen de manifiesto la colaboración existente entre las universidades y los hospitales del sector público. Es ésta una acción coordinada que no debe limitarse al grupo de médicos residentes, en cierto modo privilegiados por cuanto se benefician de programas debidamente organizados en las

distintas especialidades, sino que debe abarcar a todos los médicos que, no habiendo tenido acceso a las residencias, se ven en la necesidad de perfeccionar por sí mismos su preparación profesional. Surge así la importante y compleja tarea de la educación continua, en la cual, una vez más, comparten la responsabilidad el gobierno y las escuelas de medicina.

Estrechamente vinculada con la enseñanza del personal de salud figura la investigación en este campo, que ha de recibir la mayor atención en su modalidad designada ahora con el nombre de investigación sobre servicios de salud. Esta última, destinada a mejorar tales servicios, debe recaer de manera principal en el dominio de los organismos donde se prestan esos servicios.

De lo dicho hasta aquí se desprende que la educación médica, en todas sus etapas y en sus distintas modalidades, así como la investigación sobre salud, requiere una constante y estrecha colaboración entre las instituciones docentes y las gubernamentales de servicio.

En México, este punto de vista ha tenido ya cabal reconocimiento, como bien lo prueba el reciente Convenio de Coordinación de Actividades sobre Educación Médica establecido entre las Secretarías de Educación Pública, de Salubridad y Asistencia, el Instituto Mexicano del Seguro Social, el Instituto de Seguridad y Servicios Sociales para los Trabajadores del Estado, la Universidad Nacional Autónoma de México y la Asociación Nacional de Universidades e Institutos de Enseñanza Superior.

En el convenio se declara que las instituciones del Sector Salud y el Sector Educación comparten la responsabilidad del proceso de formación de los médicos que el país necesita, en virtud de lo cual convienen en coordinar sus actividades en materia de educación médica.

Se constituye la Comisión Nacional Coordinadora de la Educación Médica, representada por los titulares de los organismos mencionados, cuyas principales funciones son las siguientes: estudiar las áreas de coordinación entre las instituciones de educación y de salud en el proceso de formación de profesionales y técnicos de la medicina; realizar acciones tendientes a orientar en forma adecuada la oferta y demanda de estudios en el campo de la salud; y emprender la acción pertinente para la planificación de la educación superior en el campo de la salud.

Creo sinceramente que el enfoque que se ha dado al problema en México puede servir de ejemplo a otros países, especialmente de Latinoamérica, que tienen condiciones semejantes. De este aspecto va a ocuparse el Dr José Ferreira, de la Organización Panamericana de la Salud.

Summary

Teaching institutions must be independent in order to assume full responsibility in the light of their purposes.

Medical schools in Latin American countries form part of universities that have autonomy to elaborate their teaching programmes, and command the resources necessary to implement them, with the goal of training good physicians.

The National Government cares for the health of the population, operates medical institutions and dictates norms and regulations for both public and private medical institutions. It also detects the health needs of the community, determines the goals and plans the strategy to reach them. In this way the teaching system and the government converge in their quest of individual and social health.

It follows that it is the responsibility of society, through its government, to ascertain the needs and establish priorities in such a way that the medical schools can train professional personnel properly adapted to the situation in which they will work.

This puts emphasis on the so-called teaching-service partnership. Properly planned, the teaching of health personnel provides services to the population, and these facilitate further teaching. Closely related to this, the concept of health services research can point the best way to attain health-related goals.

With these relations in mind, in Mexico, the different medical care organizations dependent on the federal government have concluded an agreement with the National University and the National Association of Universities to cooperate in the planning of the training of health professionals in accordance with the needs of the country.

LA NECESIDAD DE UNA COLABORACION EFECTIVA ENTRE LA EDUCACION MEDICA Y EL SERVICIO DE SALUD

José Roberto Ferreira

El decenio 1971-1980 se ha caracterizado, en el contexto de la salud, por el amplio y continuo debate sobre su significado 'como un derecho de todos y no el privilegio de algunos'.

Así, entre la III y la IV Reunión Especial de Ministros de Salud de las Américas y, posteriormente, en la Conferencia de Alma-Ata (1978), se ha consolidado el concepto de extensión de la cobertura de los servicios de salud para la totalidad de las poblaciones.

Particularmente en esta última reunión, que contó con la aprobación oficial de 134 gobiernos de todo el mundo, se señaló que la atención primaria es la clave para alcanzar la meta de la salud para todos en el año 2000 y se hizo hincapié en la necesidad de reorientar la formación profesional ajustándola a un contexto más práctico de trabajos sobre el terreno.

Esto, por supuesto, se aplica a todas las profesiones de la salud, pero interesa en forma especial a la formación médica, en la cual las distorsiones son posiblemente más grandes. Durante el próximo decenio, el número de médicos en América Latina deberá duplicarse, y su absorción por el mercado de trabajo será dudosa si no se les asigna un papel definido en el desarrollo de la atención primaria.

A este respecto cabe preguntarse qué papel desempeñará la escuela de medicina en la promoción y puesta en práctica de esta reorientación y cómo se deberá formar a este médico general más dedicado a los problemas de la comunidad.

En realidad, la estructura de la práctica médica representa el factor principal que determina, en cada contexto, el patrón que sigue la educación médica.

La aceptación de esta premisa conduce a dos consideraciones de orden práctico: la primera, en cuanto al cambio estructural que demanda la expansión de la atención primaria, con la integración y regionalización de los servicios y con la transformación del propio mercado de trabajo; y la segunda, poder prever y poner en práctica los reajustes del proceso de

educación médica, paralelamente con el desarrollo de los cambios a nivel de la práctica médica.

El médico incorporado a la práctica de la atención primaria estará necesariamente ubicado en la puerta de entrada del sistema regionalizado. Actuará en el punto de contacto entre las acciones de salud de la comunidad y los servicios más oficiales del sistema de salud. Contará con una capacidad técnica orientada a la patología prevalente y al cuidado de los grupos de población más expuestos. Tendrá que dirigir el trabajo de un grupo auxiliar, y actuará en el seno de la misma comunidad, estimulando su amplia participación. Su formación deberá concentrarse en las áreas fundamentales de la medicina interna, la cirugía general, la obstetricia y la pediatría, sin mengua de su capacidad de interpretación de los fenómenos básicos y de la visión de conjunto. Todo ello le permitirá establecer el nexo con los otros niveles de atención, a través de los sistemas de referencia o envío de enfermos.

Estos ajustes incluirán una más estrecha coordinación de la escuela de medicina con los servicios de salud. Así, se incorporará la medicina comunitaria a la integración de las acciones preventivas y curativas, dentro de un modelo docente para la formación profesional, puesto en práctica directamente a nivel de los mismos servicios.

La medicina comunitaria y su corolario inmediato, la integración docente asistencial, responden en primer plano a la más importante distorsión de la educación médica tradicional. Así lo señaló Kerr White en su estudio sobre la utilización de los servicios de atención médica, cuando demostró que en el hospital universitario se concentraba una clientela referida, muy poco representativa de los problemas locales de salud.

Esta medicina comunitaria desempeña, además, una importante función al promover la integración de los aspectos asistenciales o curativos, preventivos o sanitarios, educativos y de rehabilitación física y psíquica, a cargo de un equipo de profesionales, técnicos, auxiliares y administradores, en el que cada uno realiza su aporte al proceso de prestación de servicios de salud.

En la medida en que esta coordinación se dé a nivel del servicio, se establecen las bases para que el proceso docente se ajuste en términos de una verdadera integración docente-asistencial.

En este planteamiento se estima necesaria una amplia participación de la escuela de medicina. Dada la aparente simplicidad de las acciones de salud propias del nivel primario, es común que la primera reacción de los grupos académicos sea considerar innecesaria su propia participación, sin tener en cuenta que, en este nivel de acción, casi elemental, no se han aplicado soluciones más apropiadas por falta de la orientación que podría aportar un personal profesional de más alto nivel.

Incluso en el propio contexto de la educación médica, cuya programación suele ser planeada y desarrollada por grupos aislados, se puede imaginar la amplia gama de posibilidades que se ofrecería gracias el intercambio constante entre los profesores que representan las diferentes áreas de conocimiento y que manejan distintos instrumentos, formando un conjunto verdaderamente interdisciplinario.

Sorprende, en este caso, que a pesar del gran potencial de investigación de la escuela de medicina, poco o ningún trabajo se esté desarrollando en el campo que en los últimos años se ha dado en llamar de la 'investigación sobre los servicios de salud'. De hecho, los grandes progresos alcanzados en la comprensión de los fenómenos fisiopatológicos y en el desarrollo de nuevas armas inmunológicas y terapeúticas encuentran su mayor restricción en la imposibilidad de aplicarlos en beneficio de las poblaciones.

Esta investigación sobre los servicios de salud no puede desarrollarse en toda su amplitud mediante el esfuerzo individual del especialista o planificador de salud pública. En muchos casos requerirá del concurso de inmunólogos, patólogos, clínicos, antropólogos, ingenieros de sistemas y muchos otros especialistas, que usualmente ya pertenecen a los cuadros de las Facultades de Medicina.

En este contexto, seguramente el cuerpo docente de la escuela de medicina encontrará excelentes oportunidades de desarrollo, en estrecha coordinación con las instituciones de servicios. No se trata de promover la apertura de nuevas líneas de trabajo, sino de responder a una necesidad eminente para la aplicación de las políticas de extensión de la cobertura de los servicios.

Sólo así será posible estudiar los factores que influyen en la accesibilidad a los servicios de salud, mejorar la racionalización del proceso de atención o analizar los efectos de las distintas estrategias de salud. Sólo así será posible conocer

en su mínimo detalle la utilización de los servicios existentes y reprogramar la distribución de los recursos disponibles para mejorar su rendimiento. Sólo así será posible evaluar la acción médica, preventiva y curativa, para reforzar a su vez el desarrollo de la ciencia médica.

Si se acepta esta argumentación en favor de una más estrecha relación de la educación médica con los servicios de salud, es necesario complementar este análisis con la caracterización de esta integración docente-asistencial.

En todo el Continente, en países desarrollados y en desarrollo, se encuentran ya ejemplos de una más amplia relación de la enseñanza con los servicios de salud a distintos niveles. Esta integración se completaría si se ajustase a una red regionalizada de servicios.

En el nivel primario, el alumno estaría orientado al cuidado del individuo en el contexto de su ambiente familiar y comunitario, proporcionando atención personal en la esfera de su competencia y enviando a los enfermos a otros niveles cuando fuese necesario.

En el nivel secundario, el hospital general o comunitario complementaría la formación, permitiendo la observación detenida, con una manipulación diagnóstica más amplia, basada en recursos de laboratorio clínico, radiología y anatomía patológica. También en este contexto se pueden atender las situaciones de mayor riesgo y aplicar procedimientos terapéuticos que no se pueden realizar a nivel de consulta externa.

En la práctica, y mediante una estrecha coordinación entre los niveles primario y secundario, se podría centrar la actividad del alumno en la consulta externa, y, a partir de ella, facilitar el acceso a los niveles más complejos, a los que podría llevar sus propios casos en función del tipo de asistencia requerida en cada situación.

En el hospital terciario, su utilización selectiva en los casos de gran complejidad impone la necesidad de aumentar su rendimiento institucional y limita las posibilidades de aprendizaje práctico de los estudiantes de medicina; la permanencia de alumnos de pregrado en estos hospitales debería ser siempre una medida de excepción, aunque puede cumplir una función importante en la formación de especialistas y en la educación continua de los profesionales de los demás niveles.

En este esquema, la formación médica y la atención progresiva, por niveles de complejidad, se identifican en un mismo principio, según el cual un porcentaje significativamente más elevado de la población demanda un cuidado general y elemental que debe ser accesible a todos, y, en la medida en que se presentan más complejas la patología y la atención requerida se reduce en proporción inversa el número de enfermos, que pueden ser atendidos a través de un sistema de referencia.

Todo este planteamiento, si se analiza a la luz de los datos del estudio de Kerr White (mencionado anteriormente) permite establecer en términos teóricos la necesidad de contar con una población de medio millón de habitantes para justificar el desarrollo de una red de servicios que contemple todos los niveles de atención y en la que se pueda establecer un programa de educación médica.

El potencial de la red de servicios para el aprendizaje está basado en la utilización de la consulta externa, siempre en una relación unitaria - de un alumno para un enfermo - en contraposición con el método tradicional de la demostración ante un grupo de estudiantes alrededor del paciente encamado. Este hecho se opone a la costumbre de definir la capacidad docente de un servicio por el número de camas hospitalarias, y permite cuantificar esta capacidad en función de la proyección de la atención en todos los niveles.

La comunidad referida, en términos de población y servicios disponibles, no podrá tener su cobertura asegurada por la escuela de medicina; ésta es, además, una responsabilidad específica de los servicios de salud. La solución, por lo tanto, estaría en una estrecha coordinación entre el sistema docente y el sistema de servicios, en una verdadera integración docente-asistencial.

La tendencia, ya evidente en América Latina, a establecer un Sistema Nacional de Salud deberá facilitar este esfuerzo de integración.

La racionalización de este sistema dependerá de la reunión de todas las actividades asistenciales bajo una orientación única, de manera que permita la planificación global de los programas de salud. La escuela de medicina deberá participar en esta planificación y podrá influir en el desarrollo de los servicios, pero tendrá que utilizarlos también ampliamente en la ejecución de sus programas de adiestramiento.

La viabilidad de estas proposiciones, por más difíciles que puedan parecer, ya se ha demostrado en algunos programas experimentales; y ya se manifiestan como una tendencia que a plazo medio llevará a la consolidación de la integración docente-asistencial.

Summary

In the 1970s, the concept of health has emerged as 'The right of all and not the priviledge of the few'. To reach this goal, several meetings, especially that in Alma Ata (1978), have pointed out that primary health care is the means to reach the objective: 'Health for all in the year 2000'. To this end, it will be necessary to change the attitude of physicians in order to direct them to primary care.

The physician thus educated, will be technically prepared in the prevailing pathology of the most exposed communities. He will have the ability to guide an auxiliary group and will act within the community, stimulating the participation of every member in reaching health goals. His training will emphasize internal medicine, general surgery, obstetrics and pediatrics.

These adjustments will require a very close coordination between the medical school and the health services, the two forming an integrated teaching-service team. The medical school will participate in the field of health services research. This investigation cannot be undertaken by individual public health offices, as it will depend on the cooperation of immunologists, pathologists, clinicians, antropologists, etc. Only in this way will it be possible to study the factors that influence accessibility to health care and other important considerations.

To optimize the delivery of medical care, it will be necessary to integrate the medical facilities at three different levels of medical care and medical education.

At the primary level, the student would be instructed in the care of the patient in its familial and community environment.

The secondary level will be covered by the general or community hospital. In it, the student would further develop his education, by using the more complete diagnostic procedures based on the resources of clinical laboratory, radiology and pathology.

The third level is to be employed in complex cases. It will need to optimize its productivity, and does not lend itself to the teaching of medical students. Rather, it will cover the training of specialists needed by the system.

The full use of the system in the teaching of health personnel will put emphasis on the use of the outpatient clinics, making obsolete the grading of the teaching capacity of a hospital by the number of its beds.

There is a very apparent tendency in Latin America to establish national health systems. The rational use of such systems will depend on the integration of all medical care facilities under a single organization. The medical schools will participate in the planning of the services and will take advantage of them in their training programmes.

THE NATIONAL HEALTH SERVICE CORPS OF THE UNITED STATES OF AMERICA

Fitzhugh Mullan

I am pleased to be able to share with you here the efforts that are being made in the United States to improve the access of all of our citizens to health care by a programme called the National Health Service Corps. The National Health Service Corps offers scholarship support for students in the health professions in return for a commitment to serve in medically under-served areas upon completion of training. This concept - service contingent medical education - is one of emerging importance as modern nations attempt to deal with the twin-headed problem of the rising costs of medical education and the traditional inequities in the distribution of health manpower across the countryside.

It is propitious that CIOMS has chosen to deal with this subject at the present time. Medical science has developed to the point where its services are of indisputable benefit to the population. This could not have been said 100 years ago and would have caused considerable argument 50 years ago. But few today would disagree that the availability of health care services is of benefit to mankind and sought after by populations throughout the world. Most nations agree that whatever the role of free enterprise medicine, the government has some role in stabilizing and equalizing access to certain medical services. Increasing numbers of countries now acknowledge responsibility in assuring the availability of primary care services for their citizens.

At the same time, inflation and the heavy cost of technology have combined to drive the expense of educating physicians ever higher. Those nations that subsidize medical training have been forced to allot more resources to this activity. Governments, such as that of the United States, that have played a small role in underwriting medical training costs until recently have been obliged to become involved to a much more extensive degree. In all cases, the result has been a larger expenditure of public funds for the training of the medical work force of the future.

Reasonably, therefore, many countries, the United States among them, have sought to tie the public financing of education to an expectation of public service designed to redress inequities and inconsistencies in the availability of primary medical care

services. The natural linkage of these two phenomena is a critical concept which will bear increasingly on medical education and medical practice throughout the world. It is from precisely this conceptual linkage that the National Health Service Corps was developed in the United States.

History

Ten years ago, the President of the United States signed the Emergency Health Personnel Act of 1970 creating the National Health Service Corps. That Act called on the United States Public Health Service - a unit of the Federal Government - to recruit physicians and other health professionals for placement in areas of the country that were medically under-served. The programme was to be a joint community-government project with the community providing the space, support personnel, and overhead expenses and the Public Health Service supplying the health professionals. Patients were to be seen on a sliding fee scale with no one being denied services. The community was to reimburse the government some portion of the cost of the health professional's salaries. A local community board was to establish local policy and be accountable to the government for on-site management.

Twenty placements were made in 16 communities in January of 1972, followed by 162 more in the summer of 1972. The majority of those recruited and placed then, as in later years, were physicians.

Modifications in the programme occurred through legislative amendments and policy development through the mid-1970s. These included a more rigorous delineation of the areas which were eligible for National Health Service Corps assistance, a broadening of the programme to include urban inner-city clinics as well as rural ones, and the expansion of placements to include other Federal programmes such as Community Health Centres and Migrant Health Centres as well as State and local government clinics.

The most significant change to occur during this period, however, was the birth of the National Health Service Corps Scholarship Programme in the legislative amendments of 1972. In the early years of the programme, the only source of recruits were 'volunteers' - professionals employed at modest Public Health Service salaries with no obligation. No more than 300 'volunteer' physicians have been recruited in any single year which, combined with a predictably high turnover rate, never promised to develop a manpower resource of more than limited scope.

The Congress, therefore, established the National Health Service Corps Scholarship Programme by which the Federal Government would pay for professional school tuition and a monthly stipend in return for which the student incurred a year-for-year obligation with a minimum of 2 years of service. By law, 80% of the scholarships were to go to students of medicine and osteopathy, 9% to dental students, and 10% to other health professions students. Scholarships are awarded annually on a competitive basis to health professions students throughout the United States. The primary factors taken into account in making awards are:

(1) Community background with preference going to those with rural or inner-city ties,

(2) Work experience, and

(3) Primary care specialty preference.

Initial awards were made in February of 1974 with the first scholarship recipients joining the National Health Service Corps in 1976. Currently, there are 6100 health professional students in school receiving scholarship awards, (8% of the medical student population) and 2700 additional physicians in deferment pending completion of primary care residency training.

The impact of the maturation of the Scholarship Programme on the National Health Service Corps has been considerable. The size of the Corps has gone from just over 700 professionals in 1977 to more than 2100 today. While the programme still recruits and places individuals who do not have an obligation to serve, the majority of the new placements and the growth of the Corps have come from the Scholarship Programme. By all measures, the service contingent scholarship has proved an effective vehicle in the development of a professional field force to provide services to the poor and isolated populations of the United States.

Currently, National Health Service Corps professionals serve in every State of the Union, Puerto Rico, the Virgin Islands, and the Pacific Trust Territories. Of these, 58% are physicians, 17% are dentists, 15% are physician extenders, and 10% are other health professionals. Among the physicians, two-thirds are board certified or board eligible.

Corps physicians staff Migrant and Community Health Centres in the Rio Grande Valley. They care for American Indians in the

Southwestern United States, and Alaskan natives above the Arctic Circle. They serve black families in New York's Harlem, white farm families in small midwestern towns and prisoners in the Seattle City jail.

A critical question for a programme that seeks to redistribute health manpower is that of long term retention. The programme's retention rate has improved steadily over the years. Presently, 31% of those completing an initial assignment remain in their placement for further service while another 10% convert to private practice in that same setting. At this point, therefore, well over a third of the professionals placed remain in under-served communities for extended periods.

The Future

What will the second decade of its history hold for the National Health Service Corps? Current projections by the Federal Department of Health and Human Services predict a large and relatively intractable shortage of physicians in certain parts of the country for the next 10 years. The Department's plan is that the National Health Service Corps should continue to expand in an effort to meet a significant portion of this projected need. The National Health Service Corps, in short, will remain the centre piece of the Federal effort to assure services to under-served populations throughout the country.

At the same time, however, there is growing national concern that previous efforts to produce more physicians in the United States may result in an over-supply of medical manpower by 1990. Most observers agree, however, that even with an abundance of physicians geographic maldistribution will remain a problem. The current debate that will govern the role of the National Health Service Corps in the future centres on the question of whether the marketplace will adequately serve the needs of all of the population given an adequate supply of physicians or whether significant Federal intervention in the form of the National Health Service Corps will continue to be needed.

While that debate moves ahead, the cost of medical education is likely to remain high with the attendant pressures for government subsidy. It would seem that fiscal, educational, and political reality will all continue to argue for service obligation in some form for whatever tuition subsidy is provided by the government.

Problems and Promise

The National Health Service Corps as a continuum of education, training, and service delivery is not without problems. First, the programme has not been as vigorous or successful as it might have been in getting the medical schools of the United States to meet it part way in the challenge of training practitioners for under-served areas. The National Health Service Corps programme underwrites a significant part of the cost of medical education in the United States. Every college of medicine and osteopathy in the nation has some NHSC scholarship recipients and a few have large percentages of their student body on Corps scholarships. Schools need to develop primary care courses in their curricula which focus on the specific issues of health care for the poor, the isolated, the institutionalized, and the disenfranchised. The NHSC needs medical schools to take the problem of training practitioners for under-served areas seriously and creatively.

Second, the management of the National Health Service Corps itself is a difficult task in public administration. Developing and supporting health care practices in highly disparate communities that are poor and isolated presents many challenges to both the practitioners and the programme. Efforts are currently being made to decentralize the management of the programme as much as possible to insure an understanding of and responsiveness to local conditions and priorities.

Finally, relationships between the publicly supported National Health Service Corps and private practitioners are not always simple. Perceptions of competition or philosophical disagreements with Federal health care cause certain practitioners to oppose the programme. By law, local professional societies are to be consulted prior to placement of Corps practitioners in their areas. While this has not eliminated all points of contention, it has provided the means for establishing generally good relations between National Health Service Corps professionals and the private sector.

On its tenth anniversary, the National Health Service Corps can point to a number of significant accomplishments as well as continued promise for the future. Today more than a million citizens of the United States receive medical care from members of the National Health Service Corps. These citizens are residents of distant rural areas, bleak inner-cities, Indian reservations, and drab institutions. Many of them would have no

care at all or, certainly, no care that they could call personal if it were not for the National Health Service Corps. Significant numbers of the professionals that the Corps places are choosing to remain in these communities for a prolonged portion of their careers. Despite the difficulties cited in making major curricular changes, publications, conferences, and preceptorships sponsored by the National Health Service Corps have done a great deal to promote the concepts of community medicine, social medicine, and primary care in the minds of a significant percentage of the nation's medical students and young physicians.

Finally and most simply, in the late twentieth century any nation that believes in human rights should be concerned with the provision of medical care to its poorest and most disenfranchised citizens. To take its brightest and most promising young people and support their training as healers and then to put them to work across the countryside among the sickest and the poorest of their countrymen is an agenda of simple social justice. That is the plan and the purpose of the National Health Service Corps.

Resumen

El Cuerpo de los Servicios Nacionales de Salud ofrece becas para estudiantes de las profesiones de la salud a cambio de que se comprometan a ejercer, al término de sus estudios, en zonas desprovistas de dichos servicios.

En la mayor parte de las naciones del mundo se reconoce que, cualquiera que sea el papel de la medicina privada, el gobierno debe intervenir en la regulación del acceso a ciertos servicios médicos. Va en aumento el número de los países que reconocen la responsabilidad estatal de asegurar el acceso a los servicios primarios de salud para todos sus ciudadanos.

La inflación y los costos de la tecnología se han combinado para encarecer la formación de los médicos. Las naciones que subsidian el costo del adiestramiento médico se han visto obligadas a destinar cada vez más recursos a esta actividad.

Es lógico, pues, que muchos países, entre ellos los Estados Unidos, traten de vincular la financiación pública de la enseñanza para las profesiones de salud con una obligación de servicio público, con el fin de mejorar las injusticias y las inconsistencias que se registran en el acceso a los servicios médicos del nivel primario.

En 1970 se creó en Estados Unidos el Cuerpo de los Servicios Nacionales de Salud, unidad del gobierno federal destinada a reclutar médicos y otros profesionales de salud para las zonas del país más desatendidas en materia de atención médica.

El programa se realiza como proyecto en colaboración con la comunidad, la cual aporta los locales y el personal auxiliar y sufraga los gastos fijos, en tanto que el servicio de salud pública costea los sueldos de los profesionales de salud.

El programa de becas del Cuerpo de los Servicios Nacionales de Salud se inició en 1972. Bajo este programa, el Gobierno Federal paga los gastos escolares y un sueldo mensual a los estudiantes, a cambio de lo cual éstos se comprometen a trabajar en el cuerpo al término de sus estudios. Las becas se conceden anualmente, mediante concurso entre los estudiantes de las profesiones de salud, en toda la extensión de los Estados Unidos. Los principales factores que se toman en cuenta para otorgar las becas son los siguientes.

1. Procedencia comunitaria, dándose preferencia a los que vienen de los medios rurales o de las zonas marginadas de las ciudades.

2. Experiencia en el trabajo.

3. Elección de una actividad a nivel de atención médica primaria.

En los comienzos del programa resultaba difícil retener al personal al término de su compromiso. En los últimos tiempos, por fortuna, más de la tercera parte de los profesionales así colocados permanecen durante largos periodos de tiempo en las comunidades antes desprovistas de servicios.

Se prevé que en lo por venir el Cuerpo de los Servicios Nacionales de Salud continuará siendo un elemento básico en el esfuerzo del Gobierno Federal para facilitar servicios a las poblaciones marginadas de todo el país.

La Institución tiene planteados algunos problemas. Uno de ellos consiste en que no ha logrado la colaboración resuelta de las escuelas de medicina de los Estados Unidos; por otra parte, la administración del Cuerpo constituye una tarea difícil; y, por último, las relaciones entre el Cuerpo de los Servicios Nacionales de Salud, sostenido por el Gobierno Federal, y el

personal que ejerce la medicina privada son delicadas y poco satisfactorias.

Sin embargo, a fines del siglo XX, cualquier nación que se preocupe realmente por los derechos humanos debe hacer todo lo posible para facilitar a sus ciudadanos menos privilegiados el acceso a la atención médica.

Elegir a los jóvenes estudiantes más brillantes y más prometedores, subvencionar su adiestramiento como trabajadores de la salud, e inducirles a trabajar en bien de sus conciudadanos más pobres y más enfermos constituye un simple acto de justicia social. Este es, en esencia, el plan y el objetivo del Cuerpo de los Servicios Nacionales de Salud.

TRAINING PHYSICIANS IN HEALTH POLICY AND MANAGEMENT

Howard H. Hiatt

Extraordinary advances have occurred in recent years in our knowledge of fundamental biology and chemistry, and much of this new information has been applied to medical problems. Insights have been provided into many previously poorly understood diseases, and our capacity to deal with some has improved considerably. Biology and chemistry have been integrated into the medical curriculum, and teaching of these subjects is now often done in the context of clinical problems.

This progress, however, has contributed to certain new, or newly recognized problems for which we are less well prepared. Let me cite three examples:

(1) Most physicians are not adequately trained to evaluate the effects of medical interventions. This is in part because our understanding of the natural history of disease is limited. We also need better methods to evaluate the effects of interventions on the quality of life. Further, special skills are needed to design, carry out, and interpret the results of clinical trials. This latter consideration is particularly important to research programmes involving human subjects, for if they cannot yield meaningful information because of poor design, they are by definition unethical.

(2) Resource constraints are severe, while our capabilities to intervene medically are growing, and the costs of intervention are increasing. Therefore, we must develop the skills to assess the benefits and costs of each intervention. In this way physicians and their colleagues can help develop methods to permit society to make informed choices among worthy alternatives. Further, we can help ensure the elimination of those interventions that bring no benefit or whose benefits are outweighed by risks.

(3) As decision makers in government and in private institutions, physicians are often not equipped to manage scarce resources.

The Harvard School of Public Health has been attempting to address these needs in several of its new teaching and research programmes, described below.

The Graduate Programme in Health Policy and Management

A survey of health personnel, particularly in government, led to the development of this two-year programme, which is designed to meet needs in government and private sectors for health policy makers, planners, analysts, and administrators. The curriculum includes:

(1) analytic methods: quantitative policy analysis, epidemiologic methods, decision analysis and evaluation;

(2) policy: health economics, economic analysis, economics of health planning, the design and implementation of health care regulation, quality assurance in health services, and health insurance and reimbursement systems; and

(3) management: administration of health services programmes, planning in the hospital setting, financial management in health institutions, financial and cost accounting, operations management, and management control systems.

Two additional features are a practical, supervised work project in the summer between years one and two, and an applied research seminar that runs throughout the second year.

Executive Programmes in Health Policy and Management

Because decision makers in key health positions, particularly in government, often lack policy and management training, we have designed a series of short, intensive courses ranging in length from one to six weeks. These are offered to physicians and health executives in such areas as health systems management, health policy, planning and regulation, environmental policy and management, and in direction of clinical services. In recent years, more than 1000 health leaders have participated in these programmes.

Their curricula use the case method of instruction and are tailored for specific groups. The Programme in Health Systems Management, for example, brings together senior managers and interdisciplinary faculty for six weeks of intensive and systematic study of some of the critical management problems facing

health care institutions. The curriculum is organized around ten inter-related courses presented in 95 class sessions. Course topics include financial management, health economics, analysis of clinical decision making, labour relations, legal and legislative structure and organization, organizational issues, management of health operations, marketing and international analysis of health issues and health policy.

Similarly, the three-week Programme in Health Policy, Planning and Regulation includes major emphasis on statistical and analytic techniques in decision making. The goal is to teach participants to appreciate the meaning, virtues, limits and deficiencies of such techniques, to enable them to manage technical resources effectively and to make judgements about the degree to which they should accept the results of studies performed by others.

The Programme in Environmental Policy and Management is intended for senior level officials of federal, state, and local environmental agencies, environmental officers of corporations, and legislators involved in environmental affairs.

The Programme for Chiefs of Clinical Services is directed at the heads of departments of medicine, surgery, pediatrics, psychiatry, etc. in large teaching hospitals. The subjects covered include health economics, legal issues, financial analysis and control, management of operations, and cost-effective clinical decision making. Organizational issues that are discussed include topics in human behaviour and organizational design. Policy issues include concepts of organizational strategy and the process of strategy formulation, administrative tools for programme implementation and matters of politics and governance.

Post-Doctoral Training in the Numeric Sciences

This activity, now at an advanced planning stage, is designed to train independent investigators who will develop clinical research programmes requiring extensive use of the numeric sciences. The programme will offer statistics and biostatistics, epidemiology, computer science, bio-mathematics, modelling of complex processes, and actuarial methods. A second goal is to prepare managers of major programmes in government, health care delivery systems, pharmaceutical companies, etc. who need a better understanding of statistical theory and practice.

The programmes will include a two-year course of instruction, a one-year course, and intensive short courses of one to three months duration.

The Centre for the Analysis of Health Practices

Many critical health issues have not been subjected to necessary investigation because their complexity requires an interdisciplinary approach that is rarely available. For this reason, we have created this health services research centre, which brings together physicians, statisticians, economists, lawyers, and others to carry out research on a variety of problems confronting the health care system. Products of the centre include such books as Cost, Risks, and Benefits of Surgery, A Policy Analytic Study of Hypertension, Cholesterol, Children and Heart Disease: An Analysis of Alternatives, and Clinical Decision Analysis. The Centre projects are diverse and currently include the following: de-institutionalization of mentally ill patients; a critical review of outcome studies; testing of chemical carcinogens; cost-effectiveness of arthritis treatment; a coronary artery disease data bank; coronary artery bypass graft surgery; the cost-effectiveness of automated laboratory tests and equipment; screening of donor blood for hepatitis; and the costs, risks and benefits of flammable anesthetic agents.

Programmes in Environmental Health

The foregoing programmes relate largely to health services. But most other public health problems also have major policy and management implications. Many of the School's teaching and research programmes concerned with disease prevention recognize this reality. For example, one of our environmental health programmes is designed to identify, understand and control toxic chemicals that adversely affect health. This programme has three components.

The first involves chemical and biological laboratory studies. The second is directed by a group of epidemiologists and other statistical scientists who seek to correlate patterns of disease with exposure to chemicals. A third group of policy analysts and economists is attempting to formulate public policy about toxic chemicals on the basis of laboratory, epidemiologic, economic, sociologic and political considerations. The scientists in all three groups have frequent interactions, are involved in joint research and teaching programmes, and have come to understand and respect the potential and limitations of the disciplines of their colleagues.

Conclusion

Most of the programmes I have described have been designed primarily to address health problems within the United States, although participants regularly include many physicians and other health personnel from abroad. Clearly, similar problems confront governments, health care systems, and physicians in all countries. We seek more and better ways to collaborate with colleagues and institutions from other countries. We are confident that collaborative arrangements could benefit all participating partners. Our School has had a long tradition of international collaboration and we are eager to extend and improve joint efforts with other nations.

Resumen

En los últimos años se han hecho grandes progresos en el conocimiento de la biología y la química fundamentales, y muchos de estos conocimientos han sido aplicados a la solución de los problemas médicos. Este progreso, sin embargo, ha contribuido a la aparición de problemas nuevos o identificados recientemente, para los cuales no se estaba preparado. Entre ellos destacan los siguientes:

1. A la mayoría de los médicos no se les ha enseñado a evaluar los efectos de las intervenciones médicas. Para diseñar, conducir e interpretar los resultados de las pruebas clínicas se requieren habilidades especiales. Esto es particularmente importante en los programas de investigación sobre sujetos humanos. Cuando, por defectos de diseño, no pueden proveer información útil, los programas de esta clase deben ser considerados antiéticos.

2. Los recursos disponibles son cada vez más limitados, relativamente, debido a que las capacidades para intervenir médicamente aumentan rápidamente, en tanto que los recursos económicos lo hacen a menor ritmo. Es importante, pues, desarrollar la capacidad para evaluar los beneficios y los costos de cada intervención.

3. Los médicos que desempeñan cargos gubernamentales o ejercen en instituciones privadas no suelen tener la capacidad necesaria para tomar decisiones que redunden en un mejor aprovechamiento de recursos escasos.

La Escuela de Salud Pública de la Universidad de Harvard ha intentado subsanar estas necesidades por medio de sus nuevos programas de enseñanza y de investigación, a saber:

1. El programa de graduados en política y gestión de la salud. Este programa, de 2 años de duración, tiene por objeto atender las necesidades de los sectores privado y gubernamental en materia de administradores, planificadores, analistas y ejecutores de las políticas de la salud.

2. Programas ejecutivos de política y gestión de la salud. Habida cuenta de que los que ocupan las posiciones claves en las organizaciones de la salud, y particularmente en el gobierno, a menudo carecen de adiestramiento en materia de política y gestión, se ha organizado una serie de cursillos intensivos, que van de una a seis semanas de duración. Estos cursos se ofrecen a médicos y ejecutivos de la salud, y versan sobre distintas materias, como gestión de sistemas de salud, política de salud, planificación y reglamentación, ordenación del medio ambiente y dirección de servicios clínicos.

3. Adiestramiento de postdoctorado en ciencias estadísticas. Esta actividad, que se encuentra en una etapa de planificación avanzada, ofrecerá estudios sobre bioestadística, epidemiología, ciencias de la computación, biomatemáticas, modelación de procesos complejos y métodos actuariales. Uno de sus objetivos es adiestrar investigadores independientes, capacitados para desarrollar programas personales de investigación que requieran un uso extensivo de las ciencias estadísticas.

4. El Centro de Análisis de Prácticas de Salud. Este Centro reúne médicos, economistas, abogados, profesionales de la estadística y otros, con objeto de investigar una serie de problemas que se plantean en relación con los sistemas de salud.

5. Programas de Higiene del Medio. Estos programas tienen varios componentes. El primero se refiere a los estudios de laboratorio, tanto químicos como biológicos. El segundo está dirigido por un grupo de epidemiólogos y otros científicos de la estadística, que tratan de correlacionar la distribución de las enfermedades con la exposición a diversos agentes químicos. Un tercer

grupo, formado por analistas de política y economistas, intenta formular políticas sobre las sustancias químicas tóxicas, basándose en consideraciones de laboratorio, epidemiológicas, económicas, sociológicas y políticas.

Aunque la mayoría de los programas descritos han sido diseñados primordialmente teniendo en cuenta los problemas de salud que se plantean en los Estados Unidos de América, participan en ellos de manera regular muchos médicos y otros miembros de las profesiones de salud del extranjero. Los organizadores del programa tienen gran interés en colaborar con colegas e instituciones de otros países. La Escuela de Salud Pública de la Universidad de Harvard tiene una larga tradición de colaboración internacional y está muy bien dispuesta a aumentar y ampliar sus actividades conjuntas con otras naciones.

Ladd: I would like to make just one brief comment about what Dr Robbins and Dean Hiatt have said and its relationship to medical ethics. I am glad that the discussion has turned to the more general question of health care rather than tying the ethical problems so narrowly to the doctor/patient relationship that Dr Siegler discussed this morning. I would just like to point out that there is a substantial interest among people who are doing medical ethics on the philosophical level in the general question of allocation of resources. I anticipate that in the next few years there will be a good deal of productivity in this area. Let me mention briefly why I think so.

As you probably know, one of the most influential moral philosophers in the last ten years in the USA has been John Rawls, a professor of philosophy at Harvard, who is the author of an extremely important book called The Theory of Justice. In this book, Rawls presents a theory of distributive justice which is essentially a theory about the allocation of resources. As a result of the impact of Rawls's book, many of his students and even those who disagree with him have become interested in the application of the whole theory of distributive justice to the specific medical context of delivery of health care and of other public health problems. Not much of their work has appeared yet in print, but I have read a number of manuscripts by extremely able young people on this subject. The new developing interest in applying theories of distributive justice to medicine is very promising and worthwhile. In the next year or two, you may expect to see some writings on this subject by philosophers, which you may find of interest, not because they will solve your problems, but because they may help you to understand the problems and to analyse them better.

The other point that I would like to make about this subject is a more personal one. At Brown University, where I teach, we have an undergraduate biomedical ethics programme, which I head up. The students who elect this programme do a large part of their work in biomedical ethics and related subjects. The programme itself is administered by a joint committee consisting of medical faculty and philosophers. I mention our programme because it is interesting to note that a number of the students in the programme are especially interested in the allocation of medical resources problem. I think that it may be right to say that there are more who are interested in that than are interested in the kind of issues

that Dr Siegler mentioned this morning, or in other kinds of issues that have received more notoriety, like euthanasia and abortion. Perhaps as many as a third of the students in this programme have decided on a career in health administration, understood in the rather broad sense to cover the kind of thing that Dr Hiatt talked about. These young people are, I believe, very idealistic, open, intelligent and, by now I hope, well-trained students. If this trend is a general one, then we may expect a new generation of students to graduate from American colleges in the next year or two who will be heading for health administration as a career and so we may expect a substantial addition of qualified people to help out Dr Hiatt and others who share his concerns.

Farber: I am one of those doctors whose proficiency in economics, sociology, statistics and so forth, is questioned - maybe my professional qualities might be questioned too. With all respect to the last two speakers on the panel, I would like to speak on behalf of those doctors who are so ignorant of these various young and very interesting sciences.

What practising doctors feel and have always felt is that to practice medicine is to wage an everlasting battle against the laws of nature. By denying all efficacy to modern medical therapeutics, we accept the argument according to which in many cases of therapeutic abstention a good number of patients survive or are cured. This is partly true.

Before medicine was even known the human race survived for many centuries against the onslaught of epidemics, accident and infected injuries. But of course a very small survival rate is the result of nature's cures. In my home town, in Brussels, way back in 1748 an epidemic of bubonic plague befell the population. Well, considering the lack of antibiotics and the ignorance of our colleagues the record was not too bad : 40% of the population survived. Now if you accept that rate we have found the ready solution to all financial problems in our medical world.

But all of you know that this is not the real situation. Not only do we fight the laws of nature but we also vie against the laws of economics. The more sophisticated costly treatments are not necessarily handed out to citizens because they increase their social or economic worth. Our experience in Western Europe teaches us quite a different lesson.

The eradication of infectious disease is a relatively cheap procedure and can mostly be performed by collective measures. When this is done, and the economic situation permitting, medical care is offered to every citizen at no cost or at least without financial obstacles.

Contrary to what a non-medical scientist would think this free access to medical care vastly increases health expenses. In most European countries the nearly free access to medical care did not have as a result the disappearance of all disease but a shift from one kind of disease to another.

When I was a medical student, 90% of all patients suffered from one or another form of tuberculosis. This disease is nearly unknown in Belgium to our youngest doctors. But we are faced with the problem of the steadily aging population with a very high rate of metabolic, neoplastic and cardiovascular disease. Many of these patients only survive by the virtue of the most sophisticated machinery. This is the case of renal dialysis, coronary by-pass and organ grafting.

We are faced with a problem of social ethics or political ethics. What authority is going to deny a citizen the benefit of a costly procedure? This burden cannot be the lot of a practising doctor.

Do you want us, ladies and gentlemen, to give the following information to our patients: 'Look, with renal dialysis and maybe renal grafting your life expectancy would be at least 5 years. Now this is only a medical advice. I have to warn you that you are perhaps going to die within a few days. You may be denied the privilege of modern treatment if our experts in economics, statistics, politics or whatever are not pleased with your personal profile'.

To conclude, I wish you to remember that there are no limits to the expectations of a patient and no limits in medicine if progress is not hampered by political or economical considerations.

Towers: We have heard much today about inter-disciplinary and multi-disciplinary studies. I have been engaged in such studies throughout my professional life. I welcome meetings of experts from different disciplines. But the implications of the words we use militate against possible good effects

of such meetings. By inter-disciplinary and multi-disciplinary, one implies separateness of those disciplines. In so many meetings that I have attended, I have heard experts from different disciplines each deliver his or her own monologue and then sit down and either leave the room or turn off the hearing aid, or whatevery it may be, and not, in fact, listen to what is being contributed by another expert. I have come to the conclusion - I would commend it to your consideration - that we ought to look instead to the use of the word trans-disciplinary. This is inherent in the philosophy of the programme that we initiated some years ago. We call it 'The UCLA Program in Medicine, Law and Human Values'. It does not have a single director, but rather two co-directors. My colleague, Dr Winslade, is trained in philosophy, law and psychoanalysis. I am trained in basic medical science, clinical medicine and in history of philosophy. Between us we cover a lot of bases. All the time we are learning from each other. In the meetings that we organize, we insist that each expert who comes should not only give but should also receive so that the whole conference becomes a learning process for the community.

Riis: I have been very inspired by the comments on medical education. Our present medical education is inadequate for the future. In today's medical schools we teach medical students the basic sciences according to scientific principles. But then, we switch gradually over to clinical medicine, teaching students that diseases are something like demons. We further teach them clinical medicine as apprentices, without teaching them taxonomy of diagnostics, logic of reasoning, the nature of clinical decisions, probability aspects of statistics, etc.

Teaching students fundamental aspects of clinical medicine and clinical research would at least have three advantages:

1) Among the 400,000 medical articles/publications per year, we would make them able to perform a vertical filing instead of a horizontal filing of most of them. In other words, they could select what could be exploited in clinical decision-making.

2) We would create much more flexible clinicians not just doing what we did yesterday, and by adopting new things, not just adding on top of what we did yesterday. We could even make them more flexible within fixed budgets of medical activity.

3) It would create much more resistant clinicians, much less easy victims of the industrial medical impact.

Gomaa: I would like to comment on Professor Hiatt's presentation. Our experience of fellows who are sent to schools of public health in the United States for courses on management and administration is really not fully promising from our point of view. The programmes are not perfectly tailored to requirements of our administrators who are sent there. Of course they are given the basic principles of administration and management and this is the easiest part of the problem. But the application of these principles and adjustment to the local problems is what concerns us really. In many cases we find that those who return from these courses are unable to apply the knowledge and the experience they have acquired to our local problems. I would suggest that more adjustments and tailoring of these programmes and courses organized for fellows of developing countries be considered. Perhaps sending faculty members of the schools to such countries to get acquainted with their problems, and thus to have insight into what is there and how basic principles could be applied to a solution of these problems.

FINAL SUMMARY

Alfred Gellhorn

To sum up our work over these last days, it seems to me that we have two very specific objectives. The first was to examine the changing role of the physician in the physician-patient relationship. The second was to consider and affirm the guidelines which have been prepared, in order to offer to countries which have not developed a particular system of ethical review a possible format which they could use. We have, I think, had a very useful exchange of views during our session and enjoyed the stimulating and thought-provoking presentations that have been made to us. I would like then, on behalf of all of you, to thank all our speakers and in closing I would like to introduce a resolution in the following terms:

Resolution

The XIVth CIOMS Round Table Conference, having discussed the document entitled 'Ethical Review Procedures for Research Involving Human Subjects'

expresses its appreciation of the document;

notes that this document was presented to the Advisory Committee for Medical Research of the World Health Organization and was favourably received;

confirms that this document reflects the needs of developing countries and contains necessary elements for the establishment of guidelines;

suggests, however, that in the light of the constructive comments made at this Round Table Conference, further revision to clarify issues and simplify language may be helpful in its evolution toward a final form.

RESUMEN FINAL

Alfred Gellhorn

Si tratamos de resumir nuestros trabajos de estos últimos días, creo que podemos decir que teníamos dos objetivos muy precisos. El primero era examinar la evolución de la función del médico en su relación con el paciente. El segundo era estudiar y corroborar las pautas preparadas, con el fin de ofrecer a los países que no disponen aún de un sistema determinado de examen médico un modelo que pueda serles de utilidad. Creo que podemos decir que en el curso de nuestra reunión el intercambio de pareceres ha sido muy útil, y que las comunicaciones presentadas han sido verdaderamente estimulantes y adecuadas para provocar la reflexión. Séame permitido, pues, en nombre de todos, dar las gracias a todos nuestros oradores, y terminar proponiéndoles la siguiente resolución:

Resolución

La XIV Mesa Redonda del COICM, después de haber examinado el documento titulado 'Procedimientos de Examen Etico para las Investigaciones en Sujetos Humanos'

expresa su apreciación del documento;

toma nota de que este documento fue presentado al Comité Consultivo de Investigaciones Médicas, de la Organización Mundial de la Salud, que lo acogió favorablemente;

confirma que este documento refleja las necesidades de los países en desarrollo y contiene los elementos necesarios para el establecimiento de pautas;

sugiere, sin embargo, que a la luz de las constructivas observaciones formuladas en esta Mesa Redonda, una nueva revisión encaminada a precisar las cuestiones y simplificar el lenguaje podría contribuir útilmente a su evolución hacia su forma definitiva.

CLOSING REMARKS

Murillo Belchior

On behalf of the CIOMS I should like to make some closing remarks.

At this Round Table Conference we have discussed at length the ethical review of clinical research and also the place of medical ethics in medical education. I want to thank first Dr Gellhorn who was the Chairman of the Conference and knew so well how to select so many distinguished and excellent speakers. He deserves our congratulations for his work in the organization of this Round Table Conference. I want also to thank the speakers and all the discussants. Their contributions were really first-class and a special source of inspiration that CIOMS will certainly take into consideration in drafting the final version of Guidelines for Ethical Review Procedures for Research Involving Human Subjects. I would express our special appreciation to the representatives of the National Academy of Medicine of Mexico for their collaboration and the hard work they dedicated to the good success of this conference. Our thanks are also due to the Pan American Health Organization, which so kindly agreed to co-sponsor this meeting and especially to Dr Acuna for his illuminating keynote address. I would once more thank ICCA for the great help it offered in the realization of this conference, and also the National Council of Tourism of Mexico for its valuable contribution. Special thanks must be given to Dr Bankowski for his fervant and efficient work so well known by all of us. In this task he had the help of Mrs Dübendorfer and the secretarial staff of the National Academy of Medicine of Mexico and we hope that all of them accept our very best thanks. Our thanks also go to the interpreters for their excellent contribution.

CIOMS is having its next Round Table Conference in September 1981 in Manila, where the subject will be 'Human Experimentation and Medical Ethics'. I hope that all of you will be able to come to Manila to contribute to the success of that meeting.

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