MEP 9412-2A.1

FORM 'G'

PROPOSAL FOR APPROVAL OF MEETINGS, SEMINARS, WORKSHOPS (ORGANIZED FROM WHO COUNTRY BUDGET)

I. BASIC INFORMATION

1. WHO Project Number and Title: IND/HMD/017

2. Operational Officer: Dr. S.Chandrasekar, Director, JIPMER.

3. Title of Meeting: Introduction of bioethics and quality care concept in medical education and practice.

4. Duration: 6 days - August 1991

5. Indicate whether in Delhi or outside, please specify location. If to be held outside, provide justification. Pondicherry

JIPMER has the infrastructure for such activities. In 1989 - 1990 two similar workshops on essential drugs and managerial sciences have been held at JIPMER. A good number of faculty members of JIPMER are trained in educational science in India and abroad.

6. Type of meeting (please check the appropriate box below)

Expert Committee ☐ Study Group ☐

Scientific Working Group [X]

Symposium ☐ Conference ☐ Seminar ☐ Workshop ☐

Others (specify)

II. TECHNICAL INFORMATION

A. Justification

Please (a) provide background of the proposed activity and state how it is justified in relation to the sequence of activities undertaken in the past and to be taken up in the future; (b) state the problem which the sequence of activities, including the present meeting, is expected to solve; (c) justify why a meeting of the type proposed is the most appropriate method of achieving the results.

We have been involved in the formulation of a new curriculum for undergraduate and postgraduate studies in Medicine for the Central University of Pondicherry. In December 1989 we have conducted an international course cum workshop (Dec. 3-9) on the concept of essential drugs and rational prescribing. We have already introduced these concepts into the curriculum for undergraduates during their internship training. We feel it a logical sequence to follows up introduction of rational drug use with concept of quality care and bioethics keeping in mind the growing importance of bioethics and cost effective quality care in the context of rapid advance in medical sciences that is occurring and is expected to occur in the next decade. This scientific working group is expected to dwell at length on objectives 1, 2 & 3. (Refer appendix I)

B. Specific Objectives

Please state clearly as far as possible in "measurable" terms, the immediate objectives of the proposed meeting, show the relevance of these objectives to the programme area(s), and identify the expected outcomes/outputs.

See APPENDIX I

C. Methods and Approaches to be used

(Please enclose a copy of the tentative agenda)

See APPENDIX II

D. Proposals for Evaluation and Follow-up

Please indicate: (a) the methods of evaluation that you intend to use during the meeting to assess its effectiveness; (b) the methods of evaluation you intend to use in order to assess the long-term impact of the meeting; (c) the follow-up actions that are intended to be taken and their time-frame; (d) the time-frame for the preparation and submission of the Report.

(1) Daily evaluation of the various sessions of the work-shops.

(2) Programme evaluation

(3) Pre and post tests

(4) Outcome analysis is to be done through questionnaires to deans of medical colleges seeking if the areas of bio-ethics and quality care are included in the curricula and finding out the extent of coverage.

E. Participants/Invitees

(i) Number of participants from States	16
(ii) Number of participants from U.Ts.	
(iii) Number of participants from Ministry/DGHS (Give designations)	
(iv) Other outside Invitees - 8	

Total Number 24

F. Technical Staff Support

Resource persons/Guest Lecturers
(Please give names and designations with justifications)

Technical advisor	-	1
Technical staff for preparation and duplication of course materials	-	2
Audiovisual assistants	-	2

III. BUDGETARY AND FINANCIAL DETAILS

(i) Total under the Project:

(ii) For Group Educational Activities:

(iii) Amount committed so far: **Rs.2,93,500**

IV. EXPENDITURE SANCTION REQUIRED FOR

(1) T.A. for ____ participants (air/train/others) — Rs. **NIL**

(2) Daily allowance for outside participants at the rate of Rs.____ per day for ____days. — Rs. **NIL**

(3) D.A. for local participants at the rate of Rs.____ per day for ____ days. — Rs. **NIL**

(4) D.A. for 10 (no.) outstation experts at the rate of Rs. 400 per day for 10 days — Rs. 40,000

(5) T.A. for 10 (no.) outstation experts (air/train/others) — Rs. 2,00,000

(6) D.A. for 14 (no.) local experts at the rate of Rs. 200 per day for 10 days — Rs. 28,000

(7) Secretarial assistance **(Rs.50 per day)** (Please indicate rate of payment) **(2 persons for 30 days)** — Rs. 3,000

(8) Stationery etc. (Please indicate articles and quantity required) — Rs. 10,000

(9) Tea/Coffee for 40 persons daily for 10 days — Rs. 2,500

(10) Any other item — Rs. 10,000

Payment for technical assist.
Refer F p-4

TOTAL Rs. 2,93,500

Name, designation and complete address of the officer to whom the funds are to be released by WHO (state name of the Bank, its address and account number, if any).

Dr. S.Chandrasekar, Director,
J I P M E R
Pondicherry 605 006
India

Date:

Signature of the Programme/Operational Officer

APPENDIX - I

B.

(1) To identify areas of ethics and quality care that need to be incorporated into medical curricula.

(2) To identify areas of ethics and quality care concept relevant to various levels of health care.

(3) To prepare teaching/learning modules relating to content areas that are found to be relevant to medical education.

(4) To test the teaching/learning modules developed on (a) medical students and (b) medical practitioners in order to test the usefulness of this approach and make necessary modifications based on the feed back obtained and the experience gained.

(5) To plan strategies for dissemination of these concepts through educational interventions in India and other developing countries.

APPENDIX - II

C. To realise objectives 1,2 & 3.

(1) Scientific working group meeting to deliberate on various issues relating to bioethics and quality care that are of relevance to medical education and practice.

Tentative agenda

Day 1. Overview of bioethics

Day 2 & 3. Selection of priority areas for curricula and for different levels of health care

Day 4,5 & 6. Preparation of teaching/learning modules.

(2) To realise objective 4.

Pilot workshops to test the usefulness of the teaching/learning modules on the target groups viz. undergraduates, postgraduates and medical professionals from primary, secondary and tertiary health care.

Workshop for medical students - 2 days

Workshop for practitioners - 2 days - 3 workshops

(3) To realise objective 5.

A 4 day workshop to sensitize medical educators on bioethical issues and motivate them to incorporate these into curricula and continuing medical education programmes. With 3 educators per college and 8 colleges per workshop, 5 workshops would cover about 40 medical colleges from all over India.

Time schedule

August 1991	-	Scientific working group meet
Jan/Feb. 1992	-	Pilot workshops for medical students and practitioners.
1992-1994 (6 monthly)	-	Series of 5 workshops for medical educators.

MODELS OF DOCTOR-PATIENT RELATIONSHIP

A STUDY BASED ON HOSPITAL ORGANIZATION IN INDIA

by

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The present paper deals with the organizational setting and cultural matrix, in which the doctor and the patient interact. The personality characteristics of the doctor and expectation patterns of the patient provide the several modes of doctor-patient relationship. Five models of doctor-patient relationship are presented in this paper as probable hypotheses for empirical verification. In connection with his research work the author had an opportunity to meet doctors and patients both in hospitals and private clinics. Whatever impressionistic data thus gathered, the author has used them in framing the model.

With the rise of new medical values to make man immortal from the medicinal point of view, and change in the concept of medical practice (preventive and promotive aspect), the doctor-patient relationship has assumed new dimensions. The medical profession is a phenomenon of interactional co-operation and behaviour. The doctor-patient relationship occupies a key position in the functioning of medical profession. Proper functioning of any hospital system depends upon the functionally congruent relations among the doctor and patient and auxiliary workers.

The concept of doctor-patient relationship denotes a situation in which the doctor and patient along with their motivational requirements interact with each other in a meaningful way for clinical objectives. This doctor-patient relationship does not operate in vacuum. But it is an end product of various interacting factors, such as the professional training and competence of the doctors, the role expectation of the patients, socio-psychological characteristic of the doctors and the patients and the last but not the least important point is the socio-cultural matrix within which the whole medical system operates. Keeping in view all these factors, it may be said that the doctor-patient relationship is not an individual phenomena but a socio-psychological phenomena operating in the growing complexity of medical profession.

A typology of doctor-patient relationship with the following specification may be framed for empirical investigation.

(1) *Role-performance*—It implies overt and covert influence exercised by the doctor over the patients in interaction. A cordial, sympathetic and warm relation with the patient is informal and a cold impersonal relation is formal.

(2) *Way of dealing*—The main variable of doctor-patient relation is the 'way of handling' the patient, having the degree of interest as the key variable. If the doctor keeps his interest confined to the "disease and cure aspect" of the patient, it is specificity oriented relation. If he is oriented qualitatively in the whole personal well-being and extra 'disease-cure' syndrome, his relation is diffuseness oriented.

(3) *Organizational bureaucracy*—In doctor-patient relationship, several variations are possible in following the rules and regulations of bureaucratic structure. If the doctor follows them rigidly he is termed bureaucratic and if he follows them with flexibility he is non bureaucratic.

* The models are based on the findings of the author's research work conducted on the "Sir Sunder Lal Hospital, B.H.U."

The author is very grateful to Prof. S. K. Srivastava, Malaviya Professor and Head, Department of Sociology, B.H.U., and Prof. S. M. Marwah, Professor and Head of the Department of Preventive and Social Medicine, Medical College, B.H.U. for their valuable guidance.

Typology of Doctor-Patient relationship

(with doctor as Orientation agent)

Serial No.	Role-Performance Model	Performance		Socio-cultural matrix of dealing		Organizational Setting	
		Specificity	Diffuseness	Formal	Informal	Bureaucratic	Non-Bureaucratic
1.	Medico—Technocratic	+	-	+	-	+	-
2.	Magico—Angelic	-	+	-	+	-	+
3.	Angelic—Technocratic	+	-	-	+	-	+
4.	Medico—Particularistic	-	+	+	-	+	-
5.	Medico—Idealistic	+	-	-	+	+	-

Note + = Acceptance

\- = rejection

D - P = doctor patient relationship

Model 1— Medico-Technocratic

The doctor is an expert of his branch of specialization and works instrumentally. He adheres to the bureaucratic structure of the hospital and maintains formal relations with patients. His self image is of a specialist demanding recognition of his skill. He does not enter into formal conversation with the patient or pays attention to the patient's extra-symptomic description. He ruthlessly advises and maintains a distance from the patients and auxiliary medical workers.

Model 2—Magico-Angelic

In the doctor-patient relationship in Indian cultural matrix, a magico-angelic doctor is viewed with reverence as an 'angel' or 'messiah' of cure. He is seen as the saviour of life. This image of the doctor is born out of his interaction pattern with the patient. Charismatic qualities are projected upon his personality. Such an image is generally acceptable to the average Indian who has a tradition of 'Vaidyas' and 'Hakims'. The private practitioner acquires this image. He is sympathetic and helping. He enters into informal chats with the patients and shows utmost care for the convalescence of the patients. Except a few simple and convenient rules, he follows, no bureaucratic rules - regulations in his privately managed clinic.

Model 3—Angelic Technocrat

Of course, he has all the qualities found in the medico-technocrat except the 'dealing' aspect. Inspite of his 'expertise' he maintains all the cordiality and certain amount of patience to bear the strains of informality. Because of his expertise and warmth in handling the patients, he is the most sought for doctor in Indian cultural matrix.

Model 4—Medico-Particularistic

He is expert and bureaucratic having the apparent aim of 'impersonality', he develops sometimes a soft corner for certain patients. He enters with cathectic relations, may be due to particularistic consideration-caste, community, sex, status etc. His model of relation is not a consistant with the doctor, rather it is a "situational emergent" relation. For the well being of 'his' patient, he may 'deviate' from organizational matrix and medico-ethics.

Model 5—Medico-Idealist

The variation of D. P. relation model 1 and model 5 is subtle. Again the basic factor of distinction is the 'way of dealing' with the patient. The medico-idealist is 'impersonal'. He follows generally the rules and regulations of the organization. He is specificity oriented in D-P relation. He is informally sympathetic in relation with the patients but refuses 'politely' to deviate. He is polite but 'stern' in following rules-regulation of the organization which makes him a medico-idealist.

The models of relation presented above are ideal types and by no means they exhaust the typology. We have presented only a few of them for empirical testing. It is a conceptual scheme derived out of observation. It needs vigorous testing in various socio-cultural matrix.

MEP. 546
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Mp-2A.3

ORGAN TRANSPLANTATION IN INDIA

Solid organ transplantation is a rapidly evolving discipline currently involving the heart, lungs, liver, pancreas, intestines and kidney. However, the Indian experience is confined to Renal transplantation. The incidence of end stage renal disease (ESRD) is 40-60 patients/million/year. Every year 30,000 patients are added to this large pool. The logical solution is renal replacement therapy which is scarcely available and condensed around the major cities. A survey concluded in March 1990 revealed that approximately 22,000 patients were dialysed in one year for acute or chronic renal failure in our country. It is also estimated that approximately 2000 live donor kidney transplants were done in 1989 on India.

Renal Transplant Centres:

The major academic institutions, as a matter of policy accept only those patients for maintenance dialysis who have a prospect of line related transplantation. The obvious reason for this rationing and denial of life saving maintenance dialysis to this large pool is grossly inadequate facilities for dialysis and absence of cadaver renal transplant program in the country. The situation is by no means static as the last decade has witnessed a phenomenal growth with establishment of around 200 centres for regular dialysis and 30 centres performing renal transplantation. However, despite this growth, the existing facilities are woefully inadequate for the needs of this vast country.

Cadaver Renal Transplant (CRT) Program:

Instead of taking a logistic approach of developing a CRT program, there has been a trend towards the path of least resistance ie., the unrelated transplants with the spectrum of associated unethical practices. It is true that CRT in India is beset with numerous difficulties, such as scarce availability of hospital care for the critically ill, legislative silence on brain death criteria and organ donation, inconsistent and unreliable telecommunication and transport facilities and unawareness amongst the public and professionals regarding organ transplantation. Though a tedious task, a viable local CRT program is desperately needed to meet the growing need of organs and to combat the practice of unrelated unethical renal transplants.

The 'Kidney trade':

Recently there has been a lot of press coverage of the kidney trade. An estimated 2000 or more kidneys taken from live donors are now sold every year in the country - up from 500 in 1985 and around 50 in 1983. And while initially it was restricted to hospitals in the metropolitan cities, it has now moved to smaller cities. The 'Kidney business' now has a turnover of Rs 40 crore.

(Contd. ..... 2)

Altruistic Donation:

The concept of Altruistic donation has gained momentum in many of these centres. Invariably most of these altruistic donation is backed by gratification and financial transection. Many a times the transection is involving the doctors too. Lets go into the 'live related donors'. The results are very good in this group and the financial transections are relatively less. There has been a lot of allegations where the donors have been made 'related donors'. There is no agency to check the integrity of these related donors.

Un-related Donors:

What do you do for a patient who does not have a suitable related donor? Will you refuse treatment for a patient whose relatives refuse donation for various reasons. These are some of the considerations for those who propagate unrelated donors.

RECOMMENDATIONS

I have a few recommendation to make to this august gathering. The three major Christian teaching institutions can play a major role in organising an ethical organ transplantation program.

1. **Cadaver Renal Transplant (CRT):**

   Political pressure must be instituted to have a viable legistalation for cadaver transplantation. At the moment only the state Governments of Maharashtra, Tamil Nadu and Karnataka have obtained legal clarity on vadaveric organ donation and detailing the legal procedure for retrieving organs from cadavers. Despite these efforts, the CRT movement has failed to gain the desired momentum. There is an urgent need for the parliament to pass a bill on cadaver organ donation for other states to follow.

2. **Concept of Altruism in CRT:**

   Unless the public is made aware of the importance of organ donation, they will never realise the need for the same. Altruism is a complex phenomenon. People don't just decide to be altruistic, charitable or benevolent. They must be motivated and guided by their philosophies, upbringing, religious & social attitudes and the immeasurable contacts that effect their perception and determination. It is here

(Contd. ..... 3)

that media may be enlisted to play a paramount role in presenting positive attitudes about organ donation. We must therefore be over sensitive to opportunities to work with the media and with the public directly, to inform and educate in order to disseminate correct and meaningful information.

There is also a need to evaluate the emotional and other responses felt by donor families after a loved one has died. The death could be traumatic, due to stroke, primary brain tumour (not metastatised), or due to methanol poisoning (these patients can be dialysed & then organs harvested). This is a critical and traumatic time in the life of the family and the approach must be psychologically befitting to the environment to initiate discussions on organ donation. This is a unique area of endeavour, and gentle care and concern by those of us in the field will inspire and motivate altruism.

Lack of knowledge or understanding about organ donation, may generate fear and mistrust in the minds of families. In the same way, religious attitudes might raise concerns about the moral or religious propriety of invasion of the body of the removal of part for transplantation. There may be mistrust or concern as regards the care or proper respect for a body after donation and a lack of confidence that it will not be mutilated. There may be understandable apprehension that voluntarily donated organs, perceived to be the act of generosity would somehow be sold for commercial gains. One of the most significant areas of fear or mistrust is that organs might be removed from a person prematurely before death has occurred. People may be superstitious that if they sign a donor card or even talk about the concept while they are alive, the event of death might in some fashion be preponed.

All these fears and concerns can be alleviated and dispelled by proper education, & judicious use of audiovisual media and the written word. It is imperative for the medical professionals to take up the challenge of educating the public at large about the need for organ donation.

To promote altruism, there is need for advance planning to provide positive, accurate and informative message so that transplantation may be better understood & practiced.

Medical professionals engaged in the care of trauma victims and, ICU staff are to be appraised of the need for organ donation, brain death and care of such patients. These professionals are the referral source to the organ procurement team.

(Contd. ..... 4)

3. **What else is the Option?**

Till CRT becomes a reality we have to rely upon live donors. Ethically we are justified to perform transplant on live related donors. But what do we do for those patients who do not have a suitable donor? Is it ethical to deny them the option of a live unrelated renal transplant? This needs to be discussed in detailed in appropriate forums within our hospital infra structure. I would suggest that each hospital have a organ donation ethical committee consisting the physician, transplant surgeon, social worker, representatives from the citizens council and legal profession to monitor the integrity of these unrelated donors and avoid financial transections. It is better to openly do an unrelated organ transplant in exceptional cases by using a set protocol mentioned above.

CHRISTIANS IN MEDICAL EDUCATION Date: 28&29/2/92

MEDICAL COLLEGES AND THEIR ETHICAL RESPONSIBILITIES

Ethics: Science of morals. Moral behaviour or code.

Moral behaviour or code is known to all of us. There is a need, however, for us, a group, to dwell on this responsibility as Christians, working in and as part of a Medical College.

In this context of a Medical College, the areas that need to be looked at carefully are, our ethical responsibilities,

A) As Teachers
B) As Managers/part of a working-team of a department
C) As members who are part of the Institution
D) As part of the vast realm of medical professionals in a country of numerous medical colleges and varied types of medical colleges
E) As part of the Society in which we live

As Teachers

"Few boys are incorrigibly idle, and a few are incorrigibly eager for knowledge, but the great mass are in a state of doubt and fluctuation, and they come to school for the express purpose, not of being left to themselves because that could be done anywhere but that their wavering tastes and propensities should be decided by the intervention of a master" Syndney Smith.

We are responsible for the finished product of our College. The child that enters the portals of the Medical College and the Doctor/Nurse/Allied Health professionals who leaves it.

- The one who enters has his qualifications and has made the required grade.
- The process of education and training is over.
- He/she makes his/her place in society.

Broadly this may be -

a) A purely academic career - research, teaching
b) Where the skill acquired is used in the service of the society
c) Professionalism or commercialising of the training.

.....2/

Each College represented here has its own policies for selection which are sound and carefully worked out. The role played by St. John's Medical College in the moulding of students to face ethical issues is basically in two phases:

Phase I. Make known what the Institution stands for -

a) Institutional objectives spelt out in the prospectus
b) Ethical values paper included in the Entrance examination
c) The pattern of interview also conveys to the student, "the ethical stand" of the Institution.

Phase II. Create an ethos where the students are nurtured in these ethical values by -

a) Classes on medical ethics/where the principles are taught
b) Providing role models - as teachers, doctors, administrators, nonteaching staff and research staff.

The above steps will provide the student with the basic foundation in ethics as a subject and the practice of ethics. This in turn will provide the guidelines in decision making.

I would add the Institution should look to Christ for example. A Christ-centred life together with the knowledge of ethics as a subject is the right amalgam.

There are stumbling blocks to the achieving of this goal. You will be able to list many out of your experience as a teacher.

As Managers, or Heads of Department

There is a need to constantly remind ourselves about the stand we take in ethical issues that arise. The one I find most difficult is to be a good example. Some of the areas that need to be considered are -

- Using working time for personal errands
- Misuse of office stationery
- Expecting the 'Helpers' to run errands at home and in the office
- Overtime wages and compensation for every bit of extra work

.....3/

- Fear of the "Workers' Union" when disciplining is necessary
- Discrepancy in "Management policies" in the various other departments
- Writing "Confidential reports" on staff who have been irksome. Do I misuse this hold I have?
- Our responsibilities in departmentally acquired infections and injuries.
- Need to protect, educate and constantly supervise the staff in the department.

C) As members who are part of the Institution

In a Christian Institution, it is only correct to expect a feeling of a common bond with unity of purpose, working for the common good of the Institution. This may be the case most of the time but cannot be the case all the time. Few examples are -

- Management versus staff issues. Either as individuals or collectively.
- Protection of the Institution's reputation in the wake of public criticism.
- Our stand when various categories of staff from other medical colleges strike work.
- Facilities, perequisites and higher pay scales in corporate hospitals which lure trained personnel away.
- Mission institutions under the control of the Church/Churches/ Councils. If there is a resentment do we allow it to grow?
- The Universities to which the institution is affiliated can pose problems. At times, the University expects Christian Institutions to be "Lead Institutions" and at other times laws and rules are laid down which require major policy changes within the Institution - this may even at times affect admission policies and the Institutional objectives. What do we do?

E) Each one of us here belongs to the in we live. What is our role as health professionals? Do we have an ethical responsibility towards -

- Building healthy communities?
- Do we discharge this responsibility as
  a) individuals
  b) groups of like-minded medical people
  c) through philanthropic groups such as Rotary Club
  d) as part of our Church activity
  e) any other

Do we consider it as a mandate and find time for it?

Ethical issues in Biomedical Research

There are many facets to this. The guiding principles are laid down by WHO.

In St. John's Medical College there is procedure for ethical clearance of a scientific project. The project is submitted to the"Ethical Review Board" comprising of a senior and a junior representative of the pre and paraclinical departments; one from the clinical section, a senior research consultant (one who has had many years of research experience). Ethics Consultant, a legal consultant and the Principal of the College. This committee/board meets, reviews the projects for its ethical clearance and issues a certificate to that effect. The board has the liberty to reject or modify the project in order to make it ethically acceptable.

The other areas to be considered in ethics of research, certain issues that are not discussed in books. Some of them are: (1) Authorship of the research outcome and the order (ii) Interdepartmental research projects are best discussed by the participating personnel and all issues agreed upon. (iii) Using of departmental registers, patient's charts for analysing data. Bearing in mind the ethics of confidentiality of patients reports.

Medical Education, 1984, 18, 67–70

page 70 is missing.

MEP 54.8
I THOMPSON
MP-2A.5

Editorial

Medical ethics and medical education

ME-1392

Medical ethics, at any rate in the West, has been traditionally based on the Hippocratic Oath, with its threefold principles of respect for human life, confidentiality in fiduciary relationships and beneficence ('the duty to care and do no harm'). For many doctors and health professionals the Hippocratic Oath has been a sufficient basis for medical practice and they do not see the need for new codes or guidelines. However many developments in the modern world and contemporary health care have, in the view of others, made it imperative to clarify these general principles of medical ethics and consider in more detail their application in clinical practice and the larger areas of health care administration in both developed and developing countries.

Public outrage at the discovery, during the Nuremberg War Crime Trials, of what had been done by Nazi doctors in the name of medicine and scientific research, gave major impetus to the review and elaboration of medical ethics. The Declaration of Geneva (1948 amended 1968) attempted to restate the Hippocratic Oath in modern terms, affirming the doctor's duty of respect for human life and service of humanity, the duty to care regardless of race, sex, religion or social class; and respect for the secrets of the patient. The Declaration of Helsinki (1964 revised 1975) sought to further clarify the ethical principles governing clinical research involving human subjects emphasizing informed consent and proper scientific research design; and the Declaration of Tokyo (1975) stressed that medical ethics precluded doctors from participating in torture and other cruel, inhuman or degrading treatment or punishment.

Recent developments in bio-medical science and technology have made it possible to achieve successful organ transplants, safe abortions, resuscitation of, and artificial life support for, those who would previously have died. This in turn has produced pressure for further clarification of medical ethics: the Declaration of Sydney (1968) on the determination of death, the Declaration of Oslo (1970) on therapeutic abortion, and the Declaration of Hawaii (1977) on the responsibilities of psychiatrists particularly with reference to possible misuses of chemotherapy and invasive brain surgery.

The World Health Organization and in particular the Council for International Organizations of Medical Science (CIOMS) have long been concerned about ethical issues in health care and the need for the integration of medical ethics in medical education. While in the past the concern has arisen within the medical profession and has been related either to the control of medical malpractice or the dilemmas of clinical medicine (particularly related to new developments) now the pressure is increasingly coming from the public and the media and relates to a series of new issues of growing importance.

The first issue relates to the exponential growth in clinical research and particularly in the trial of new drugs, and public concern that there should be adequate control and protection of the rights of experimental subjects. This issue is particularly focussed in the developed countries on the role of Research Ethics Committees or Institutional Review Boards in providing ethical review of clinical research, and concern at the absence of adequate controls on pharmaceutical companies and medical entrepreneurs in developing countries.

The second issue relates to the politics and economics of health care in a period of world recession, and the ethical issues to which economic scarcity has given prominence—namely questions concerning the ethics of resource allocation. These arise at several levels; in clinical practice (e.g. in deciding between patients for renal dialysis or intensive care when equipment and facilities are limited), in the management of personnel and resources within a health care system (e.g. in shifting resources from the acute high-technology hospital

medicine to primary care or to care of the elderly and mentally ill), and in attempts to achieve justice in health-care at an international level (e.g. in providing for more adequate staff and resources for developing countries).

Medical training tends to focus attention on the clinical relationship of doctor and patient, and much recent discussion of medical ethics tends to have concentrated on ethical dilemmas in one-to-one clinical relationships. The discussion of such issues tends to be couched in terms of personalist ethics and individualistic values. This tends to overlook the fact that doctors also frequently are involved in clinical research with groups of patients, exercise considerable power in the management of staff and allocation of resources within institutions, and may play a crucial role in determining policy at regional or national level in their respective countries. The fact is that personalist and individualistic ethics are in general inadequate to deal with ethical decision-making at this level. Understanding of institutional and political ethics with its more universalistic concerns with justice in health-care and the common good may be necessary, and these values may in fact conflict at times with more personal understanding of patients' rights and professional duties in a clinical situation.

While there is a growing recognition that medical education should include medical ethics, the emphasis in existing courses tends to be either very traditional (concerned with forensic medicine and medical etiquette) or at best concerned with ethical dilemmas of clinical medicine. Little attention is given to the broader questions involved in medical research, public health policy and the national and international allocation of health resources, and yet it is obvious that most doctors have to address these questions at some time or other in their professional life.

Medical Ethics and Medical Education,* a report of the proceedings of the XIVth Round Table Conference of CIOMS held in Mexico City from 1–3 December 1983, gives evidence that WHO and CIOMS are attempting to address themselves to these questions. The first two sessions of the Conference relate to the ethical review of clinical research, dealing both with general principles and considering local applications in several different countries in the Americas. The publication also includes the most helpful Provisional Guidelines for Ethical Review Procedures for Research Involving Human Subjects. The third session was devoted to discussion of both the theoretical importance of medical ethics in medical education and some interesting practical examples of courses where the attempt has been made to integrate medical ethics into the medical curriculum. The final session was concerned with the broader ethical and policy questions involved in the relationship of medical education and government.

The introductory papers were particularly outstanding. John Ladd, a philosopher, in addressing ethical issues in human experimentation criticized Research Ethics Committees (or IRBs) for being unduly pre-occupied with questions of informed consent, pointing out that most committees are less concerned with the ethical issues of protecting patient dignity and autonomy than protecting themselves and the institution from legal action. Informed consent as a legal notion pre-supposes an adversarial relationship between doctor and patient which encourages defensive responses on the part of both. He pleads for a disentanglement of moral and legal aspects of the subject, greater awareness that 'bourgeois' ideals of freedom are largely inapplicable to patients who are highly dependent because of need, institutionalization or socio-economic circumstances, and that the real challenge of facilitating patient autonomy means getting away from legalistic interpretations of informed consent.

On the subject of research he pleads for a greater awareness of the different value-conceptions or ideologies underlying those whom he calls 'enthusiasts' and 'restrictionists'. Both those who consider all scientific research invariably benefits mankind and those who are afraid of its Faustian pretentions tend to argue from absolutist premisses. He argues very persuasively that both positions need to be qualified by human compassion and insistence on maintenance of the highest standards of scientific research. He concludes that there are three factors which must be taken into account in determining the moral quality of a medical experiment on a human subject: (a) the balance of risk and benefit for the subject; (b) the adequacy of the project and its potentiality for reducing suffering or benefitting future patients; and (c) the relationship between the experimental subject and those who stand to benefit from the experiment—that is, whether they are remote from him or

*Medical Ethics and Medical Education. Edited by Z. BANKOWSKI & J. CORVERA BERNADELLI. Council for International Organizations of Medical Sciences, Geneva. 1981. Pp. 281. Sw. Fr. 20.

people to whom he is related by some kind of community of interest.

Robert J. Levine, in discussing the value and limitations of ethical review committees, makes some provocative comments as a clinician which must be of interest to those serving on such committees. He first points out that the limited research on such committees in the U.S.A. suggests both that they have contributed to better protection of the rights and welfare of human subjects, and also contributed to the improvement of the quality of research proposals submitted and the quality of the research done. The values which such committees attempt to uphold (in the light of the Declaration of Helsinki and other directives) are the following: (a) there should be informed consent; (b) there should be good research design; (c) there should be competent investigators; (d) there should be a favourable balance of harms and benefits; (e) there should be equitable selection of subjects; and (f) there should be compensation for research-induced injury. However, he suggests that ethical review committees are often limited in what they can do because they lack credibility. This lack of credibility is related to the fact that many spend too much time on unimportant details, that there is poor co-ordination between different committees where multi-centre trials are involved, there may be inconsistent criteria determining which projects require review and which do not, in the absence of standardized procedures committees will vary in the quality of review given, there is no provision for monitoring research approved, and some committees have difficulty in recruiting members who command the respect of the institution or community they serve.

Francisco Vilardell gives an excellent analysis of ethical issues in gastroenterology and how these can be monitored effectively by laying down clear criteria. The paper is very specific and detailed and is a model of how ethical review can be developed in specific clinical areas.

John F. Dunne gives a masterly overview of ethical review procedures for research involving human subjects, distinguishing three different kinds of research each with its own attendant ethical problems: (1) detailed studies of a physiological or pathological process in response to specific interventions, in one or more individuals; (2) prospective controlled trials of specific therapeutic regimens in larger groups of patients; and (3) field studies in which consequences of prophylactic or therapeutic measures are determined within comparable communities.

In relation to these different kinds of research he draws attention to several kinds of ethical problems. First, whether in determining research policies countries will use public funds competently for the general benefit of society. Second, in developing countries there are specific problems which arise because of external sponsorship of research. These include research projects which are unrelated to the country's primary needs, make heavy demands on limited medical staff and resources, may be in conflict with local customs and mores, and do not involve long-term commitment to the country or accountability to its people. Third, developing countries lack the medical infrastructure in toxicology and pharmacology to support the regulatory apparatus for monitoring new drug developments. Fourth, there is a risk of exploitation of the underprivileged by sanctioning research in developing countries that would not be tolerated in countries with better general levels of education and health care.

More generally his paper also contains some excellent observations on the limited usefulness of the notion of 'informed comment' when dealing with research involving children, pregnant women, the mentally ill and when public health measures (e.g. fluoridation) involve whole communities. These situations require other safeguards such as proxy consent, review tribunals, provision for compensation for personal injury and public accountability of individuals or institutions involved in research.

The succeeding papers were of considerable interest in documenting the specific provisions for ethical review of clinical research in Argentina and Chile, specifically and more generally in the Latin-American Association of National Academies of Medicine. Two papers of particular interest deal with difficulties of doing paediatric research in Latin America with conservative attitudes of parents and established institutions (Kumate), and research related to fertility control in women (Stoltz) where the same difficulties apply compounded by the subordinate and oppressed condition of many women.

Other papers deal with the teaching of mainly traditional forensic medicine and medical etiquette in Venezuela and Brazil, and reveal a debate internal to North American medical schools, namely between the teaching of 'bio-ethics' or 'clinical medical ethics'. The development of the Hastings Center and the Society for Health and Human Values focussed attention on the need to examine medical ethics in the wider context of ethical and value questions in

the bio-medical sciences in general. The initiative in research had come from theologians and ethicists rather than doctors. Mark Siegler criticizes this development and argues for a restriction of medical ethics to what he calls 'clinical ethics' and preferably taught by ethically literate but clinically competent doctors. Edmund D. Pellegrino, doyen of bio-ethicists, defends the broader view and argues strongly for the injection of more training in the humanities into medical education. In part the debate is about method and content of medical ethics teaching: whether it should be theory based or case based, whether it should be given by philosophers or clinicians, or in a multi-disciplinary mode, whether it should be primarily medical or concerned with the bio-medical sciences in general. In part also the debate is about the scope of medical ethics: whether it should be restricted to clinical, doctor-patient relationships or whether it should take in the ethical responsibilities of doctor as researcher, hospital manager, public health planner, policy maker for health services generally, and international issues as well.

The final closing addresses deal with some of these issues but less satisfactorily, perhaps because no one has really thought through these issues very carefully just yet. The two Latin-American contributions are mainly a plea for the independence of medical schools to be respected, for epidemiological rather than political criteria to be employed in defining priorities for developing health services at national and regional level, and for realistic partnership in striving to attain the WHO objective of Health for All by the Year 2000. Fitzhugh Mullan's paper is a rather smug defence of the U.S. National Health Service Corps as a means of dealing with the health problems of deprived areas by scholarships to medical students, requiring them to do compulsory service in deprived areas following qualification. Why those who can afford to finance their own medical training should not have to do so is not made clear. Howard H. Hiatt's paper is a most useful beginning to a discussion about the need for training of doctors in health policy and management and the ethical issues involved at that level.

What this excellent publication lacks is a detailed discussion of the wider ethical issues of justice in health care between the developed and developing countries. What is needed is a WHO 'Brandt Report' which would deal with the ethical and educational challenges to doctors of the North-South polarization of wealth and poverty, health and disease, medical resources and the lack of them.

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Medical Ethics and its Place in Undergraduate Curriculum

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"Amongst our contemporary experts physicians are those trained to the highest level of specialised incompetence for this highly needed pursuit".

(Ivan Illich - 1976)

ABSTRACT

Ethical consideration have a bearing in most disciplines of medical practice, including, research on human beings, therapy on children, mental aberrants, geriatric patients and similar other groups. A 20 hour teaching programme at undergraduate level and intern level is recommended, which may be incorporated in the existing curriculum.

The relationship between a physician and a patient, in a wider sense, has been a peculiar one; of absolute blind faith bordering on worship to complete mistrust and hostility. Both the responses are understandable and justified. Certain codes were laid down since ancient times which governed relationship, based on correct perspectives, with a view to protect the interests of the patients as well as safeguard the legitimate interests of the physicians.

Medical people like to describe themselves as professionals rather than tradesmen which per se means professing to a certain code of ethics, but on the other hand traders also have a code of ethics and some groups have tried to question this distinction (Kass, 1983). All the same, lack of a strict code can cause havoc with the interests of a sick and therefore gullible and open to suggestions.

Ethics is a much more complicated problem these days with the availability of assisted life processes, use of cadaver or near dead and live donors, trials and therapy and Investigations on human including use of placebos, question of informed consent when applied to children or mentally retarded, euthanasia, medicolegal aspects taking into account the laws governing the community and the social structure. Requirements of an informed consent even for the tried and accepted surgical or other therapeutic

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measures is not easily spelled out. There is also a problem of certain drugs which have been discontinued in some countries, but considering all aspects, may still be useful in some of the less developed countries where the priorities may be different,

Ethics Through the Ages

Ethical codes are as old as medicine. Strict codes were laid down in ancient Egypt and by Summarians in about 3000 B. C. Hammurabi's code in 1200 B. C. laid down severe penalties for harm following treatment (Thorwald 1962). Susbrutha laid down a moral obligation on the part of surgeons, the patient and a strict criterion for selection of a candidate, which may not accord with modern concepts (Shankaran, 1976). It is recorded that during the Buddhist period, in India, a public affirmation of conduct and etiquette was laid down (Thorwald 1962). Hippocratic Oath is well known to need any mention and it is still in vogue in some places, though parts of its are totally out-moded; some of his aphorisms have still an eternal message. However, most of the codes, oaths or affirmations were more in the way of ethics laid down regarding personal relationships between the physician and his patient and do not have answers for the problems of to-day.

The modern interest in a suitable code arose when the world conscience was stirred by what happened in Nazi Germany and was the Nuremberg code of 1947. This insisted on a "voluntary consent" for all experiments where human beings were involved. World Medical Association in their meeting at London in 1949 laid down a code for medical research. In 1964 W. M. A. adopted HELSINKI I declaration governing clinical research and informed consent. In 1975 HELSINKI II declaration broadened its scope to include biomedical research involving human subjects (Bankowski, 1982). Most of these principles were incorporated by the I.C.M.R. Committee headed by Justice A.K. Khanna in 1978 (Satyavathi, 1982; Medappa, 1980).

Research on Humans

Research on humans is accepted as justified but is governed by a strict stipulation in the way of its necessity, because of an inadequate animal model, its relevance, peer acceptance, informed consent, rules regarding suspension of the project if there was any adverse development or a withdrawal by the volunteer.

Informed Consent

This is difficult to define, particularly in the context of routine therapy or an operative procedure. Warning the patient about all the possible complications will scare away most patients from useful medical aid. The Supreme Court of Canada in 1980 justified informing only of special risks of the contemplated therapeutic procedure (Brown 1984.) On the other hand, a free informed consent will not absolve the clinicians from liability in the case of negligence. Some principles would apply to invasive investigative procedures. Consent for therapy for the benefit of the patient may not pose an ethical problem, but a procedure to benefit some other person or purely for research can be open to objections (Bankowski, 1982.)

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Consent in Children

It is not clear if a guardian can give a consent for an invasive procedure on a child which is not of direct benefit to it. What is more important is whether a child be permitted to die or come to serious harm, because an important parent withholds consent for a life saving or a vital procedure.

Research in children is permitted only for such studies which are exclusively for their benefit and cannot be done except in that age group. In older children it should be possible to obtain their consent apart from that of their guardian. Similar criteria will govern mentally unsound patients, patients in coma, etc. Question may also come up when research involves less sophisticated communities incapable of appreciating the nature of the trial. No trial can be done on false pretenses or misrepresentations. Prisoners are a closed community and a suitable group for trial, but on the other hand any research based on financial or other inducement or anyother considerations or would be not free consent and thus be illegal (Bankowski, 1982).

Placebos in Therapeutic Trials

Placebos have a place in therapy and also in double blind trials. However, if their use results in withholding proved beneficial treatment, it is open to objection.

Untried and New Therapeutic Procedures; Peer Acceptance :

In 1874, Sir John Eric Ericksen opined in favour of sanctity of the abdomen, chest and brain from the surgeon's knife. This was in spite of the fact that a successful laparatomy had been done in U.S.A. in 1814 and that intestinal surgery was performed by Sushrutha in 600 B.C If such authoritative opinion had been accepted, there would have been no progress in medical sciences (Aird, 1961).

Peer acceptance is important but it has to be remembered that top medical opinion in early nineteenth century declared Simla as unsuitable for Europeans because of lack of oxygen at those heights. Lice in boys' hair were considered part of masculinity. Smoking was considered good for the lungs on medical grounds and was introduced in public schools like Eton. Breast feeding was considered an imposition on women, only a few years ago.

Life Support Systems and Concept of Death :

Introduction of mechanical respirators in 1950 and cardiac resuscitations in 1950 have led to a large number of patient being kept 'alive' for months or years. A patients' committee in USA recommended defining death when there was an irreversible cessation of function of the entire brain, including brain stem. This has led to the anomalous positions such as in the case of Karen Ann Quinlon where higher brain function was lost but not that of the brain stem (Editorial Annals of Internal Medicine, 1983). Youngner and Bartlett (1983) favoured irreversible upper brain loss, i.e. permanent loss of consciousness and cognition as the criteria. Support systems are expensive and relatives may be unable to afford and may even feel disturbed at a irrecoverable relative being kept part alive to a vegetative existence. On

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the other hand, in the absence of clear cut guidelines, the hospital authorities may expose themselves to charge of murder, if patient is taken of such systems.

Sanctity of Human Life :

Social ethos in this context are paradoxical. It is patriotic to kill the enemy in war but to give him full succour and respect, if the person is taken as a prisoner. Dozens die in increasing civic unrest round the world, but a doubtful default in a patient care even with an irrecoverable illness may hit head lines and lead to serious difficulties for the physician. A number of individuals commit suicide when a political or screen hero is seriously ill, and this behaviour is aeccpted socially and seldom discouraged. Death due to social inequalities are common in the poorer countries, but most societies frown on euthanasia in any circumstances. Sanctity for life extending even after death to a cadaver or near cadaver, has a bearing in obtaining organs like the kidney for transfer as well as utilisation of cadaver parts such as cornea, blood, bone and split skin graft. Most of this material could be of great benefit to the living with no harm to anybody, unlike obtaining parts from live donors. Most donations, irrespective of what the declaration are for a consideration, social pressure, emotional involvement, financial inducements, media publicity, hero instinct, etc. Is it ethical to use a major organ from a live donor ? France forbids use of live donors (Holston and O'Conner, 1966). In India there appears to be no law in favour or against such donations and most countries do allow such donations after a suitable informed consent and psychiatrical or other assessment. There must be substantial safeguards, including a suitable heavy insurance for such donors.

Robertson (1983) has raised a pertinent point about loss of human dignity in an incontinent old person, unable to look after himself who becomes a social burden and source of embarrassment, since he might expose his body or behave or conduct himself in someother indecent manner. The family had built up an image of him through the years, of a highly revered and respected symbol in the family. This is lost causing lot of pain and anguish to all friends and relatives. Why can one not permit a will for self deliverance when one is in his senses ?

A similar case could be made out for patients born with gross congenital defects or incurable painful and distressing conditions, such as advanced malignancies. Are support systems justified in such cases ? Is it the physician's job to prolong the act of dying ?

Professional Etiquette

This is governed by rules laid down by the Medical Council and this governs advertising, responsibility of a professional act, conduct towards patients and fellow physicians, etc. Jurisprudence lays down laws regarding abortion, sex, marriage, professional liability and they may vary in the same country for different communities. There is also controversy as to how far a professional person is liable in his individual capacity and how far he acts as an agent when he is employed by an agency, such as the government, in which case the liability may also be of the

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employer and as a consequence he may lay down constraints on his professional work.

Commnnity Programmes Without consent

Community bodies also permit compulsory drugging in the way of supplemented foods, such as iodised salt or flour supplemented with calcium and enforced innoculations or vaccinations. Pollution of the environment is common and is often permitted by the community. Smoking in public places is a classical example and exposes a large number of unwilling people to passive smoking, which may be more dangerous, even then smoking by the individual himself. This exposure to drugs and chemicals is without any informed or uninformed consent.

Quackery

In 1551, Queen Elizabeth-I could not get Margaret Kennix, a traditional practitioner, registered with either of the colleges which had obtained the royal charter from her (Simpson, 1962). An association with an unqualified person was forbidden in the Hippocratic Oath. On the other hand in some countries, particularly the poor countries, traditional healers have a useful role to play and this has been well accepted by the WHO. Also with the present day highly sophisticated modern therapy, association with non-medical non-professional personal is inescapable.

Medical Ethics in Undergraduate Curriculum

In view of the complexity and wide range of the subject, it stands to reason that a suitable part of the curriculum should be allotted to exposure to it. Olukoya (1983) of the Logos University of Nigeria found that 88% of clinical students showed interest in the subject and recommended inclusion of this subject as a part of the curriculum. Givner and Hynes (1983) found a positive advantage in outlook of students exposed to medical ethics for three months. Cassidy, Swell and Stuart (1983) incorporated this subject as a part of family practice clerkship for the year IV year students. Thung (1981) emphasized exposure of medical students to the pleuralistic morality governing patient's acceptance of medical advice in the cognitive and non-cognitive fields. In the case of a child patient, he analysed the role of the child, parent, doctor and society in acceptance of treatment. Keller, 1977 recommended a course for residents consisting of 5 half days in I year, 3 days in II year and a day including an assignment in III year.

The present curriculum allows for two to three lectures on the legal aspects of the subject as a part of the forensic medicine curriculum. The first year students are exposed to 20 hours course in community medicine including sociology. Medical ethics is very akin to the subject and it is proposed that a 20 hour programme distributed between first to fifth year be introduced. Four lectures could be devoted to the definition of death, informal consent, etc. and could be part of the PSM teaching programme in the first year. The lecture programme for the jurisprudence could remain unchanged and be covered in 3 to 4 hours of teaching. Department of Pharmacology could devote one to two hours in relation to drug trials. Similarly the other clinical and non-clinical departments could

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devote one to two hours teaching programme in the ethical aspects pertaining to their specialities. The stress should be on exposure to the existing problems and taking into account the accepted norms of the society. This aspect can be evaluated as part of evaluation of the subject. The interns may be given suitable assignments during their posting in Community Medicine with the PSM department.

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Doctor Patient Relationship — The Neglected Domain of Medical Education

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ABSTRACTS

An analysis of the lacunae existing in the field of doctor-patient relationship during the training period of medical personnel revealed intresting facets many of them amenable to correction with little outlay of man or material. It appeared that a small shift in emphasis during training along with other miner remedial measures may go a long way in correcting this unhealthy state of affairs. An analysis of the existing problems has been presented and detailed suggestions made to evolve a strategy to rectify the same.

Introduction

The entire duration of medical training, undergraduate and postgraduate is concerned mainly with the cognitive and psychomotor domains, to the detriment of achieving proficiency in what might be the most important quality expected of the doctor, and perhaps the one most difficult to master, viz. an ability to establish rapport with patients and to communicate with them to the patients' satisfaction. At the termination of their training period the end products of medical education are left to acquire this proficiency in the affective domain entirely on their own.

This state of affairs is unfortunate, since doctors' work involves not only activity and decision making but also communication. It cannot be denied that currently there exists a profound communication gap between trainee doctors and patients due to lack of either ability (physical or mental), understanding or motivation which leaves the patient sometimes bewildered but more often dis-satisfied.

Much of the research on the relations between cognitive achievement and attitudes and values shows them to be statistically independent (Bloom et. al., 1964). This is illustrated by Mayhew (1958), who reported little relationship between attitude changes and growth of knowledge in a college course. Inspite of research and writings to the contrary by Tyler (1934, 1951), Furst (1958), Dressel and others there still persists an implicit belief that if cognitive objectives are developed, there will be a corresponding development of appropriate affective behaviours. Jacob (1957) has raised serious questions about the tenability of this assumption.

Bloom et. al. (1964) studied the history of several major courses at the general education level of college and found that in the original statement of objectives there was frequently as much emphasis given to affective objectives as to cognitive objectives and even small attempts were made to secure evidence on the extent to which students were developing in the affective behaviour. However, as these courses were followed, there was a rapid dropping of the affective objectives and an almost complete disappearance of efforts at appraisal of student growth in this domain, perhaps because it is easier to teach and evaluate cognitive objectives.

In medical college curricula in India also, institutional objectives often make mention of the need to develop certain attitudes in students but little if any effort is paid to this aspect of their training.

Evaluation material in the affective domain is rare and is usually connected to some national educational research project or a sponsored local research project (Bloom et al, 1964). In the medical curriculum evaluation work for effective objectives are non-existent.

A study conducted by the author amongst patients and colleagues, especially those undergoing training, to identify the extent and nature of this problem of lack of adequate rapport and communication between them and reasons for the general discontent amongst patients regarding doctors' attitudes to them, presented interesting facts. The study was initiated with the idea that if definite lacunae could be identified, remedial measures might be possible and could be incorporated in the training. For obvious reasons of affiliation of the author the investigations were mainly confined to surgical patients and surgical trainees.

PROBLEM

a] Patient's Problem

Questioning several patients in the hospital and during outpatient attendance revealed interesting findings. These problems recounted by patients and affectiag their faith and trust in doctors are mentioned below. These have recounted as far as possible in patient's own words.

i) Ununderstood "manipulations" especially investigative in "strange" surroundings with no explanations forthcoming from the treating doctors.

ii) Unexplained delay in securing definitive treatment e. g. surgery when compared to other patients whose turn comes earlier even though admitted later. This in many cases due to the necessity for detailed investigations in the individual case which are not conveyed adequtely to the patients.

iii) Certain beliefs regarding the lack of safety of surgery generally based on superstitions not cleared.

iv Need for surgery as opposed to nonoperative treatment not explained.

v) Fears and anxieties regarding surgery as a procedure—both endogenous and acquired as a result of watching/covering with other patients left to linger in them with the doctors apparently unaware of this fact.

vi) No information given after the operative procedure as to "what was done" and

"what is to be expected". In most cases they are left in the dark as to whether the surgery is palliative or curative. Is the procedure complete or does it require a second stage?

vii) Need to come for rutine follow up not explained adequately. This is directly responsible for the poor turn out at the follow up clinics as patients do not understand why, if they are feeling otherwise will, they should go to the hospital, perhaps missing a day's earnings.

viii) Reasons for sudden discharge sometimes not explained especially when symptoms have not been completely relieved. Is it for further investigations as an outpatient or is it because of incurable disease or because the patient is unfit for surgery?

ix) Doctors appear almost always to be extremely too busy to be disturbed with trivial problems.

x) Doctors are generally not available during visiting hours when the relatives of patients want to know more about the patients 'illness'.

xi) An important irritant to some patients especially those who are educated was in being referred to as 'a case' and never by name.

It is evident that most of the patients' problems stem from a lack of communication between them and the doctors. This situation may be peculiar to the developing countries. In the west most patients are aware of their right to know and understand what is being done to them and do not hesitate to exercise such rights. Such an atmosphere; naturally, develops certain attitudes in their physicians which is lacking here.

Trainee's problems

A similar study of junior colleagues mentioning the patients difficulties to them elicited the following responses.

i) Language—lack of ability to communicate in the "patients language". This mainly applies to central government institutions where doctors from all parts of the country work.

ii) A feeling that there is a lack of knowledge or desire on the patient's part to know about their disease. This was intriguing in view of the contradictory opinion expressed by the patients.

iii) Overlapping responsibilities since many doctors are responsible for the same patient's welfare and hence none feels involved personally.

iv) Lack of time, workload, tiredness.

v) Patient's relatives are not available except for a short time when the doctors would like to relax themselves after a busy day and hence an inability to explain to them.

vi) Extermely short duration of posting in each discipline during the internship and hence follow up of patients is difficult.

vii) An inability to follow the individual patient from admission to discharge due to frequent changing of the "patient's beds", within the ward itself leading to transfer of further responsibility in management to another doctor.

viii) An absence of any formal training in patient psychology at any point in the curriculum.

ix) The existence of a communication gap between faculty/staff/trainees due to lack of detailed discussion during or after rounds. Hence, the trainee himself is left sometimes unconvinced regarding correctness/advisability of the decided method of management. The trainees generally felt that they lack complete knowledge of the overall plan of management and hence could not communicate satisfactorily with patients even if they desire to do so.

x) Lack of material and aids including facility to recall previous patients to explain the need for procedures like colostomy and their compatibility with normal living to other patients waiting for such procedures.

It is apparent that many of the problems mentioned earlier are easily correctable with little outlay of men or materials. The following strategy is suggested as a workable model.

DESIGN OF STRATEGY

Extra resources required

A. Staff:

i) Mandatory—Nil as it mostly involves a shift in emphasis during training with existing staff.

ii) Optional—(a) It would be advantageous in certain special situations as in Central Government Institutions referred to earlier, if language instructions in the vernacular are available to the fresh entrants. Such facilities already exist at JIPMER.

a) The part time services of a clinical psychologist and more important of medical social workers are necessary. These workers should be available at least one per ward for one to two hours daily, if possible during visiting hours. The doctors will find it easier in some cases to accept their help in communicating with patients.

B. Ancillary materials-like simple audio-visual aids, health education charts, clinical photographs of patients with external intestinal stomas would enable the doctor to more effectively convey his ideas to the patients.

C. Planning-This would involve the following steps.

i) Inclusion in the curriculum of the undergraduate and all other trainees, instructions in the spoken form of the regional language, as opposed to the grammatical, right from the time of admission. Attendance at such classes should be compulsory and an evaluation system introduced to increase motivation for learning. Social workers may help in this regard. The period of training would last atleast for a year at not less than three classes per week. This of course is a minor problem and exists only in certain selected institutions.

ii) Impartment of basic training in patient psychology during the first year of the clinical course.

iii) Shifting emphasis during the internship/resident training period on the lines

suggested below. These constitute the major recommendations and do not involve extra resources.

Methods and Activities Required for Implementation

Implementation of the above at various levels would involve the following steps.

a) Personal example by faculty/senior colleagues. The importance of this single factor cannot be overstressed and it perhaps outweights in importance all the subsequent points.

b) Instituting as far as possible continuity of management from admission through the period of hospital stay, operative procedures etc. to discharge and further to follow up. In practice there is no allocation of individual responsibility and several ranks of trainees are involved in each patient's management performing tasks allotted to them according to their position in the hierarchy There is no shortage of personnel in a medical college for providing individual attention to patients, and since all doctors must pass through the portals of a medical college, the experiences gained during their training here is likely to affect a change in the future behaviour of all of them.

c) As an adjunct to the above, overlapping responsibilities should be avoided and trainees should be incharge of complete care with senior colleagues performing only a supervisory or advisory role.

d) Trainees must be encouraged to be the primary focus of contact with patient—i.e. all information must be passed on to the patient through them. This is extremely important in view of the fact that they spend the largest duration of time in the wards with the patient.

e) Institution of detailed discussion on all patients especially those whose management is individualised, unusual or controversial. between faculty and residents. This must be done atleast after every admission day or once a week, preferably outside busy hours. This will give confidence to the trainee to communicate with the patient as he will have the requisite background knowledge.

f) Institution of two different types of clinical rounds.

i) Teaching/academic conducted during working hours.

ii) Service rounds devoted entirely to patient management. These should preferably be held in the evenings when deadlines do not have to be met for sending investigations filling up requisitions etc. Part of the service round atleast, should overlap visiting hours. In the presence of relatives patients feel freer to interact with doctors. Undergraduates posted in the department should be asked to attend these service rounds so that they learn by example.

g) Provision of aids (charts, materials) to trainees so that they can be used for demonstration to patients.

h) Provision of facilities to recall certain types of patients at hospital expense (e.g. colostomies) for demonstration to other patients.

i) Trainees should be encouraged to visit and follow up some of the patients living nearby. This impresses on patients the fact that doctors care for them and on thetr part the need to go for a follow up.

Departmental and institutional cooperation needless to say is mandatory.

Evaluation

There are a great many ways of assessing people's attitudes, the more sophisticated of which are known as attitude scales (Oppenheim, 1966). A considerable part of the hesitation in the use of affective measures for grading purposes stems from the lnadequacy of the appraisal techniques and the case with which a student may exploit his ability to detect the responses which will be rewarded and the responses which will be penalised (Bloom et. al. 1964).

However, in the facet of doctor-patient lnteraction, no system of evaluation is required. Complex abilities in the cognitive domain may be learned in a short time and the evidence of learning may be seen at the end of the course. In contrast interests, attitudes and personality characteristics are assumed to develop relatively slowly and to be visible in appraisal techniques only over long periods of time, stretching perhaps to years (Bloom et al, 1964), The only sure guide to success of the plan would be an appreciable change in patients' feelings and response over a period of time.

An important cause of the lack of healthy patient doctor relationship is inadequate motivation in the trainees apart from the factors mentioned earlier. It is suggested here that the learning experiences must be of a two way nature in which both trainees and teacher are involved in an interactive manner learning by experience and example rather than having one present something to be "learned" by the other (Bloom et al, 1964). Such an atmosphere of personal example by senior staff will go a long way in bringing about the desired change in attitudes of the trainees.

It appears that a small stress in emphasis during the formative period of training can go a long way in correcting this lacuna in patient-doctor relationship. Many of the recommendations here apply to postgraduate trainees but can be applied with modifications to suit undergraduates and interns.

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MEDICAL MALPRACTICE : WHAT IT IS AND HOW TO FIGHT IT

(Report of a Workshop)
Medico Friend Circle (Bombay Group)

Introduction :

Rapid proliferation of private medical care sector in last two decades in our country has brought in its wake the menace of medical malpractices. Medicine has become a business. 80 % or more of the health care services are in the private sector which operates in an unregulated market. Compared to the other business, medicine has ill(eputation of being more capable of generating what is called 'Supplier induced demands.' In a way, the malpractices were always a part of medicine but so far it was belived that they were curbed by the internal regulations of the profession or perhaps they were kept under the lid by people's apathy and by their blind faith in the noble character of medical profession.

This is no longer so. The medical profession's credibility is nose-diving. The people have awakened to the reality of malpractices and they are angry that many in the profession are now behaving as merchants of death and diseases. However very few have clear idea of what is malpractice and what to do when victimised by the malpractice. Hence, the Bombay Group decided to organise this workshop on September 9, 1990, Sunday, at ICSSR Seminar Hall, JP Naik Bhavan, Bombay University Campus, Santacruz East, Bombay.

The invitation letter for the workshop made an attempt to define medical malpractice. It was suggested that discussing malpractice was essentially a discussion on a larger aspect of medicine, namely, the medical practice. The Medical malpractice was, therefore, in its broadest meaning, defined as " a variation (it can be graded) from the normally acceptable, scientific and average standard of medical practice at a given point of time."

Organisation of Workshop:

A packet of background material was prepared for the participants. It contained : (1) "Irrational and Unethical Medical Practices" by Dr. Mohan Deshpande (2) "The Political Economy of Medical malpractices in India" by Ravi Duggal (3) "Patient's Right" by Anil Pilgaokar (MFC Bulletin No :146, Dec. 1988) (4) "Medicine and Law" issue of Radical Journal of Health (March 1988), particularly "Medical Malpractices and Law" by Mihir Desai.

The workshop was conducted in three sessions. (1) Irrational and Unscientific Medical practices: This session discussed the variation from rational and scientific curative medical care which was harmful to the recipient. The pre-workshop coordination of this session was done by Dr. Mohan Deshpande. He, along with Dr. Anant Phadke (Pune) made presentations while Dr. Dhruv Mankad (Nashik) chaired the session. (2) Negligence In Medical Practice: The pre-workshop coordination as well as the chairing of the session was done by Dr. Amar Jesani whereas Dr. Pritam Phatnani (a well known forensic scientist from Bombay) and Mr. Mihir Desai (advocate, Bombay) made presentations on the subject. (3) Future Programme : Discussion, Action and Organisation: This session was coordinated and chaired by Ms. Annie George.

The workshop was attended by sixty two individuals comprising of medicos, Social workers, health workers, activists and journalists.

I. Irrational and Unscientific Medical Practices : (IUMP) :

IN his presentation, Dr. Mohan Deshpande, identified five areas of irrational practices, namely, (1) while actually treating/investigating patient (2) While diagnosing the ailment (3) concerning the relationship with the drug industry, (4) concerning other doctors and (5) miscellaneous. He grouped irrational practices in these areas into three categories. (a) Overt and intentional, wherein the doctor knowing fully well that what he/she is doing is irrational, resorts to it for some other gains (money, prestige, holding on the patient etc.) (b) non-intentional: Here doctor is ignorant of the irrational nature of his practice. (use of banned or bannable drugs, anti- cold preparations having multiple drugs in them etc.) (c) Gray areas: The interphase of irrational and unethical practices (high rate of caesarian due to over-cautious approach, use of routine ECG, sonography done on all pregnant women etc.). He gave numerous examples of irrational and unethical practices to support his arguments. He concluded his arguments by stressing the need to study epidemiology of irrational and unethical medical practices.

The second presentation was made by Dr. Anant Phadke (Pune). He concentrated on identifying irrational practices on priority basis so that a group like MFC can tackle the problem in an effective way. He suggested three criteria for identification. Firstly, how common is

the malpractice? Secondly, what level of harm (financial and physical) does it cause? and Thirdly, Is it amenable to action in short or medium term (say in a year or two)? He also connected this to the availability of human power, expertise, resources and time with us. He recommended four areas for beginning the campaign. (a) Over-the-counter (OTC) drugs (b) Misuse of injections (c) Misuse of intravenous injections (d) Screening tests for people who have no clinical symptoms. For the last he gave example of ECG (electrocardiogram) which is used as screening test for people over 30 yrs. of age. He argued that such test is giving significantly high false positive diagnosis of heart ailments. Similarly he mentioned misuse and wrong use of stress test (to detect heart ailment) and angiography (where patient is not informed of costly operation needed (if the test is positive). The also raised hissue that at many places the cardiac monitor is kept as cosmetic device to fleece the patient as such hospitals don't have a trained professinal to monitor the cardiac monitor.

The presentations were followed by intense discussion in which many participants asked questions and raised new points. The contribution of participants is summaraised below:-

(1) Why to restrict only to the allopathy? Is it a Malpractice when a non-allopathic healer practices allopathy in a village where allopathic doctor is not available? (2) Is the use of PAP smear as a screening test (like the ECG) irrational and harmful? (3) What is the role of drug and instrumentation industry in encouraging malpractices? (4) How relevent is the text-book knowledge in actual practice? Is there a need to change syllabus in medical education? (5) There is a target oriented approach in certain govt. health programmes, eg, Family Planning. Is such an approach a malpractice? Similarly there are certain industrial malpractices affecting people's health, e.g. Bhopal gas disaster. Do we include them in our struggle against malpractices? (6) There is one doctor (of all systems taken together) for 800 -900 persons in the country. However there is overconcentration of them in urban areas. This leads to overuse of medical care in urban areas and underuse in rural areas as in the health care, there is supplier induced demand. Further, unhealthy competition in the urban areas is leading to "criminalisation of medicine." Three examples from Bombay were cited. Firstly, murder of a doctor by the goons of other doctor. Secondly, a cardiac surgeon was stabbed by goons of another doctor. Thirdly, increasing investment by builders and mafias in the nursing homes. (7) Irrational use of medical technologies in the urban areas whereas the same is not available for even emergencies in the rural areas. Two examples, first, the sex determination used for female foeticide but not made available to women in Bhopal who needed it to detect genetic defects due to gas effect. Second, cesarian section overused in urban area but not available to rural women when they really need it. (8) Is the structure such that malpractice is inevitable ? for instance, it is difficult to get rational single ingradient drugs. (9) There is a political aspect of malpractice, e.g. the doctor colluding in torture in jails, lock-ups etc. (10) There is no stringent internal regulation of medical profession, nor thereis regulation of medical care market. Doctors are dependent on the drug industry for information. Very few subscribe to medical journals and read them. While drug industry targets doctors, the instrumentation industry is directly approaching people through media. (11) Doctors can be educated by other doctors. For this, build credibility of the MFC in minds of doctors. (12) A mass educational programme of people on drugs and diagnostic procedures is needed. (13) The doctor's education should begin with unintentional irrational practices and after attaining some success, should embark an education on intentional practices. (14) Demand standardisation in health care, right to information, question the role of institutions like ICMR in perpetuating malpractices (e.g. infertility and in - vitro fertilisation, NET- EN injectable contraceptive etc), the manufacturer's "insert" should not be "jargons" but in simple language that the patient can understand, and so on. (15) The consent form for procedures should be case specific and must have full details of the pros and cons of the procedure. The same should be explained to the patient. (16) The drugs distributed in medical & diagnostic camps are irrational (17) The doctors cannot refuse to treat serious (e.g accident) patients (18) For "good" doctors it is not suffient to follow ethics. They must make their 'passive ethics' into 'active ethics' and thereby join forces with the people affected to bring about changes in medical practice.

Dr. Dhruv Mankad, the Chairperson, summarised the discussion and identified issues for discussion in the third session.

II Neglegence In Medical Practice:

Dr. Pritam Phatnani made a detailed and informative presentation. He started with the question of how to define negligence and then explained the remedies available to the patient.

Negligence is a legal concept and comes under the law of tort. When A owes duty of care of B, and there is breach in duty and B suffers harm, A is said to be neglegent. Thus there are three basic ingradients, (a) duty of care to patient (b) dereliction of duty (c) patient suffers damage directly due to the dereliction of duty. Thus, legally, if there is no damage, there is no dereliction of duty. For instance, if hands are not scrubbed and needle, syringe,forceps a not sterilised before giving injection, and there is no harm coming patient due to such 'malpractice' legally, the doctor is not neglegent.

When there is harm sufferred, the aim of civil law is to monetarily compensate the person who sufferred the harm. Whereas,the aim of criminal law is to book the doctor, but in such case the patient must prove beyond doubt that a particular doctor committed the crime. In the Civil case, the onus lies on the patient to prove harm and it's connection with the negligence. Thus, there is a preponderance of evidence.

About medical records, he said that there is no specific law in our country but it is assured that records belong to the doctor (in private practice) and to the hospital (in case of hospital case). However, some participants disputed this assumption and argued that it can be successfully challenged, using the constitutional rights.

The concept of reasonable case is related to the qualification and experience of doctor. Moreover, the doctor is duty bound to keep pace with advances in medical science. In case of camps (eg. eye camps, FP camps), if there is any mishap, the organisers can be held responsible. The product liability (in our case, eg. drugs) lies with the industry. The industry is supposed to inform the doctor who in turn is liable to inform patient. Legally, in private practice, the doctor has a right to accept/refuse patient on certain grounds but the refusal should not be discriminatory based on caste, religion, race etc.

Doctor's 'duty of case' starts from the moment the patient accepted as his/her own by the doctor and not necessarily that fee is charged. The doctor patient relationship is governed by law of contract. There are certain features of contract. (1) Both the parties should be competent to enter contract (2) they should be doing it willingly (3) the contract has it's dos and don'ts, ie, to do certain things and not to do others (4) a breach of it is liable for compensation (5) the contract is about something needed. Once the "duty of care" starts, the contract comes into existence. The doctor must take history, examine patient, carry out tests to diagnosis, reach provisonal and confirmed diagnosis, treat the patient. If the doctor does not do any of these, there is breach of duty. The medical record must contain information on all stated above. In addition,it should have if any, opinions of treating doctor, consultants etc. and in case of death, post martem report. However, wrong diagnosis alone is not negligence provided, all steps and procedures stated above are properly followed. At the same time it should be kept in mind that there is a thin line dividing genuine error of judgement and negligence.

How long are the medical records maintained/preserved? There is no definite law. However, one can file a suit within 3 years from the date of occurance of negligence or from the date of discovery of negligence, whichever is later. In case of children, the suit can be filed 3 years after attaining majority, so in the case of children, the medical records ought to be preserved/maintained for longer time.

The doctor cannot treat patient against will, hence, consent is essentail. But the consent does not absolve doctor of the charge of negligence. The consent has six ingredients, all of which must be fulfilled. (1) the patient must be competent to give consent (i.e. above 18 yrs, mentally sound etc.) (2) it must be free (voluntary) consent (one cannot use duress, fear of life or death etc) (3) it must be informed consent, i.e. the patient must be informed of procedure in language and words he/she understands. The information must include advantages and disadvantages, other alternatives, etc. The final choice of selecting from alternatives must be that of patient. (4) it should be intelligent consent. Thus, it is not sufficient to give information, but the doctor must cross-check to find out that the patient has properly understood the information provided. (5) The consent must be specific, i.e. specific to the procedure undertaken. If another procedure is to be done, new consent must be obtained. (6) It must be expressed consent ; i.e. in writing. Normally, for surgical procedures (diagnostic or therapeutic) expressed/written consent is obtained. But for medical examination, giving injections etc. the consent is supposed to be implied if patient volunteers to undergo them.

Dr. Phatnani explained that in our country the law of medical negligence is only recently used, and therefore, it was necessary to select "good" cases to develop the law for taking legal recourse against irrational practice, he identified two ways, (a) When there is side effect due to unnecessary/ irrational medication (i.e. patient is harmed), it can be construed as harm due to negligence (b) it can be said to be tresspass against the body.

The second presentaion was made by advocate Mihir Desai. He informed that law on medical negligence is a judge-made law. Thus, unless more cases are tried till the end, the law can not be properly developed. He explained that the doctor never guarantees correct diagnosis/care. But guarantees correct method to reach diagnosis and to take care.

What is standard care? How is it measured? It is time and location specific. In the developed countries it is only time specific as location - wise the same standard is demanded. However, perhaps, the locality rule may apply in India as say for example, the facilities available in the rural and the urban areas are different.

The Civil law is used to get damages from individual doctors or the hospitals. Especially when more than one doctors are involved in care, the law of vicarious liability is used to sue the hospital. In criminal law, only individual(s) can be sued because the hospital can't be jailed. One can go to the medical council when unethical practice is involved and there the maximum punishment for the doctor, if proved guilty, is deregistration.

About medical records he agreed that there was no specific law but argued that one should fall back on constitutional law. Normally now the court instructs hospital to get the records. But this should be recognised as patient's right, and if the medical record is withheld from the patient, it should be considered a criminal offence.

III Future Programme : Discussion Action and Organisation

The session chairperson, Dr. Annie George, with the help of Dr. Dhruv Mankad identified following issues which emerged from the previous two sessions for discussion.

Issues for Action : (1) Drugs, particualarly over- the counter drugs (2) Screening tests (eg. ECG, Pap smear etc) (3) Self regulation of medical practice by the profession. (4) malpractices in medical research (5) Malpractices related to human rights violation (6) target orientation in health programmes, 'Camp' approach etc.

Methods for Action : (A) Demand based campaigns (1) right to information (2) standardisation of medical facilities and charges (3) guidelines pertaining to duties of doctors in the case of human rights violation (eg. torture) (B) Educational Campaigns : (1) Know your health rights (2) Consumer awareness (3) to reach out to people through media, particularly, vernacular press. (C) Individual litigation : (1)helping victims of malpractice in fighting suits (2) filing public interest litigations.

In the discussion that ensued, there was a general agreement on all except one, namely, to get involved in individual litigations. The discussion on this area of disagreement was sharp and heated, primarily because the Bombay Group is already involved in this method of action. Two viewpoints came to the fore and as it happens with such strong disagreements, the workshop could not satisfactorily resolve them.

The first position was not principly against undertaking individual litigation but felt that it should be taken up afterwards at an appropriate time to produce desired effect. In support, this position advanced following arguments : (1) We are a small group, our first task is to attracts doctors to our cause. (2) This can be done best by starding with unintentional irrational practices. (3) Individual litigations would demand lots of time, energy, study and labour. It would also involve fight against corrupt medical and legal estblishments. There is also a possibility of threats, goondaism, victimisation etc. (4) the struggle against malpractices can make an impact only if we have a critical mass of doctors to be part of struggle. In order to do so, a strategy must be worked out. Such a strategy must prioritise tasks keeping long team implications.

The second position not only thought it appropriate to take up individual litigations but considered it as a better strategy to attract commited doctors to the movement. Following arguments were advanced : (1) Individual litigations also bring out general issues like right to information, what regulations for nursing homes/hospitals etc. (2) Once we educate people on their health rights, we should be with them when even one of them wants to take legal action. (3) We are neither pro - doctor nor anti - doctor. The issue is that of malpractice. Those who are against it are with us, the rest not. (4) We can't create critical mass by taking "soft" issues, because those who come for "soft" issue may desert us when we take up "hard" issues. Thus even those ethical practitioners who don't stand up against malpractices are weaklings and will ally with the establishment. (5) Only a sharp compaign will polarise the profession. (6) Can we, ethically, refuse our help to the victims of malpractice ? (7) The best way to win over reluctant ethical practitioners is to have strong campain against their harassment and victimisation.

The discussion ended without resolving the issue. But it was agreed that the Bombay Group will continue with its work on malpractices and the same can be reviewed from time to time.

It was also unanimously agreed that MFC should coordinate with other individuals and organisations to develop effective campaigns on the issues identified at the workshop.

Report prepared by Amar Jesani, from the notes of Dhruv Mankad and Saraswathy Anantaram

(Note :- The workshop background material is available on payment of Rs. 20 =00 to The Coordinator, MFC (Bombay Group) 310, Prabhu Darshan, 31,S. Sainik Nagar, Amboli, Andheri West, Bombay - 400058, Tel: 6230227)

Editor's Note

Malpractices-Intentional or otherwise - in medical care have by now become a serious public health problem and not confined to individual clinics or happenings in isolated surgeries. Agressive over-use of drugs and other interventions, bleeding the patient for money, rackets of referral, negligence have all acquired gross proportions in the medical bazaar monopolised by doctors of all hues and degrees; although it is heartening to note that there are many who are willing to stem the rot.

That Bombay MFC group has embarked upon a real fight is quite evident from the accompaning article. Bombay is the commercial leader and its practices and malpractices are picked up sooner or later by professinals elsewhere and in this sense it is a fitting start in the right place. While writing this editorial I also feel that it is a duty for all like minded activists to help the

cause, so that the group does not experience isolation.

The Bombay group will no doubt go into the intricasies of malpractices that are commonplace to Bombay and similar situations. But there is a rural dimension too. To start with the current legislation, even if enforced meticulously, can not obviously take care of the rural situation. The existing legislation generally appears to protect the right of the patient (only the qualified doctors should diagnose, treat etc.) but its original historical purpose was to protect the interests of the medical profession, (and 'weed out' the non-professional health care) and this element persists atleast as a side effect. This effect would be all more obvious if we imagine the rural situation. First of all the rural areas are underserved since qualified doctors are unwilling to work in rural areas. Majority among them are non allopathic but would use nothing but allopathic drugs. What do we make of this situation ? Eulogise this ? Ban this ? Regulate this ?and how ? I think the current legislation can not allow this but law enforcement is absent from the scene. Secondly, we have to make a due legal slot for our ANMs, Health Workers etc., if we are to squarely face the paucity of services for rur al communities. The law is nearly mute in this (except the statement on midwifery services that are deleted from medical Intervention)

For the average rural general medical practice I would like to mark out these as problem areas (1) Not diognisingthe sickness, or making a wrong or 'too late' diognosis - all this is usual with the non-allopathic practitioner. (2) Overuse of antibiotics including higher antibiotics (3) Overuse of useless drugs - like tonics etc. (4) Overuse of steroids and some other select catagories (5) Unnecessary Injection - almost each patient receives and injection or two. (6) I/V infusions for any and every occasion - now this is the most popular means of making quick money - Rs 60 to 100 a bottle within 15 -20 minutes - 10 such patients a day and the doctor touches thousand Rs a day practice. (7) Subjecting patients to unnecessay referral to obliging consultants and thus carrying more of hysterectomies, tonsillectomies, appendicectomies and other procedures. (8) Exhorbitant fees.

So here is a strange situation - ignorance and yet agression on the part of the doctor; and ignorance and helplessness of vulnerable community.

So for the rural situation,- this is my personal opinion - following line of action should serve well.

1. Necessary changes in legislation to accomodate package of allopathic drugs and procedures in non-allopathic practitioners range of services - with due training and certificates etc. ; also fixing the rates of fees for particular services. And ofcourse strict enforcement.

2. Accomodate health workers (in a minimum essential cur role) in the legislation- fixing a list of drugs & procedures

.3. Regulation of private clinics/ Nursing homes

4. Community education in select topics of strategic importance e.g. I/V infusions, injections, Antibiotics, select clinical conditions capable of becoming mothers. By involving ANMs as motivators in (diarhoeas, Pneumonias),services available at PHC etc.

5. Strict Regulations of medical stores - prescription etc.

6. Sample audits of cases/ rcords etc by medical college staff/Directorate of Health Services (?)

7. And atleast one institution (RH) in a block that ensures good quality medical care to the community without malpractices & negligence.

THE WILL TO SURVIVE : Aditi Iyer

How Auxiliary Nurse Midwives cope Within The System

Sr Renu was deserted after 14 years of marriage. Her husband, a taxi driver in Bombay, had an affair with another woman. When he left, Sr Renu's whole life changed. Till then, her existance seemed to revolve exclusively around conjugal and domestic duties. Earlier, when she wished to teach in a Primary School, the choice was denied to her by her pregnancy -one in four - and her husband's refusal to grant her permission. Finally, after 14 years (and four children), with nothing but a Std 10 education, Sr Renu was thrown to her own devices. She heard of nursing and the ANM's course and though she knew nothing of what the job involved, she recognised the potential of being economically self sufficient. This was to be a regular job. A job she needed very badly .....

Sr Shanti was married to her cousin while she was still in school. This was an arrangement worked out by her father who had only a modest income coming through cultivating 7 acres. This was countered by the additional responsibility of building up dowries for his 5 daughters. However, Sr. Shanti has reason to rue her life. Her husband soon started making dowry demands and when these could not be met, he started using physical violence to bully her. He was unemployed, had a drink problem and gambled. Finally, he went on and married for a second time leaving Sr. Shanti nursing feelings of vulnerability and anger, a few broken teeth and a stunned sensibility that she must somehow get on with building her life again. By the time she applied for the D.Ed course, she was rejected because of her age (she was over 26 years old at that time), and was declared as being "unelegible " because of her declaration of her marital status in the necessary forms.

This was during the mid 1980's when an expansion of the health infrastructure was accompanied by a shortage of nursing personnel. Sr Shanti applied and got in as an ANM. Since then, she has managed to support not only herself and her children but has been able to contribute substantially to the upgradation of the family land. She depends on the health services for her livelihood and can't afford to let it go .....

The fact that ANM's play a subordinate role within the administrative and functional structures of the health services is obvious enough. The knowledge that empowerment of women is only partially achieved by participation in the labour force is well known. What makes ANM's like Sr Renu and Sr Shanti more vulnerable is the fact that their lives are precariously dependent on their jobs.

This article strings together the experiences of a few ANM's as they try to cope in a spirit of survival, within a system that empowers them on the one hand, while creating and justifying their subordination on the other. This information has been gathered while travelling through four districts of Maharashtra : Pune, Wardha, Beed and Ratnagiri.

In the PHC approach to health care, women are viewed as mere targets - especially those women who are mothers or potentially the Family Planning and MCH Programmes, the bureaucracy uses its women workers to circumscribe the scope of 'motherhood' - the "idealised state of being for women"! - within those definitions that are approved by the State.

This creates problems for ANMs.

Sr Renu, who works in a tribal PHC of Pune District, was faced with some truisms when she set out to explain sterilisations to some al women. They faced her and said, "you do not want us to have _ _ sons. Alright, give us yours then." Sr Renu was shocked and her son who was accompanying her was upset on hearing this. Later, she had a hard time assuring her son , who was already disturbed by the changes in the family, that she did not intend to send him away.

ANMs live on the edge both within the health services and in the community as well. The health bureaucracy is quick to penalise their workers for not fulfilling targets yet take little care to ensure that adequate supplies and support services reach them. ANMs work within these constraints, with limited resources, but a determination to build up legitimacy and respect for themselves.

ANMs do curative work in a limited sort of way. Most of the time, they do not have adequate medicines to last them through to the end of the year. Given the distances that need to be negoclated inorder to reach a dispensary, people look towards the ANM for their supply of medicines. When stocks of medicines do not suffice and the ANM is forced to send patient away, she is charged with being involved in their welfare for selfish reasons.

Sr. Lata, like Sr.Shanti, is acutely aware of this. In order to ration stocks, she gives her patients less than to the prescribed dosage - 2 tablets instead of 4 - and takes care never to question the authenticity of the complaints of her patients. That way, she projects herself as being a person who can be trusted upon when they need her. In cases here medicines do work, they provide her patients with temporary ief. Nobody goes back empty-hended after approaching Sr. Lata and she is richly rewarded by their respect.

Owing to the primacy that is placed on the Family Planning work over all other activities, many ANMs draw up the link between the two in their own way. So much so, that their involvement in deliveries , Immunisation, ANC/PNC are perceived as preconditioning factors for motivation. Sometimes, curative work is also placed within the perview of family planning.

Sr Anandibai, a veteran in her 50's has had to use her wits to survive in the system. Her medicine kit is more incomplete than complete. Instead of having to explain her inability to provide medicines, she has set up a small private practise in the village. she purchases vials of basic medicines and administers injections to her patients. When it comes to charging them, she forfeits her "fees" from those who have had operations registered under her name and charges Rs.4/- from those who haven't done so.

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I, Sham Ashtekar declare that the particulars given above are true to the best of my knowledge.

Dated : 31-3-1991

Sham Ashtekar
Publisher.

In the face of unrealistic targets, some ANMs are compelled to show fake cases of Copper T, oral and nirodh. However, not all ANMs are ready to challenge the necessity and value of having targets in their work.

Sr Shanti takes a moderate view as she looks at problems within the system. She says, "If targets are removed, some ANMs will work, some won't. Targets are needed but the authorities should be less rigid about it than they are now. The way targets are enforced, the pressures it creates, makes ANMs do "khotha kaam". So instead of spending so much money on copper-T's all of which may never be inserted, the government should concentrate on supplying adequate meicines and injections to us."

Sr Renu, on the other hand, questions the system within which she is being made to function. She states categorically, "I'll tell you the truth. Where I work, people have no demands from us. They work so hard that they have no time to think, let alone ask for health care. They have no time to be sick. What they need is a release from poverty, not family planning!"

Family Planning, especially the target approach, has set up the practise of depersonalised involvement. This is particularly apparent in Wardha and Ratnagiri.

Sr Lata, who works at Wardha, is just one person among several others vying for targets. The teacher, talathi, gram sevak, the second Medicial Officer and compounder have the same interest in seeing that their targets are completed. This sets up a market situation at the villae level where the price for an operation is set up according to the competition prevailing at the moment. For ANMs, this works out to Rs.200.00 per case as her personal contribution in addition to the official rate of Rs.130.00. Further, this practise is fully endorsed by the authorities at the PHC level who evince more interest in ensuring that targets are being completed rather than understanding the mechanisms that are brought to play in the process.

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MEDICO FRIEND CIRCLE BULLETIN

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Sr Lata, however, is lucky. She pays an average of Rs.100.00 per case. This is because of her policy of looking after every need of her subcentre population. By doing this, she ensures that her family planning work is simplified - and made cheaper - for her.

For Sr Sulochana, family planning has become the bane of her existence. Sr Sulochana, a Gond woman, took to nursing so as to strengthen the family's economic position and to protect herself from the marital disharmony that she was experiencing. She imagined that her life would be easy after she started working. Unfortunately for her, her life has been far from smooth.

When she joined the services, she was taken on as a temporary member of the staff with a 11 month period of probation and the possibility of being removed from service without being assigned any reason. Her term ended in December and three months later she was dismissed without intimating to her the reason.

Sr Sulochana attributes this to the fact that, in the 13 months of her service, she was able to complete only one case due largely, to the unfamiliar nature of her job and its accompanying apprehensions.

For Sr Sulochana, this meant more than losing a job. It meant a loss to her newly found freedom. She didn't have a union to go to for redressal and so fought her battles alone. With the help of her neighbours who were lawyers, she filed a case in the high court but the proceedings, far from questioning the rationale of targets, implicated her "non-performance" and begged for reinstatement.

Since her reinstatement, Sr Sulochana concentrates on surviving within the system, having been made a victim of it once. She concentrates on family planning to the virtual exclusion of all other activities. As part of her motivational strategy, Sr Sulochana promises and conducts follow up services which takes the form of weekly injections of B Complex. She does this with her own syringes without always taking care to sterilise the needles after each prick.

In spite of creating an effective work record, Sr Sulochana is still issued 6 monthly orders. She has yet to complete 6 months of the Step Ladder Course (she doesn't get certificate till then). And she can't become permenent till she completes the course. She has been moving around in cicles inspite of making a number of compromises in work. Sr Sulochana angry and alienated from her work and with good reason. She is never sure for how long she is going to have her job and the thought of returning home and to her old life scars her immensely.

ANMs in Wardha District have felt the absence of a strong union very strongly. Suspensions or the threats of suspension have become a recurrent feature in their careers. They live constantly in a state of tension and wonder when turn might come next. Some of their colleagues have been brutally raped and murdered.ANMs accuse the DHO's office of doing nothing to help matters for them. No inquiry. No promise of support to new recruits who fear their safety. At Ratnagiri, the CEO calls ANMs "administrative nuisances" and feels that motivation is a bad word in a democracy that has no discipline. He laments that the country is going to dogs .....

The bureaucracy feels that it is helping ANMs, but by the attitudes and indifference of its officers, no trouble is being taken to find out the odds under which ANMs are compelled to work. Workers' Unions, like the ones in Beed and Ratnagiri, provide some solidarity but tend not to look beyond the confines that are drawn up for nursing within modern medicine. Their victories are translent and their battles are never quite finished. What needs to be done is to help ANMs look beyond the next hurdle the next case for family planning or the next immunization camp - and to question the assumptions that underlie all that they do in the village community

CORRECTION

The theme for the forth coming Annual Meet (September 5, 6. 7, th 1991) at Bombay is " Private Sector In Health Care : A need for regulation

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POLICY STATEMENT ON ETHICAL CONSIDERATIONS INVOLVED IN RESEARCH ON HUMAN SUBJECTS

INDIAN COUNCIL OF MEDICAL RESEARCH
New Delhi 110016
February 1980

INTRODUCTION

There is at the moment considerable medical research being carried out on human subjects at different centres throughout the country. It is expected that the number of clinical investigations undertaken on volunteers and patients would increase in the coming years due to a number of reasons. It is being increasingly felt by scientists, clinical investigators and national health authorities that the resources of the country should be utilized for carrying out research that would be relevant to large numbers of persons living in rural areas in order to develop appropriate health measures for such persons. This would result in an increase in the epidemiological and sociological oriented research involving large numbers of individuals. Further, there is growing awareness in the scientific community that results on experimental models are not always predictive of what would eventually occur in the human and that a few well controlled investigations on a limited number of human subjects for a relatively short duration would yield much more relevant information than a large number of animal experiments carried out for a longer period of time. This awareness and the fact that in certain areas of research there are no animal models at all would lead also to increasing number of human subjects being involved in clinical research. Finally, research on clinical evaluation of remedies used in indigenous systems of medicine and on plants reputed to possess therapeutic properties is also increasing. This factor together with the continuing need for clinically evaluating new drugs developed in national laboratories and institutions and in pharmaceutical houses both in India and abroad would again require clinical trials to be carried out on human subjects throughout the country.

In addition to the increased quantum of medical research being undertaken on human subjects, the scope of clinical investigation has also undergone a change in the last decade. The type of experimental procedures that a patient is submitted to has become more complex and varied as the complexities of medical research have increased.

It is clearly understood that it is essential to carry out research on human subjects if progress is to be maintained and better medical and therapeutic modalities discovered for the benefit of man. It is equally clear that such research on human subjects and patients is associated with some degree of risk to the individual patients or volunteers. The Indian Council of Medical Research (ICMR) feels that in view of the increasing research being carried out on human subjects and the ever widening complexities of medical research, guidelines for experimentation on human subjects in the country are required to make certain, as far as possible:

- that the rights and welfare of human subjects on whom experiments are carried out are adequately protected;
- that the risks to an individual are outweighed by potential benefits to him or to society or by the importance of the knowledge to be gained;

- that informed consent is obtained from the individual by methods that are appropriate and adequate;

- that the clinical investigation on human subjects is carried out by an investigator who has the requisite background and competence to carry out such research; and
- that the investigator has a framework for obtaining advice, support and assistance from his peers before embarking on a particular clinical research programme.

It is hoped that these guidelines formulated by the Central Ethics Committee of the Council would assist investigators involved in clinical research to plan their clinical research in accordance with the principles enunciated in the World Medical Association Declaration of Helsinki (1964) as modified by the 29th World Medical Assembly at Tokyo in 1975 and the Nuremberg Code which has clearly laid down the ten principles to be kept in mind when conducting research on humans. It is expected that the guidelines would protect volunteers and patients participating in clinical research from being exposed to unjustified hazards and risks during their involvement in the research project. These would also protect clinical investigators and researchers by enabling them to obtain support from their peers for the research they intend to carry out.

INSTITUTIONAL ETHICAL COMMITTEES

The Council feels that clinical research on normal volunteers or on patients, whether for therapeutic, non-therapeutic or diagnostic purposes, should be undertaken only after an ethical committee of the concerned institute or college has gone thoroughly into the proposed research, assessed carefully the balance between the possible benefit to the patient/volunteer or to society and the potential risk to the individual participating in the trial and on the basis of such an assessment has approved the project from an ethical point of view.

The Council would, therefore, urge all medical colleges and research centres involved in clinical research to form ethical committees if they do not already have a functioning ethical committee at the moment. The ethical committee should consist of experienced clinicians who have been carrying out clinical research and clinical evaluation in the past, should have on it an expert on drugs and one or two non-medical persons who could provide guidance to the committee in the matter of ethics and law. Wherever possible, a lawyer or a judge should be a member of the institute ethical committee. It is suggested that the ethical committee be kept fairly small (5-7 members) but that appropriate expertise available at the centre, in the region or the country be consulted wherever necessary. The ethical committee at any institute or college should not hesitate to have on it members from other institutes, if there is need for such a step.

The ethical committee should meet at least once every three months and review all proposals for clinical research proposed by investigators in the institute. The Committee should assess all such proposals and only after approval by the committee should the research be initiated by the investigator and his co-investigators.

The ethical committee should review every proposal for research on human subjects to assess, among other considerations, whether:

- voluntary consent of the individual is being obtained;

- the experiments are so designed that they would yield meaningful results that could not be obtained by other methods;

- the animal experiments carried out support the need for clinical experimentation;

- the experiments would be conducted in a manner to avoid all unnecessary physical and mental suffering and injury;

- the experiments have been planned in a manner so that 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;

- proper preparations would be made and adequate facilities provided to protect the experimental subject against even remote possibilities of injury, disability or death;

- safeguards have been taken to see that the experimentation would be conducted only by scientifically qualified persons who possess the requisite competence, experience and qualities to carry out the research;

- it would be made perfectly clear to the subject or patient that he would be at liberty to bring the experiment to an end at any time he desires to do so;

- the scientist in charge of the research project is prepared to terminate the experiment at any stage, if he has probable cause to believe, in the exercise of the good faith, skill and careful judgement required of him, that a continuation of the experiment is likely to result in injury, disability or death to the experimental subject.

The Council recognizes the fact that it may take time for all the institutes in the country to form ethical committees and for a period of one year the Central Ethical Committee of the Indian Council of Medical Research would undertake to review, on ethical grounds, proposals submitted to the Council, irrespective whether it is submitted for support of the research proposed or not. This would be done with a view to assisting the investigators from the different institutes during the interim period when the institutional ethical committees are being formed at these institutions. The Council would also, if required to, assist these institutes to set up ethical committees and help in their functioning in the early stages.

The Council feels that if the Ethical Committee is to play a useful role and discharge its functions effectively, it must be independent.

SUPPORT OF CLINICAL RESEARCH BY THE COUNCIL

The Council would not consider support for any proposal for research on human subjects unless the research proposal has been approved by the Ethical Committee of the institute concerned. As has already been stated, the Council would take on the responsibility of assessing proposals on ethical considerations for an interim period of one year. The Council would also carry out this evaluation for proposals that may be sought to be sent for support to international agencies such as World Health Organization which does not entertain proposals for research support unless approved by the Ethical Committee of the institute. This assistance by the Council would enable investigators in institutes, which at the moment, do not have institute Ethical Committee to obtain support from these agencies.

IMPLEMENTATION OF ETHICAL COMMITTEE'S GUIDELINES

In addition to its other functions, the Ethical Committee should monitor the implementation of these guidelines and check whether the principles laid down regarding research on human subjects are being followed and whether the recommendations made by the institute Ethical Committee about a particular project are being observed by the investigators in charge of the projects.

The Council would, of course, retain the right of reviewing at any time the ethical procedures being observed in any project being supported by it.

DRUG TRIALS

The Council would like to make it clear that clinical evaluation of any new drug to be used for prophylactic, diagnostic or therapeutic purposes should be carried out, only after approval, as is necessary

under law, has been received from the Drugs Controller of India. The investigator should then formulate the research proposal and submit it to the Ethical Committee of the institute. This guiding principle should be followed irrespective of whether the drug has been developed in this country or abroad or whether clinical trials with the substance or drug have been carried out outside India. Similar principles should be followed for evaluation of new devices or other similar agents.

CLINICAL TRIALS WITH PLANTS AND INDIGENOUS SYSTEMS OF MEDICINE

The Council would suggest that for clinical evaluation of plants being utilized for therapeutic purposes, assessment of treatments being used in the traditional systems of medicine the protocols for such clinical research should again be approved by the Ethical Committee of the institute. There is no need for clearance to be obtained from the Drugs Controller of India for such trials of products already in widespread use in the traditional systems of medicine today in the country.

INFORMED CONSENT

The question of "informed consent" and the best way of obtaining informed consent is one that is difficult and one in which the norms and forms used in other countries are really not fully relevant to the conditions prevailing in this country. Although the procedure of obtaining the signatures of the person giving his/her consent cannot be dispensed with, at the same time, it must be emphasized that in the context of the conditions prevailing in the country, mere signatures would not ensure the requirements of informed consent. The Council can only lay down the broad guiding principles that form the basis for obtaining informed consent and then leave it to individual ethical review committees to develop their own procedures. These principles are that the proposed participants in a clinical research programme should be made aware, by a person not in a position to influence the patient such as the treating physician but for example, by a social worker, of the fact that a new drug or procedure is being evaluated. The patient for a new clinical trial should be informed briefly of the potential possible benefits of the new treatment as against the existing and the possible side-effects or hazards of the new treatment when compared to the existing treatment. If it is a randomized double blind trial, the patient should be told that he would be given either the old treatment or the new. He then should be informed in clear terms that if he wished to withdraw at any time from the trial, he could do so and then asked whether, in the circumstances explained to him, he would like to participate in the trial. The question of any payments to cover his/her expenses in taking part in the trial should be discussed after his/her agreement to participate in the trial and not suggested at a time when it could be used as an inducement to him to join in the trial.

With best wishe to you from the CHC team;

If the proposed research is not a trial which would in any way directly benefit the subject or the patient, then the benefit that would accrue to society or to other persons suffering from the disease should be clearly explained to the subject, as also the possible hazards to him, before asking him whether he would like to participate in the trial. Again, he should clearly be informed that he could withdraw from the trial any time he would like to.

CLINICAL RESEARCH ON CHILDREN

Research on children should be carried out only if there is possibility of some direct benefit to the child by taking part in the clinical trial or research project. An experiment on children could be carried out if:

- it is an experiment on the clinical efficacy of a new treatment with the immediate aim of curing the child's

- it is an experiment on an ill child in order to find out more about the condition or disease from which the child is suffering.

A good indication to judge whether an experiment on a child is ethical or not is for the investigator to ask himself the question "Would I do this to my own child?" Voluntary informed consent must be obtained from the parents or guardian of the child before carrying out the research project.

CLINICAL RESEARCH ON MENTALLY DEFICIENT PATIENTS

Clinical research on mentally retarded children or adults is again a very difficult question and has been the subject of much controversy in the past. Research on such persons should, again, be carried out only if:

- the research on a new treatment could cure the patient;

- the clinical research being carried out would add more information about the condition or disease from which the patient is suffering.

Informed voluntary consent needs to be obtained from the guardian/relatives of the patient before any research can be conducted on mentally deficient patients. If the patient has intervals when he is in

possession of all his faculties, then, his consent during such a period should also be obtained before including him as a subject for the proposed research.

CLINICAL RESEARCH ON PRISONERS, MEDICAL STUDENTS & LABORATORY PERSONNEL

Research on prisoners should never be carried out as it is not only difficult to obtain informed voluntary consent from prisoners but inducements offered to the prisoner for taking part in the trial would make it unethical to include such persons as subjects in a research programme. Similar considerations also apply, to a lesser extent, to carrying out clinical research on medical students and laboratory personnel but there may be exceptional occasions when research on such subjects would be perfectly ethical. The Ethical Committee should judge each research programme involving such persons with particular reference to the fact whether the teacher or investigator is in a position to influence the decision of the subject to take part in the research.

FINANCIAL REIMBURSEMENTS TO PARTICIPANTS TAKING PART IN CLINICAL RESEARCH PROJECTS

While it is reasonable to reimburse subjects and patients for taking part in a trial for the loss in time, leave taken and other expenses that they may have incurred such as transportation expenses, expenses on food, if the procedure is a long drawn one, or in employment of a part-time helper to look after the children during absence of a housewife from the house, this reimbursement should not be of such magnitude so as to act as an inducement to the person to join the trial. The Ethical Committee of the institute concerned would be the best judge of what constitutes a reasonable reimbursement in a particular situation as that would depend on several factors such as the time required to be spent in the hospital, the procedure itself and local factors such as existing costs of transportation etc.

PUBLICATION OF PAPERS ON CLINICAL RESEARCH IN THE INDIAN JOURNAL OF MEDICAL RESEARCH

The official publication of the Indian Council of Medical Research - the Indian Journal of Medical Research - would review papers submitted to the journal for publication from an ethical point of view also before approving such papers for publication. It is expected that in due course of time, those papers that have been based on clinical research carried out only after approval of the institute Ethical Committee would be considered for publication in the Indian Journal of Medical Research.

CLINICAL RESEARCH SUPPORTED BY AGENCIES OTHER THAN THE INDIAN COUNCIL OF MEDICAL RESEARCH

These guidelines have been prepared to assist all investigators in the country who are involved in carrying out clinical research on human subjects. It is hoped that other agencies in the country supporting clinical research in India would either incorporate some of these suggestions in their own evaluation of proposals for support of clinical research or adopt the guidelines laid down by the Council. The Council would, from time to time, organize meetings of all agencies supporting clinical research in India in an attempt to make uniform the ethical safeguards that are required of clinical investigators before carrying out research on human subjects.

THE ICMR COMMITTEE TO CONSIDER ETHICAL ASPECTS OF INVESTIGATIONS ON HUMAN SUBJECTS

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We see this effort as a beginning of an interactive collective process among trainers and request your participation in it. Do keep us informed about training initiatives of your project/institution and of reports/ manuals/publications

CODE OF MEDICAL ETHICS

(Approved by the Central Government u/s 33 of the Indian Medical Council Act, 1956, Vide their letter No. F. 17-64 MPT, dated 23rd October, 1970)

MEDICAL COUNCIL OF INDIA
Aiwan-e-Ghalib Marg
Kotla Road
New Delhi-110002

MEDICAL COUNCIL OF INDIA

CODE OF MEDICAL ETHICS

DECLARATION

At the time of registration, each applicant shall be given a copy of the following declaration by the Registrar concerned and shall read and agree to abide by the same :

1. I solemnly pledge myself to consecrate my life to the service of humanity.
2. Even under threat, I will not use my medical knowledge contrary to the laws of humanity.
3. I will maintain the utmost respect for human life from the time of conception.
4. I will not permit considerations of religion, nationality race party-politics or social standing to intervene between my duty and my patient.
5. I will practise my profession with conscience and dignity.
6. The health of my patient will be my first consideration.
7. I will respect the secrets which are confided in me.
8. I will give to my teachers the respect and gratitude which is their due.
9. I will maintain by all means in my power, the honour and noble traditions of medical profession.
10. My colleagues will be my brothers.

I make these promises solemnly, freely and upon my honour.

CODE

GENERAL PRINCIPLES

1. Character of the Physician

The prime object of the medical profession is to render service to humanity; reward of financial gain is a subordinate consideration. Who-so-ever chooses this profession, assumes the obligation to conduct himself in accord with its ideals. "A

physician should be an upright man, instructed in the art of healings." He must keep himself pure in character and be diligent in caring for the sick. He should be modest, sober, patient, prompt to do his whole duty whithout anxiety; pious without going so far as superstition conducting himself with propriety in his profession and in all the actions of his life.

2. **The Physician's Responsibility**

The principle objective of the medical profession is to render service to humanity with full respect for the dignity of man. Physicians should merit the confidence of patients entrusted to their care, rendering to each a full measure of service and devotion. Physician should try continuously to improve medical knowledge and skill and should make available to their patients and colleagues the benefits of their professional attainments. The physician should practice methods of healing founded on scientific basis and should not associate professionally with anyone who violates this principle. The honoured ideals of the medical profession imply that the responsibilities of the physician extend not only to individuals but also to society.

3. **Advertising**

Solicitation of patients directly or indirectly, by a physician, by groups of physicians or by institutions or organisations is unethical. A physician shall not make use of or aid or permit others to make use of him (or his name) as subject of any form or manner of advertising or publicity through lay channels either alone or in conjuction with others which shall be of such a character as to invite attention to him or to his professional position, skill, qualification, achievements, attainments, specialities, appointments, associations, affiliations or honours and or of such character as would ordinarily result in his self aggrandisement nor shall he give to any person who-so-ever, whether for compensation or otherwise, any approval, recommendation, endorsement, certificate report or statement with respect of any drug, medicine, nosterm remedy, surgical, or therapeutic article, apparatus or appliance or any commercial product or article with respect of any property, quality or use thereof or any test demonstration or trial thereof, for use in connection with his name, signature, or photograph in any form or manner of advertising through lay channels nor shall be boast of cases, operations cures or remedies or permit the publication of report thereof through lay channels. A medical practitioner is permitted a formal announcement in press regarding the following :

(1) On starting practice.

(2) On change of type of practice.

(3) On changing address.

(4) On temporary absence from duty.

(5) On resumption of practice.

(6) On succeeding to another practice.

4. **Payment of Professional Services**

The ethical physician, engaged in the practice of medicine, limits the sources of his income received from professional activities to services rendered to the patient. Remunerations received for such services should be in the form and amount specifically announced to the patient at the time the service is rendered. It is unethical to enter into a contract of "no cure no payment".

5. **Patent and Copy Rights**

A physician may patent surgical instruments, appliances and medicine or copy right publications methods and procedure. The use of such patents or copyright or the receipt of remuneration from them which retards or inhibits research or restrict the benefits derivable therefrom are unethical.

6. **Running an Open Shop (Dispensing of Drugs and Appliances by Physicians)**

A physician should not run an open shop for sale of medicine for dispensing prescriptions prescribed by doctors other than himself or for sale of medical or surgical appliances. It is not unethical for a physician to prescribe or supply drugs, remedies or appliances as long as there is no exploitation of the patient.

7. **Rebates and Commission**

A physician shall not give, solicit, or receive nor shall he offer to give, solicit or receive, any gift gratuity, commission or bonus in consideration of or in return for the referring, recommending or procuring of any patient for medical, surgical or other treatment. A physician shall not directly or by any subterfuge participate in or by a party to the act of division, transference, assignment, sub-ordination, rebating, splitting or refunding of any fee for medical, surgical or other treatment.

The provisions of this para shall apply with equal force to the referring, recommending or procuring by a physician or any person, specimen or material for diagnostic, or other study or work. Nothing in this section, however, shall prohibit payment of salaries by a qualified physician to other duly qualified person rendering medical care under his supervision.

8. **Secret Remedies**

The prescriptions or dispensing by a physician of secret medicine or other secret remedial agents of which he does not know the composition, or the manufacture or promotion of their use is unethical.

9. **Evasion of Legal Restrictions**

The physician will observe the laws of the country in regulating the practice of medicine and will not assist others to evade such laws. He should be cooperative in

observance and enforcement of sanitary laws and regulations in the interest of public health. A physician should observe the provisions of the State Acts like Drugs Act, Pharmacy Act, Poisonous and Dangerous Drugs Act and such other Acts, Rules, Regulations made by the Central Govt./State Govts. or local Administrative Bodies for protection and promotion of public health.

DUTIES OF PHYSICIANS TO THEIR PATIENTS

10. Obligations to the Sick

Though a physician is not bound to treat each and every one asking his services except in emergencies for the sake of humanity and the noble traditions of the profession, he should not only be ever ready to respond to the calls of the sick and the injured, but should be mindful of the high character of his mission and the responsibility he incurs in the discharge of his professional duties. In his ministrations, he should never forget that the health and the lives of those entrusted to his care depend on his skill and attention. A physician should endeavour to add to the comfort of the sick by making his visits at the hour indicated to the patients.

11. Patience Delicacy and Secrecy

Patience and delicacy should characterize the physician. Confidences concerning individual or domestic life entrusted by patients to a physician and defects in the disposition or character of patients observed during medical attendance should never be revealed unless their revelation is required by the laws of the State. Sometimes, however, a physician must determine whether his duty to society requires him to employ knowledge, obtained through confidences to him as a physician, to protect a healthy person against a communicable disease to which he is about to be exposed. In such instance, the physician should act as he would desire another to act toward one of his own family in like circumstances.

12. Prognosis

The physician should neither exaggerate nor minimize the gravity of a patient's condition. He should assure himself that the patient, his relatives or his responsible friends have such knowledge of the patient's condition as will serve the best interests of the patient and the family.

13. The Patient Must not be Neglected

A physician is free to choose whom he will serve. He should, however, respond to any request for his assistance in an emergency or whenever temperate public opinion expects the service. Once having undertaken a case, the physician should not neglect the patient, nor should he withdraw from the case without giving notice to the patient,

his relatives or his responsible friends sufficiently long in advance of his withdrawal to allow them to secure another medical attendant. No provisionally or fully registered medical practitioner shall wilfully commit an act of negligence that may deprive his patient or patients from necessary medical care.

DUTIES TO THE PHYSICIAN TO THE PROFESSION AT LARGE

14. Upholding the Honour of the Profession

A physician is expected to uphold the dignity and honour of his profession.

15. Membership in Medical Society

For the advancement of his profession, a physician should affiliate with medical societies and contribute his time, energy and means so that these societies may represent the ideals of the profession.

16. Safeguarding the Profession

Every physician should aid in safeguarding the profession against admission to it of those who are deficient in moral character or education. Physician should not employ in connection with his professional practice any attendant who is neither registered nor enlisted under the Medical Acts in force and should not permit such persons to attend, treat or perform operations upon patients in respect of matters regarding professional discretion or skill as it is dangerous to public health.

17 Exposure of Unethical Conduct

A physician should expose, without fear or favour, incompetent or corrupt, dishonest or unethical conduct on the part of members of the profession. Questions of such conduct should be considered, first before proper medical tribunals in executive sessions or by special or duly appointed committees on ethical relations, provided such a course is possible and provided also that the law is not hampered thereby, if doubt should arise as to the legality of the physian's conduct, the situation under investigation may be placed before officers of the law, and the physician investigators may take the necessary steps to enlist the interest of the proper authority.

PROFESSIONAL SERVICES OF PHYSICIANS TO EACH OTHER

18. Dependence of Physicians on each other

There is no rule that a physician should not charge another physician for his service, should cheerfully and without recompense give his professional services to physicians or

his dependants if they are in his vicinity.

19. Compensation for Expenses

A physician should consider it as a pleasure and privilege to render grataitious service to all physicians and their immediate family dependants. When a physician is called from a distance to attend or advice another physician or his dependants, reimbursement should however be made for travelling and other incidental expenses.

DUTIES OF PHYSICIAN IN CONSULTATION

20. Consultation should be Encouraged

In case of serious illness, especially in doubtful or difficult conditions the physician should request consultation.

21. Consultation for Patient's Benefit

In every consultation, the benefit to the patient is of first importance. All physicians interested in the case should be candid with the patient, a member of his family or responsible friend.

22. Punctuality in Consultation

Utmost punctuality should be observed by a physician in meeting for consultation.

23. Conduct in Consultation

In consultations, no insincereity, rivalry or envy should be indulged in. All due respect should be observed towards the physician incharge of the case and no statement or remark be made, which would impair the confidence reposed in him. For this purpose no discussion should be carried on in the presence of the patient or his representatives.

24. Statement to Patient after Consultation

(a) All statements of the case to the patient or his representatives should take place in the presence of all the physicians consulting, except as otherwise agreed; the announcement of the opinion to the patient or his relations or friends shall rest with the medical attendant.

(b) Differences of opinion should not be divulged unnecessarily but when there is an irreconcilable difference of opinion the circumstances should be frankly and impartially explained to the patient or his friends. It would be open to them to seek further advice should they so desire.

25. Treatment after Consultation

No decision should restrain the attending physician from making such subsequent

variations in the treatment as any unexpected change may require, but at the next consultation, reasons for the variations should be stated. The same privilege, with its obligations, belongs to the consultant when sent for in an emergency during the absence of attending physician. The attending physician may prescribe at any time for the patient, the consultant only in case of emergency.

26. **Consultant not to take Charge of the Case**

When a physician has been called as a consultant, none but the rarest and most exceptional circumstances would justify that consultant taking charge of the case. He must not do so merely on the solicitation of the patient or friends.

27. **Patients Referred to Specialists**

When a patient is referred to a specialist by the attending physician, a statement of the case should be given to the specialist, who should communicate his opinion in writing in a closed cover direct to the attending physician.

DUTIES OF PHYSICIAN IN CASES OF INTERFERENCE

28. **Appointment of Substitute**

Whenever a physician requests another physician to attend his patients during his temporary absence from his practice, professional courtesy requires the acceptance of such appointment if consistant with his other duties. The physician acting under such an appointment should give the utmost consideration to the interests and reputation of the absent physician. All such patients should be restored to the care of the latter upon his return.

29. **Visiting another Physician's Case**

A physician called to visit a patient who has recently been under the care of another physician in the same illness, should not take charge of, nor prescribe for such patient except in a case of emergency when he should communicate to the former explaining the circumstances under which the patient was seen and treatment given, or when the physician has relinquished his case, or when the patient has notified such physician to discontinue his services.

When it becomes the duty of a physician occupying an official position to see and report upon an illness or injury, he should communicate to the physician in attendance so as to give him an option of being present. The medical officer should avoid remarks upon the diagnosis or the treatment that has been adopted.

30. **Engagement for an Obstetric Case**

If a physician agrees to attend a woman during her confinement, he must do so

Inability to do so on an excuse of any other engagement is not tenable except when he is already engaged on a similar or other serious case. When a physician who has been engaged to attend an obstetric case is absent and another is sent for and delivery accomplished, the acting physician is entitled to his professional fees, but should secure the patient's consent to resign on the arrival of the physician engaged.

DUTIES OF PHYSICIAN TO THE PUBLIC

31. Physicians as Citizens

Physicians, as good Citizens, possessed of special training should advise concerning the health of the community wherein they dwell. They should bear their part in enforcing the laws of the community and in sustaining the institutions that advance the interests of humanity. They should operate especially with the proper authorities in the administration of sanitary laws and regulations.

32. Public Health

Physicians, especially those engaged in public health work, should enlighten the public concerning quarentine regulations and measures for the prevention of epidemic and communicable diseases. At all times the physician should notify the constituted public health authorities of every case of communicable disease under his care, in accordance with the laws, rules and regulations of the health authorities. When an epidemic prevails, a physician must continue his labour without regard to the risk to his own health.

33. Pharmacists

Physicians should recognize and promote the practice of pharmacy as a profession and should recognise the cooperation of the pharmacist in education of the public concerning the practice of ethical and scientific medicine.

DISCIPLINARY ACTION

1. The Medical Council of India desires to bring to the notice of the registered medical practioners the following statement upon offences and form of professional misconduct, which may be brought before the appropriate Medical Council for disciplinary action in view of the authority coferred upon the Medical Council of India and/or State Medical Councils as provided under Indian Medical Council Act, 1956, or State Medical Councils Acts as may be subsequently amended.

2. The appropriate Medical Council may award such punishment as deemed necessary or may direct the removal altogether or for a specified period from the Register, the name

of any registered practioner who has been convicted of any such offence as implies in the opinion of the Medical Council of India and/or State Medical Councils, a defect of character or who after an enquiry at which opportunity has been given to such registered practitioner to be heard in person or by pleader, has been held by the appropriate Medical Council to have been guilty of serious professional misconduct. The appropriate Medical Council may also direct that any name so removed shall be restored.

3. It must be clearly understood that the instances of offences and of professional misconduct which are given do not constitute and are not intended to constitute a complete list of the infamous acts which may be punished by erasure from the Register, and that by issuing this notice the Medical Council of India and or State Medical Councils are in no way precluded from considering and dealing with any form of professional misconduct on the part of a registered practitioner. Circumstances may and do arise from time to time in relation to which there may occur questions of professional misconduct which do not come within any of these categories. Every care should be taken that the code is not violated in letter or spirit. In such instances as in all others, the Medical Council of India and or State Medical Councils have to consider and decide upon the facts brought before the Medical Council of India and or State Medical Councils.

LIST

1. **Adultery or Improper Conduct or Association with a Patient**

Any medical practitioner, who abuses, his professional position by committing any adultery or improper conduct with a patient or by maintaining an improper association with a patient, is liable for disciplinery action as provided under the Indian Medical Council Act, 1956 and/or State Medical Council Acts, as may be subsequently amended.

2. Conviction by Court of Law for offences involving moral turptitude.

3. **Professional Certificates, Reports and other Documents**

Registered practioners are in certain cases bound by law to give, or may from time be called upon or requested to give certificates, notification, reports and other documents of kindred character signed by them in their professional capacity for subsequent use in the courts of justice or for administrative purposes etc.

(i) Such documents include among other certificates, notifications reports—

(a) Under the acts relating to birth, death or disposal of the dead.

(b) Under the Acts relating to Lunacy and Mental Deficiency and the rules made thereunder.

(c) Under the Caccination Acts and the regulations made thereunder.

(d) Under the factory Acts and the regulations made thereunder.

(e) Under the Education Acts.

(f) Under the Public Health Acts and the order made thereunder.

(g) Under the Workmen's Compensation Act.

(h) Under the Acts and order relating to the notification of infectious diseases.

(i) Under the Employee's State Insurance Act.

(j) In connection with sick benefit insurance and friendly societies.

(k) Under the Merchant Shipping Act.

(l) For procuring the issuing of passports.

(m) For excusing attendance in courts of Justice, in public services, in public offices or in ordinary employments.

(n) In connection with rural and Military matters.

(o) In connection with matters under the control of Ministry of the pensions.

(ii) Any registered practioner who shall be shown to have signed or given under his name and authority and such certificate, notification, report or document of a kindred character which is untrue, misleading or improper relating to the several matters above specified or otherwise, is liable to have his name erased from the Register.

(iii) A Registered medical practitioner shall maintain a Register of Medical Certificates giving full details of certificates issued. When issuing a medical certificate always enter the indentification marks of the patient and keep a copy of the certificate. Do not omit to note down the signature or thumb-mark, address and identification marks of the patient on the medical certificates or report.

4. Contravening the provision of the Drugs Act and regulations made thereunder.

5. Selling Schedule poison to the public under the cover of his own qualification except to his patient.

6. Performing or enabling unqualified person to perform an abortion or any illegal operation for which there is no medical, surgical or psychological indication.

7. A physician should not issue certificates of efficiency in modern medicine to unqualified or non-medical person.

(Note : The foregoing does not apply so as to restrict the proper training and instruction of bonafied students, legitimate employees of doctors, midwives, dispensers, surgical attendants, or skilled mechanical and technical assistants under the personal supervision of physicians).

8. A physician should not contribute to the lay press articles and give interviews regarding diseases and treatments which may have the effect of advertising himself or soliciting practice ; but it is open to him to write to the lay press under his own name on matters of public health hygienic living or to deliver public lectures, give talks on the radio broadcast for the same purpose and send announcement of the same to the lay press.

9. An institution run by a physician for a particular purpose such as a maternity home. a sanatorium, a house for the crippled or the blind, etc. may be advertised in the lay press, but such advertisements should not contain anything more than the name of the institution, type of patients admitted, facilities offered and the residential fees. Name of either the superintendent or the doctor attending should not appear in the advertisement.

10. It is improper for a physician to use an unusually large signboard and write on it anything other than his name, qualifications obtained from a University or a statutory body, titles and name of his speciality. The name should be the contents of his prescription papers. It is improper to affix a sigh-board on a chemist's shop or in places where he does not reside or work.

11. Do not disclose the secrets of a patient that have been learnt in the exercise of your profession. Those may be disclosed only in a Court of Law under orders of the presiding jugde.

12. Refusing on religious grounds alone to give assistance in our conduct of sterility, birth control, craniotomies on living children, and therapeutic abortions when there is medical indication ; unless the medical practioner feels himself herself incompetent to do so.

13. Before performing an operation in writting the consent from the husband or wife, parent or guardian in the case of a minor, or the patient himself as the case may be. In an operation which may result in sterility the consent of both husband and wife is needed.

14. Do not publish photographs or case reports of your patients in any medical or other journal in a manner by which their identity could be made out without their permission. Should the identity be not disclosed his consent is not needed.

15. If you are running a nursing home and if you employ assistants to help you, the ultimate reponsibility rests on you.

16. No physician must exhibit publically the scale of fees. But there is not objection

to the same being put in the physicians' consulting or waiting room.

17. No physician shall use touts or agents for procuring patients.

18. Do not claim to be a specialist unless you have put in a good few years of study and experience or a special qualification in that branch. Once you say you are one, do not undertake work outside your specialijy even for your friends.

Form of Certificate Recommended for Leave or Extension of Communication of Leave

Signature of applicant
or thumb impression.....

To be filled in by the applicant in the presence of the Government Medical Attendant or Medical Practioner.

I.....after careful examination of the case hereby that..... whose signature is given above is suffering from..... and I consider that a period of absence from duty of.....with effect from..... ..... is absolutely necessary for the restoration of his health.

Date..... Signature of Medical Attendant

.....

Note :—The nature and probable duration of the illness should also be specified. This certificate must be accompained by a brief resume of the case giving the nature of the illness, its symptoms, causes and duration.

(Approved by the Central Government u/s 33 (m) of the Indian Medical Council Act, 1956, vide their letter No. F. 17-4/64-MPT, dated 23-10-70)

SOME ISSUES RAISED

* Has a patient the right to be delivered from incurable suffering?

* If a person has a right to life has he not also a right to take away his own life?

* Abortion, though once considered to be a criminal act is now often considered to be a benevolent and obligatory act. Should we not go along with the times?

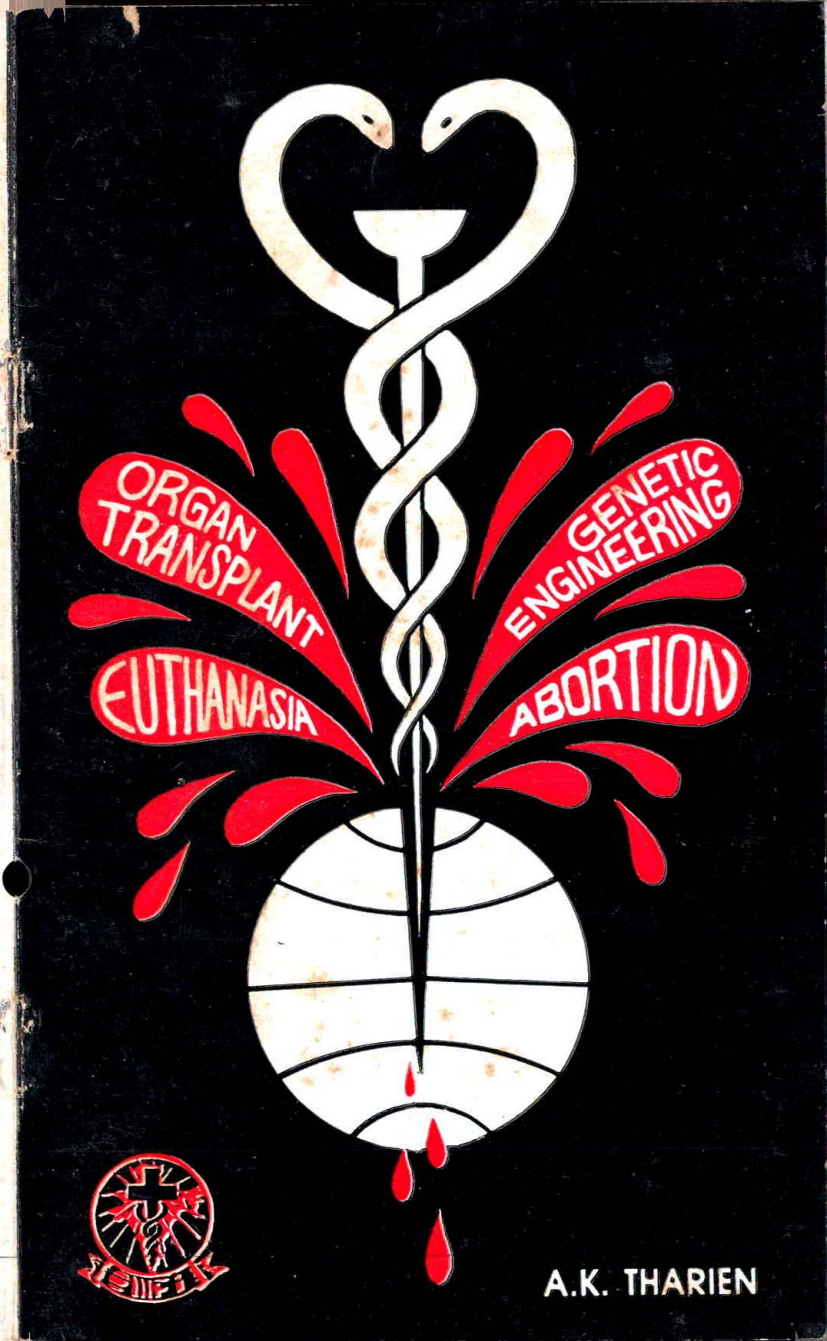
* Is it wrong to find out and eliminate a retarded foetus?

* If test tube baby is a breakthrough in medical technology, why impose restrictions?

* Is it wrong to attempt to create super-humans through genetic engineering?

* Is it ethical to sell or buy organs?

* What is our priority - to prolong life of a few or improve the quality of life of the masses?



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IS MODERN MEDICAL TECHNOLOGY A CHALLENGE TO CHRISTIAN ETHICS ?

Dr. A. K. THARIEN

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values are gradually being pushed aside or getting eliminated. Love is the foundation of christian ethics. Loving our God with all our heart, soul and mind and loving our neighbour as ourselves, are the two foundations for our ethical practice. Only a code of ethics based on the Bible and sound Christian principles, can lead our society to lasting happiness, harmony and peace.

In recent years Medical Science and Technology have made great strides of progress. The growth of technological medicine raises some moral and ethical problems. Our understanding of ethical principles should lead us to find a rational basis for our medical practice.

CHRISTIAN MEDICAL ETHICS

Christian medical ethics deals with human behaviour, relationships, biological issues of health, religious ideals, culture, decisions regarding when to treat and when to withhold treatment, dying and death. Christian medical ethics has now become complex, as it has medical, legal, theological, moral, social and

personal aspects. Medical and biological advances in knowledge and technique further pose new dilemmas in decision making. Many time honoured principles are being openly questioned or flouted. New legislative measures are under consideration, if not already in existence, particularly in areas like organ transplant, management of human fertility and infertility, use of drugs to alter brain function, genetic engineering to change human genetic stock, euthanasia, amniocentesis, termination of pregnancy etc.

THREE DIMENSIONS OF A PERSON

A person may be viewed, biologically, socially and spiritually.

a) Biological

We have a physical form to our body and keeping the body healthy is a biological activity. Health is therefore our right and we need to safe-guard it. A doctor's duty is to preserve and promote health in all its aspects, physical, mental and spiritual.

b) Social

Man is a social being. He lives in relationship with another. The most important relationship is between husband and

LET ME SHARE SOME PRACTICAL STEPS :

1. Doctors should serve and care for their patients in love based on Christian motivation.

2. Deliberate attempt to end or shorten life, whether by ommission or commission is wrong and should not be done.

3. The church should proclaim the way of righteousness and truth, against taking innocent lives, and provide compassionate, care.

4. Education of medical personnel and people with moral and spiritual values should be done, which may lead to sound legislation.

5. Bring in Christ's principle of love as the motive and mainspring.

CONCLUSION

Views and ideas and even concepts of ethics are fast changing in the context of the progress of science and technology. The traditional institutions in our society, which protect human life and spiritual

society. So they resigned from their busy clinical work and offered their lives to start a centre for children with special needs. An apparent traumatic experience became the rallying point for a new mission and for christian compassion.

OUR GUIDING PRINCIPLE

Ever since the time of Hipocrates in the fifth century BC the medical profession has been guided by the concept of the worth of each individual human life, which was recently reaffirmed by the Geneva code in 1948, which states, "I will show the utmost respect for human life from the time of conception". Suffering is evil, and we should take every step to mitigate or relieve it, but suffering has also meaning and purpose.

Hitler had a utilitarian philosophy of life. Any person who had a utilitarian value, he preserved, and others he eliminated. But as Christians we respect the unique value of human life. Man is made in the image of God (Gen 1:27) This gives human life a unique dignity and value (Gen 9:6), (Ps 8:4-8). The death of Christ on the cross demonstrates the depth of God's love for mankind, His creation. Life should be cherished, supported and cared.

wife, each being incomplete without the other. Out of this partnership, come the children; then there is the extended family of relatives, friends and the larger community. Mal-adjustment in relationships or breakdown of relationships will affect healthy living.

c) Spiritual

Man as a whole person, is responsible to God, as, life is a gift of God. We are conscious of the sanctity of human life, because of this relationship with a living God. Human being created in the image of God has a worth and is unique. Unless we maintain this right relationship with our Creater, we are likely to wonder about our purpose of existence and lack a sense of direction in our life. Not being clear about this may lead to frustration in life and all the consequences of conflict and confusion in one's life resulting in ill-health.

If we have a biological, social and spiritual dimension for our life, our conduct and behaviour would emerge from this network of relationships. How we think and behave are largely the reflections of our convictions. As people with convictions, we are constantly faced with the Biblical understanding of issues at stake. Let us look at some of them.

I. THE DILEMMA OF ABORTION

The debate on abortion is an open ended issue for most of us. It is a highly emotional subject as it touches the mysteries of human sexuality and reproduction. Pro-abortionists emphasize the rights of the mother, especially her right to choose. Whereas the Pro-life advocates, emphasize the right of the unborn child and his or her right to live. What is not usually considered in the abortion issue is the sovereignity of God and sanctity of human life.

"When we debate the rights and wrongs of induced abortion", wrote Dr. Garetts Jones, "We are debating a problem of human relationship much broader and more significant than that of a woman with an unwanted foetus. Life starts at conception and it is a continuous process. This developing human being requires protection from society through out his life".

The liberalised law of medical termination of pregnancy Act of 1971, permits termination of pregnancy on the grounds of danger to the physical or mental health of the mother or in the event of failure of a family planning

Let me share with you the experience of two of my friends who faced the issue of caring for children with disability. One was a hospital Chaplain. When a child with disability was born to him, he asked God why this happened to him, but he could not get an immediate answer. He loved that child but the child could not adequately respond to his love in the normal way. This helped the pastor to realise how God loves us inspite of us not being responsive to His love. The other was a colleague of mine and a highly qualified Paediatrician. When a child with disability was born to him and his doctor wife, they did their very best to sustain her life. The child became critically ill immediately after birth, needing exchange blood transfusions. Though their colleagues questioned the wisdom of taking such an extreme step for such a child, they choose to have the exchange transfusions. The child recovered and subsequently brought a new purpose to their life before she finally died at 4 months of age. Through this the parents realised that God had a purpose in bringing her to their home. This experience was an act of God to make them aware of the need of caring for many neglected, children with disability in our

of this is that every citizen has also a right to lay down his own life. When I showed this news item to Dr. John Wilkinson, a British medical doctor and a theologian, he reminded me that according to Christian concept, Almighty God is the giver and sustainer of life and He alone has the right to withdraw breath from life. Life is not a right, but a gift of God and so we have no right to take away a human life, even one's own, as it is a divine prerogative. The famous Arthur's trial of 1981, where Dr. Arthur had prescribed an overdose of codeine to a baby born with Downs syndrome with the object of hastening his death, can be considered here. Dr. Arthur was charged with murder. Many eminent withnesses were tried. Most of them justified the procedure. Finally the court acquitted Dr. Arthur as his motive was compassion. There is a strong arguement that if a foetus is found to be abnormal and severely handicapped it should be sought out and eliminated before birth, as such children are socially valueless. Do not the physically handicapped and mentally retarded have as much right to life like others, and get the needed care and treatment?

measure. This means that almost any one can demand abortion legally and get it done before twenty weeks of gestation. Then there are others who on humanitarian grounds justify an abortion because of an unplanned pregnancy, extreme financial or social stress due to pregnancy, the stigma of a pregnancy out of wedlock, (unmarried girl, adultery, incest, rape) and if, the unborn baby is diagnosed as physically or mentally defective.

As Christians, our convictions are to be based on Biblical guidelines. Our view of the status of the fertilised ovum will largely determine our attitude to abortion. Pro-abortion campaigners plead that medically and legally the embryo and foetus are parts of the mother's body, so she has the right to decide its'destiny. There are others like the late Dr. Francis Schaeffer and Dr. Everett Koop (Surgeon General of U.S.A.) who argue that though the embryo is carried within the mothers body, the foetus is a person in the making with all potentials to grow and develop. The growing body has a genotypic distinction from the mother and is "already a human life, not merely a potential human" (Pope Pius XII). The Psalmist in the Bible

says "You knit me together in my mothers womb" (Psalm 139:13) obviously referring to God as the orginator of every life. Arch-Bishop Ramsay of Canterbury considers the unborn baby to be reverenced as the embryo of a life capable of coming to reflect the Glory of God.

One may want to argue for freedom of decision or exception to this general rule, But every exception has to be rigorously and specifically examined (eg. a serious threat to the life of the mother or a completely malformed child as to be incapable of independent survival). In no case should termination of pregnancy be resorted to as an easy method of family planning.

II. RECENT GENETIC DISCOVERIES AND EMBRYO EXPERIMENTS

Recently new knowledge has been acquired about genetic science, like D. N· A. genetic engineering, invitro fertilisation (I.V.F.), Embryo transfer (E.T), amniocentesis. I.V.F. has found a revolutionary solution to the human dilemma of infertility by non-human technological means.

venience. The essence of a christian approach to a dying patient is to give ourselves in loving care to meet his need. A Christian doctor sees his patients not merely as a biological unit but as a person before God with family and social connections.

One of the great achievements of recent medical technology is the use of artificial life support systems which can keep a patient alive by special means, like artificial feeding, dialysis, controlled respiration, pump circulation etc. But in some cases it may be so dehumanising, painful, hazardous or costly that other consideration outweigh the aim to conserve life.

The question arises, how long to sustain life artificially? A patient might say "I do not want a vegetative existence by drips, drugs and machines. I want to die with dignity and I have a right to die when I choose". Some time ago, there was a judgement in the Bombay High Court in which two judges acquitted a man accused of attemped suicide. They said that according to Indian constitution any citizen has the right to life. Corollary

IV. EUTHANASIA

True meaning of euthanasia, is, the deliberate bringing about of gentle and easy death, making the patient's last days as comfortable as possible to ensure a calm and peaceful death, within context of relieving incurable suffering in terminal illness or disability. It is voluntary when requested by the patient; involuntary when resorted to by those attending on the person. It may be passive when death is hastened by the deliberate withdrawal of effective therapy or nourishment.

Euthanasia request may come out of depression and confusion, or out of a feeling of worthlessness or due to persuasion of interested parties with ulterior motives. Though one may not prolong the act of dying in a case of irreversal death and thereby increase suffering, respect for the person of the patient and concern for the family should lead us to use our resources as best as we can to promote life. We should oppose all attempts for the elimination of human life or the manipulation of it to suit personal con-

a) Genetic Engineering

In 1954 Watson and Crick published, the now famous discovery on the structure of "deoxy ribo nucleic acid". This has paved the way for invitro fertilisation and manipulation of the genes.

The fertilised ovum is grown in culture. The cells thus formed are then separated into individual cells which with further culture can form new individuals, identical genetically to all others. This can be stored frozen for further development. Thus a women could give birth to her twin sister if these cells are used at a later period.

By the selection of genes and it's manipulation one can choose sex, complexion, height and other such features of the foetus. Corrective gene therapy can also be done.

It is also possible to produce allophenes between species like men and monkey hybrids. Thus it is reasonable to speculate that, it should be possible to create novel mutants or entirely new species. If man, with his scientific curiosity and weak human nature, is given the knowledge and power of a creator, can one predict where it will lead him to. He may

tresspass into regions outside the laws of God. So it will be necessary to guard against potential abuses and avoid human vivisection

b) Invitro Fertilization

The procedure of invitro fertilization (I.V.F.) raises the question of the status of the fertilized ovum before God,whether in the womb or in the test tube. The fertilization of an ovum outside the uterus is a great break-trough in medical science and an alternate means of conception for many infertile woman. But some argue that laboratory production of human beings is no longer human procreation as it amounts to degradation of parenthood and deprives procreation of its human involvement and love. I.V.F. might undermine values which biological parenthood give to marriage. But it is argued by scientists that I.V.F. is a dramatic extension of the sort of interference found in delivery, by ceaserean section or in hormonal induction of labour.

In these experiments there are a few surplus fertilised embryos which are kept frozen for future use or are used for further experiments for researchers to study genetic

c) Consent for organ donation

Organs may be donated after death by 'living wills' or consent of next of kin. When an organ is required from a living donor, the age of the donor and his ability to understand the nature of the procedure, it's complications and risks are crucial issues. There have been many instances in countries like India, where organ selling was done for monetary gain, organs procured by using coercive methods, or by giving false or inadequate information. The recepient should also be given information about the risks involved, especially, if the procedure is a high risk one or of an experimental nature.

d) Resources

The question should be raised in situations where there are limited resources, whether it is justifiable to spend enormous amount of money, time and energy for prolonging the life span of a few, temporarily, while thousands are denied even the elementary and basic health needs which might cost very little. Offering a patient extended life without reasonable quality of life seems to be cruel.

a) Organ Procurement

A major obstacle yet to be overcome is the inadequate supply of donor organs, and the supply and demand imbalance is increasingly widening. Till artificial organs are designed, an ethical problem will be, establishing a fair and effective policy of allocation so that the available organs are used as justly as possible.

b) Determination of Death

The viability and suitability of certain organs depend on the time lapsed after death, and, hence the tendency is to remove the organ from the donor as early as possible. This leads to the question of the criteria for death. The traditional legal view of determining death used to be the absence of heart beat and spontaneous respiration. With the advent of recent life supporting systems, neurological death is now considered to be the criteria for death. It would be advisable that brain death should be certified by a physician who is not a participant in any phase of the transplant procedure.

and developmental abnormalities, intricacies of tissue and cell differentiation etc., or to be ultimately destroyed. Can we treat the fertilised ovum as a lump of jelly or blop of tissue which can be destroyed, like a tumour or tonsil? Is it right to use human materials for experiments and if so how far? At present the proposed law in the U. K., does not permit embryo experiments beyond 14 days (which is the implantation stage). Then the question is raised, do human embryos have any right at all? If they have rights, at what stage? Can such embryos be the material possession of the donors when they do not intend becoming the parents. The fundamental issue is whether or not respect should be shown to human embryo in view of the potential for full humanness. If embryos are produced with the expressed purpose of providing scientific information, that information has already taken precedence over the significance of human existence.

In the West, ovum is fertilised from sperm of unknown parents and children are born without identity of biological parents. (This is now changing, as donors have to record their identity). A child conceived in a test

tube can have as many as five parents; the egg donor, the sperm donor, the surrogate mother, (who bears the child,) and the couple who raise the child. The potential emotional and psychological ramifications of this could be deep and disturbing.

The Anglican Church of Australia disapproved experiments like cloning, genetic engineering, artificial placenta, surrogate motherhood, human-animal hybrids and embryo freezing. Organisations like the Order of Christian unity (London) are seeking to outlaw 'womb leasing' and 'Ovum donation, to, eliminate legal problems, human tragedies and to uphold the sanctity of human life. It is now accepted that no human being is to be treated as property, as in the days of slavery. Every one has an inviolable status as regards life and liberty. It is recognised that every human being has the right not to be used as a means to the needs and interests of others.

c) Amniocentesis

The study of amniotic fluid gives a lot of information including the sex of the foetus and of possible malformations of the unborn baby. A study of abortions conducted in Bombay

after amniocentesis, revealed that the vast majority of the babies aborted were females. This is a small pointer to the way this procedure is being used. It is used for determination of sex giving a chance for the parents to choose which baby they should keep. This attitude to females can have devastating effects on our social structure.

The real indications for amniocentesis when ethically used may be for providing therapeutic support for the unborn baby (eg. hydrops foetlis) or for diagnostic purpose to anticipate the special measures needed to assist the baby at birth. (Respiratory Distress Syndrome) The decision to resort to amniocentesis must not be with the bias to resort to abortion if needed.

III. ORGAN TRANSPLANTATION

Organ transplantation is another breakthrough in medical technology, overcoming many technical barriers like vascular anastomosis, immunological rejection problems and so forth. The process is one of high cost, prolonged hospitalisation intensive medical care and follow-up.

MFP 54.16

IVth General Meeting of the Faculties of Christian Medical Colleges/Centres

Group Discussion I ETHICAL RESPONSIBILITY

*As a group, identify the major areas of ethical responsibility in your Institution.

Group A:

What are the important ethical issues that you encounter in the Institution's Administration? Name four main areas and how in your opinion can they be tackled.

Group B:

What are the four main ethical problems you encounter at the departmental/Unit level? How do you deal with them?

Could you highlight ethical problems occuring within teaching faculty; and between teaching and non-teaching staff of your section?

Group C:

Kindly list the ethical problems encountered at inter-departmental level. Which are the three main/common ones and how are these issues dealt with?

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DECISION MAKING STRATEGY FOR CLINICAL ETHICAL PROBLEMS IN MEDICINE:

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Decision making lies at the very heart of the art and science of health care. Medical education and training aims to train physicians to make decision. As physicians we are constantly making decision. We make decisions when we listen to a patient's story, examine the patient, order a test or a treatment. None of these decisions are easy because as Osler says that 'medicine is a science of uncertainty and an art of probability'. Nevertheless physicians generally reach a clinical decision and feel reasonably comfortable about it.

Many times we prescribe even when diagnosis are not certain. Many clinical decisions are made in face of uncertainity i.e. on the basis of a diagnosis and anticipated results which are probabilities not certainities. To aid in decision making process decision trees are constructed. A decision tree can help to

1) point out background information
2) explore need for more diagnostic work up
3) expose the consequence of treatment

When the diagnosis is uncertain or the treatment has risks for the patient, a decision tree has to be applied. To apply the method of decision trees to a clinical problem, the physician has to enumerate the possible consequence of decision, estimate the probability of each possible outcome and assess desirability or utility of each outcome.

In recent years decision analysis has been increasingly advocated as a means of solving complicated clinical problems. These problems tend to involve numerous variables that must be carefully weighed before a solution can be proposed. The rationale for using this method is that it is logically constructed and mathematically based and will provide a major objective answers to many clinical questions.

Historically the professional ideal of the physician-patient relationship held that physician directed care and made decision about the treatment. The patients role was to comply with the doctors orders. Although this paterenalistic approach often took account of the patients general preference and attitudes towards treatment, it gave a minimal role to the patient in decision making. When faced with what appeared to be a patient irrational choice or preference, physicians were encouraged by this approach to overlook or overide them as not being in the true interests of the patient.

This attitude is changing and it is replaced by a concept of shared decision in which both the patient and physician have to make an active and essential contribution. Physicians bring their medical knowledge and patient bring their belifs and conviction, to make a shared decision.

When there are clinical problems which arise out of a decision tree it can be solved by mounting clinical studies or search of medical literature. But this method cannot be used when physicians have a difficulty in facing clinical ethical decision.

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eg. 1) Should we write Do Not Resuscitate (DNR) on patient with bilateral strokes and pneumonia?

2) Should we treat a patient with entric perforation who refuses surgery or antibiotics because of his religious belifs ?

3) Person on ventilator due to C.P. poisoning whose relatives are not bothered about the patient and the patient is not getting medicines as nobody is bringing any medicine and the ward stocks are exhausted and clinically patient appears brain dead?

These types of question provoke physician discomfort for several reasons

1) Life & death decision that provcke deepest human emotion.
2) Education & Training has not prepared them to approach the problems analytically.
3) Fear of criminal or civil charges.

With all these quandries is it possible to develop a systematic approach to clinical ethical decision that may to some extent improve their ability to reach a reasonable, legal and morally defensible decision in these difficult situations. Any method that is evolved should take into account all relevant factors.

Any method that is evolved should gurantee for the physician that all relevant considerations are taken into account and that none is overlooked while reaching an ethical decision.

MARK SIEGLER has described a method takes into account all the above mentioned factors.

To make a clinical ethical decision the following factors have to be taken into consideration they are

1) Medical indications
2) Patient preference
3) Quality of life
4) External factors

Medical indications:

This is the first and most recognisible part of decision making process. A physician should examine the patient and a diagnosis should be made Physician should consider all the therapeutic modalities and the finally recommend the best option available to the patient.
It does not mean that he will place all the options before the patient, and then ask the patient to choose. Certain authors like Ingelfinger characterise this type of approach as a malpractice or sheirking of physician responsibility. Hence it is a primary duty of the physician to sort out the possibilities, weigh the pros and cons and then recommend a course of action. Until this step is completed we cannot advance in the process of clinical ethical decision making.

PATIENT PREFERENCE:

After the physician has recommended the best possible treatment, patient has the preorgative to accept or reject the treatment depending upon their personal choice and belifs. If the patient is not competent then the family members or designated persons should make the decision.

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The wishes of family members are taken into consideration because it is felt that they would know the intentions of the patient better than others. Sometimes it may be difficult to judge whether the request made by the family member might have been that of the patient, If the family members derive some benefit from choosing this modality.

When the patients refuse recommended treatment then physician should judge about the competency of the patient in making this decision. If the patients are incompetent the family members should be consulted.

Once a patient makes a choice it has to be respected sometimes physicians do not accept these decisions (due to the fear of legal problems) and then it leads to prolonged legal struggles and unsavory incidents

In US courts have always upheld the right of patient to make decision starting from Karen Ann case to the latest Nancy curzan case, the right of the patient to make decision is paramount. courts have also taken pains to protect the rights of patients. In the Nancy Curzon case, in the first trial the wishes of the parents was not accepted as the court felt that there was no sufficient evidence to show the patient would have refused treatment. Only in the subsequent trial and with fresh evidence court accepted the wishes of the parents.

In the USA about 10% of the patients make a living will. In a recent study it has been shown that 70% of patients with chronic incurable diseases have indicated their preference for D.N.R. and for not using life supporting system in the event of cardiac arrest.

Most of the times the patients and physicians choices coincide But there are some instances when the medical indications are grim and in which the patients are unable to make a choice. (none of the therapies offer much improvement and patient in incompetent) Two other factors come into play they are quality of life and external factors.

QUALITY OF LIFE:

Although it is frequently used the meaning is ambigous. It is a subjective evaluation by an onlooker about a patients subjective experience of personal life. It is used in a setting where a patient is unable to make a evaluation or is unable to express it. The standard which is almost always applied by someone other then the person who is living the life that is being assessed for its worth represents an attempt to put a value on some collection of features of human experience. It is based on more of subjective feelings and less on objective facts. In routine practice physicians do not place much weight on quality of, life consideration except those that are expressed as the patients own preference. However quality oflife considerations will tend to be invoked in clinical,circumstances in which both medical indications are limited and patient preferences are not known. These are:

1) Untreatable or terminal illness
2) Patients having brain damage
3) Neonates
4) When there are no code decisions

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EXTERNAL FACTORS:

External factors refer to any consideration in a case that yields a burden or benifit to some party other than the specific patient for whom the decision is being made. This takes in account the wishes of the family, costs of medical care, allocation of medical resources and well being of the society.

Although almost any clinical decision will involve some external factors such as these, the question arises as to whether the physician should ever consider these effects and allow them to influence the clinical ethical decision making process. When, if ever is it ethically permissible to weigh the patients interest against that of the society? In general external factors do not and should not be accounted for great weight in routine clinical - ethical decision making.

In the US courts have not taken into consideration the quality of life nor other external factors like costs. In a celebrated case of Baby L the courts did not take into consideration the quality of life. In the case of Nancy Curzan, the courts did not take into account the costs of treatment. Hence most of the clinical decisions can be made by physician and patient interactio

Why do patient make seemingly irrational choice? When we analyse the causes for irrational decision making
They are Bias towards present and near future
It is rational to prefer a restoration of function now rather than later and it preferable that a loss of function occurs as far in the future as possible so as to minimise the period of disability or loss of one's life be as far as possible atleast while it remains a life worth living. It becomes irrelavant to refuse to undergo a painful experience now if by undergoing it one can avoid a much worse experience in the future. This is known as a bias to present and near future. People commonly give a disproportionate weight to securing benefits and avoiding harm in the near future as opposed to the more distant future.

It wont happen to me. Some patients will irrationally deny the possibility that an untoward event could happen to them, they also have magical illusory belifs about their vulnerability to harm or simply have a different way of viewing the medical problems.

FEAR OF PAIN:

Patient may delay or nor even consider a particular treatment for the fear of the percived nature of the experience although they may acknowledge that the treatment clearly is in their best interests.

FRAMING EFFECT:

The way a question is framed may provoke a negative response. eg. prognosis, patients tend to accept the concept of gains more than losses.
Sometimes what the patient wants to do does not make sense to the physicians. Patient may decline the course of treatment because of an obvious understandable unusual belif. Patients belif must be respected. If a patient demands a treatment in which physician believes it to be ineffective physician is not bound to provide the treatment.
When choice are judged as irrational physician have to make a change in the choice by persuading the patient. Physician lack both ethical and legal authority to override a patient's wishes. Sometimes the failure to persuade a person to change his choice may be taken as a serious impairment in decision making.
When irrational judgements are made physicians must attempt to protect the patient from the consequent of harmful effect of the choice.

CLINICAL ETHICS

Clinical ethical work up outline.

I Medical Facts: Using the problem oriented medical work up

II Human values and issues

III Practical General Ethical Fundamentals

IV Identify the major conflicting values

V Decision making

How does medical ethics contribute to patient care? Clinical ethics is intrinsic to the work of the physician and the practice of medicine. The central focus of clinical ethics is individual patient-physician decision making. Clinical ethics seeks a right and good healing decision for the particular patient. Clinical ethics is often enmeshed in factual uncertainity. This is because it is often conducted in an emotionally charged situation or in emergency circumstances. It is a fact that medicine and ethics are inseparably linked because the identification of conflicting values, a necessary step for ethics, depends on the medical context or facts. In this short paper I will present the approach used in the clinical ethical work up of a patient.

I. MEDICAL FACTS

Identify all significant medical factors and their likely consequences. Without these facts a critical understanding of how a case raises moral issues is impossible. If the prognosis is ambiguous because of improper/incomplete medical work up moral issues arising may be impossible to resolve.

II. HUMAN FACTORS

These arise in each case: Patient's age, attitudes, occupation, family situation, behavioural history indicating attitudes and values, religious beleifs and so on. Human factors often express values that come into conflict with medical management and give rise to ethical dilemma. eg. The family wants to know the prognosis of the patient, which the physicians are uncertain of.

III. PRACTICAL GENERAL ETHICAL FUNDAMENTALS

III (i) Preservation of life.
Alleviation of suffering.
Injuction that physician "first do not harm"
(Primum non nocere)
Respect for autonomy: Patient alone or their legal serrogates have the right to control what happens to them.
Concept of social justice: An effort has to be made to ensure that medical resources are allocated fairly.
Benficence: act of benefiting patients.
Nonmaleficence: refrain from harm
Disclosure: Providing adequate and truthful information for competent patients to make medical decisions.

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Informed consent.
Brain Death and Organ Transplantation.
Witholding and withdrawing life support.
The vital concept of proportionate treatment: At least a reasonable chance of providing benefits to the patient which outweighs the burdens attendent to the treatment.
Benefits and Burdens: The reasonable possibility of return to cognitive and sapient life as distinguished from biological vegetative existance eg. Instructions for "Code" versus "No Code"
Effective communication with patients and families: Some physicians communicate better than others.
Early determination and ongoing review of individual quality of life values versus Quality of Life Years. The former is essential in evaluating patients, the latter is highly controversial.

III (ii) Policy Guidelines in Hospital Departments
Criteria for admission to ICU
Policy guidelines for ventilatory care
Policy guidelines for dialysis
"No Code"
Assessment of Organ System Failure

III (iii) Ethics in ICU
In the ICU ethical principles may be more difficult due to environmental social and economic pressures. Commonly used principles are Beneficence, Nonmaleficence and Autonomy. Remember principles that may conflict: eg. Beneficence Vs Autonomy. If the patients human values (interests and wishes), medical work up and ethical issues were defined before admission to ICU by the patient their surrogates and the primary physician, many of the most ethically difficult ICU situations could be avoided. Primary care physicians are in a particularly good position to inform the patient and family about the consequences of the critical illness, life support measures and to get their response in order to help them to prepare durable powers of attorney or living wills.

III (iv) Criteria for Advanced Life Support
Young patient — Previously healthy
Strong constituion — Disease potential self limited.

Criteria for No Advanced Life Support
Elderly — Long standing illness
Terminal Disease
Emaciated chronically ill: eg. these do badly with ventilatory care - "Can never be weaned off the ventilator"

IV IDENTIFY THE MAJOR CONFLICTING VALUES AND SET PRIORITIES FOR VALUES

V DECISION MAKING

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Standard academic tests can evaluate students and physicians ability to think clearly and critically about an ethical delemma. Observation is the only way to evaluate Human values eg. whether the patient is treated with respect. A clinical ethical work up provides the physician with a meaningful experience and search for the best medical knowledge available, address of, sensitive issues and how they are dealt with by "problem solving skills". Cases may be very simple or complicated.

CASE ILLUSTRATION

48 yr male non smoker diagnosed Severe Pulmonary Fibrosis with Pneumonia and Respiratory Failure. Two years before the bronchoscopy was negative. He was advised an open lung biopsy but refused. This patient takes 3 months to improve marginally and is discharged on oxygen at home. He has copious sputum 2-3 cups per day white and frothy and a diagnosis of Alveolar Proteinosis is considered. But patient is medically unfit for bronchoalveolar lavage because of profound hypoxia. He is readmitted after 3 days because oxygen supplies are erratic at home. The patient is in profound respiratory failure.

Human factors:

- Financial, Oxygen machine costs : Rs.60,000 to be raised. Hospital stay four months cost - Rs.50,000. Wife asked family to help financially and many conflicts consequently arose. The Chest Conference raises the issue that the patient may have fungal infection of the lung and it should be treated. Amphotericin B is started. Patient deteriorated and died. Postmortum true cut needle lung biopsy taken.

Report: Broncholar Alveolar Carcinoma. The wife is informed of this report she is deeply bereaved by the loss of her husband but expressed relief of profound guilt she was experiencing because she had resufed the open lung biopsy two years before. Wife was reassured. Throughout the management of this patient his wife and her mother was treated medically (control of hypertension, and social/financial conflicts addressed. The patient during his illness went through an episode of severe situational depression. This case illustration mainly the conflicts arising from human factors and some ethical issues. Autonomy of the patient to refuse tests.

Disclosure: Patient asked to be told the complete implications of the diagnosis. As we did not have the means to confirm the diagnosis we gave the presumed diagnosis and treated for this diagnosis namely pulmonary fibrosis with steroids which failed and then immunosuppression using azothioprine which is the recommended treatment in steroid fail pulmonary fibrosis. This was reasonable treatment for this presumed diagnosis. The patient consulted other specialists but showed no wish to leave our care. This is a frequent consequence of severe illness, protracted course and when the diagnosis is not confirmed. (In this case by an open lung biopsy). During the last two weeks of the patients stay in the hospital the wife was supported by adequate explanations to her many questions and for the economical consequences and difficulties she was experiencing Imminent death was explained to the wife 1-2 weeks before the patient's demise and the necessary support given during this interview.

ETHICS IN THE UNIVERSITY TEACHING HOSPITAL

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The ethical factor is constantly present in all actions and decisions in a health care facility especially a teaching one and a Christian one at that. All hospitals should evolve a written code of ethics and morals and have an ethical committee. Ethical values and codes must be communicated to all staff in a meaningful way. Despite this, problems will constantly crop up which are not adequately covered in any formalised set of rules. Fortunately such problems can usually be satisfactorily solved with common sense and humane reasoning, against a moral background.

Ethics in a university teaching hospital has 3 dimensions:

- Secular ethics which are followed by all health care institutions.
  eg. - care of patients, cure or amelioration of disease
  - training students to become competent professionals
- Organisation with any religious offiliation have additional moral considerations eg. instilling in students and staff moral as well as secular professional values and codes, social justice in health care administration.
- Specific considerations of an institution belonging to a specific religion. A prime example would be the Catholic Church's teaching on human procreation.

Remember that a teaching hospital plays the following roles:

- service to patients
- education of medical and paramedical personnel
- research

With this as a general background, a few specific points may now be considered.

Spiritual Aspect of Holistic Care: Christian hopitals must not forget the spiritual aspect of the person who is their patient. Most institutions have a chaplaincy service but often the chaplains are not as effective as they could have been.

- adequate training is essential for hospital work is not just an extension of parish duties. SJMC&H has been running a formal 3 months course in Pastoral Health Care for the last 3 years.
- the chaplains must form an integral part of the medical team, interacting with doctors and forming a bridge between them and patients and relatives. This is an area that has been much neglected.

The Financial Crunch & Social Justice: Stringent financial management is inevitable if we are to make our institutions economically self-supporting. But we must not allow ourselves to become schools of business management turning out entrepreneurs rather than professionals.

The right message should go out:

- that our institutions have to be self-supporting
- that this can be done justly, humanely and morally
- that students and patients are looked at individually and their needs and resources considered.

- that we remain committed to equitable distribution of health care so that not "only the rich and the privelaged have access to the system" (Illich).

Containing Costs: How can we contain costs without sacrificing "academic medicine "?

- Drugs - Using generic and low cost drugs where possible and resorting to bulk purchase.
- teaching our graduates to prescribe rationally and always consider the costs involved.

- Routine Investigations:- The routine battery of tests ordered in most teaching hospitals add up to a considerable sum and most of them do not add much to diagnosis or therapeutics. Still it is felt that in a teaching instituion a certain ammount of over-investigation is inevitable. Where is the line to be drawn?

- Capital Intensive Equipment :The cost of high tech medical equipment is astronomical. The cost of single such item could provide primary health care to a village for 1-2 years. Nevertheless, we strive for excellence in all fields, and it is our duty to do so. It is the institutions moral and ethical duty
  - to carry out a cost analysis to be sure the hospital can afford to buy and run the equipment.
  - to plan an approach for patients needing use of the equipment but unable to pay for it.
  - when there are competing demands for finite resources to choose the item which will benefit the greater number of people.

Teaching Material: the General Ward Patient Conventionally the general ward patient is the teaching material for our students. It is the price to be paid for not being able to afford a private room. Our students get the wrong message for the patient is not "teaching material" but is the teacher to the profession. Medical teachers and faculty have a key role in impressing this fact on the students. The patient has a right to refuse to be examined but will often agree if he is treated respectfully and his consent obtained after proper explanation.

Do Some Moral Values Deny Learning Opportunities to Students:-
The catholic Church has strong beliefs in the field of human procreation. Catholic hospitals do not carry out IVF, abortions and many birth control procedures. Does this deny the learning of certain skill by students? It does, but that is not in any way a valid reason for changing these beliefs. These beliefs & teachings have evolved for valid and considered reasons which are above purely professional or technical considerations.

This paper attempts to show that for a Christian Teaching Hospital the ethical dimension has to be considered even in mundane, every day things. Secular institutions may find themselves uncomfortable at this fact but for us morals and ethics have to be the basis for all decisions.

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THE WHITEFIELD STATEMENT

Having discussed the role of Medical Ethics in the curriculum of Medical Colleges and being aware of a growing culture of violence in our country, we the members of the four Christian Medical Colleges/Centres, ~~the~~ together with the Christian Medical Association of India and the Catholic Hospital Association of India have deliberated on certain issues involving violation to human life and wish to express as follows:

1. Abortion

The Medical Termination of Pregnancy Act was passed in 1971 with the intention of helping married women with repeated pregnancies. However, it is noted that it has led to a great increase in abortions, totalling over 11 million annually, three fourths of which are done for unwed pregnant girls. We reiterate that it is most unethical to terminate human life from conception onwards and we decry the practice of abortion.

2. Newer Contraceptives

The health of many women in our country is greatly jeopardized by newer anti-pregnancy vaccines, hormonal implants, dangerous drugs such as RU 486. All these experimentations are carried out without any informed consent and many have "surrptiously" progressed to field services. All this human experimentation, leading to dangerous & yet unknown consequences, must s top forthwith.

3. Prenatal Sex selection

The use of ultrasound and amniocentesis in pregnancy has invariably led to female foeticide. We condemn very strongly this violation against female children and we wish to promote whole heartedly the value of equality in both the sexes and the need to protect young innocent lives.

4. IVF Techniques

Many IVF techniques being practised not always ethically, have resulted in hundreds of live embriyos frozen in the laboratories. This poses an enormous human problem which must be discussed and guidelines should be issued.

5. Handicapped children

The practices of infanticide and neglect of handicapped children is contrary to all norms of natural justice. We must spearhead a movement for special care of these children and provide facilities for their treatment and welfare, including adequate job opportunities.

6. Euthanasia

The fabric of scant respect for human life is manifest at its terminal stage, when doctors are being enticed to actively promote euthanasia. The introduction of Euthanasia Bills in some States in India will only lead to debasement of the health profession as seen in some Western Countries, where doctors and nurses have taken upon themselves the onus to terminate lives. We must emphasize the cherished values incorporated in the Hippocratic Oath and relentlessly expose and oppose such practices.

Doctors and health professionals should be true guardian of human life. It is upto us to provide this leadership through the network of Christian Hospitals and other Institutions, to oppose vigorously the present "culture of death" prevailing around us and to restore a sense of well being and protection of all human life from the moment oc conception to its natural end.

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MEDICAL HUBRIS

A REPLY TO IVAN ILLICH

DAVID F. HORROBIN

CHURCHILL LIVINGSTONE
EDINBURGH, LONDON AND NEW YORK 1978

11 Proposals for Change

'The medical establishment has become a major threat to health.' In spite of all my criticisms of his work, in spite of all his exaggerations and inaccuracies, I still feel that Illich's first sentence is right. He is wrong about the current seriousness of the threat; he is wrong in extrapolating so glibly to the whole world from the countries of his own experience, he is wrong in his estimate of the contributions medicine has made. But he is right in his assessment that things are beginning to go badly awry and that action is required if they are not to get very much worse in the near future.

So I agree that the main thrust of description of the state of medicine and its relationship with society is not too far wrong. His description of the syndrome is reasonably accurate but his refusal to recognize that most of the critical material he has assembled comes from medical sources and that much of the work has already been done by doctors themselves is totally misleading. Illich is not such a lonely prophet as he imagines himself to be. He does not have a monopoly of insight. Joseph Conrad wrote a book 'The Secret Agent' which was first published in 1907. In it the Professor says to Comrade Ossipon with regard to the views of a third revolutionary 'And so Michaelis dreams of a world like a beautiful and cheery hospital.' Ossipon replies, 'Michaelis may not be so far wrong. In two hundred years doctors will rule the world. Science reigns already. It reigns in the shade maybe – but it reigns. And all science must culminate at last in the science of healing – not the weak, but the strong. Mankind wants to live – to live.' Many doctors here share Illich's concerns but there is little doubt that they are ignored by many of their colleagues or that their plaints fall on many deaf ears.

But while Illich is not too far out in his descriptions of what is now and what things might become, he is hopelessly wrong in his understanding of the pathogenesis of the situation. Despite his claims to be an historian, he seems to have little feel for history. Despite his concern for the individual, he seems to have little understanding of how ordinary people operate. Despite his repeated desire that the earch should be a place in which Everyman should live, he consistently wants his Everyman to be a Hero.

Illich has a view of the operations of the medical profession which is

very close to th[illegible]sion that John Kenneth Galbraith has of the functioning of the modern large corporation. Galbraith sees the corporation as deciding not what the public needs but what the corporation wants to supply. It has enough influence then cynically to manipulate public desires so that people feel a great hunger for this object which the corporation supplies. In a way almost exactly predicted by the corporation, the supplies are made available. The corporation makes a profit, it reinforces its power and influence and poor individuals in society are trapped ever more deeply in the machinations of the new industrial state.

According to Illich modern medicine operates like the modern corporation. It has decided that it wants to supply perfect health for everyone. It has cynically set about persuading people that that is what they want, and having created the desire, it has made arrangements to supply it.

To me this seems to be a completely false interpretation. As far as I can see health has always been a major concern of traditional societies. At no time in the past has the great majority of individuals felt able to cope with pain, disease and death in a sturdily independent way. Most people have always felt bewildered in the face of these trials and have always been willing to put themselves in the hands of healers and priests who have offered remedies and religions to enable man to cope. In many traditional societies the role of the healer priest is all pervading and crippling. So many rules must be adhered to, so many rituals followed if an individual is to remain healthy that sturdy independence is often non-existent. For thousands of years the healer priests have been as powerful as, or sometimes more powerful than, rulers in the communities they 'served'.

One thing limited their influence. That was their near total lack of success in treating disease and preventing death. Certainly some primitive remedies worked. Certainly healer priests, like many modern doctors, were willing to exploit for propaganda a spontaneous return to health which had nothing to do with their machinations. Certainly by means of mystifying language and impressive ritual many were persuaded that the healing was more successful than it really was. But never and nowhere were traditional healer priests consistently able to point to regular major successes in man's battle with disease.

Medicine had inherited the role of the healer priests. It is obviously heir to the healers of traditional societies but the 20th century collapse of much organized religion has led in addition to many people looking to doctors for advice and comfort which they previously received from their priests. It has therefore obtained a double influence. But much more than that, although it is less successful than it and the public think it is, it can point to a long series of spectacular and consistent miracles.

The conquests of polio and smallpox, the removal of parental fear that their children will die of pneumonia or diphtheria or tuberculosis before they reach adulthood and many other successes are unequivocal and readily demonstrable. Because of the traditional desire of the sick to put themselves in the hands of others, because of the obvious power of modern medicine, society has willingly accorded to doctors an influence and a power which they have never had before. But the profession has acquired this power in a fit of absentmindedness. On the whole it has not deliberately sought it, and it does not know what to do with it. Far from using it in a heroic and Promethean manner, it has bumbled along making decisions of enormous significance without realising what it is doing. In some ways this is far more dangerous than a cold and deliberate bid for power would have been.

Finally, Illich is tragically wrong about solutions and perhaps even uninterested in them. In some ways it seems that the last thing he wants is for medicine to be reformed effectively either as a result of internal or external influence. Instead he wants doctors to behave in a ridiculous and arrogant fashion in order to horrify people so much that the whole structure of industrial society, including medicine, is brought crashing down. Hence his solutions are unrealistic or trivial, quite impossible to achieve in any democratically organized society, yet incompatible with all but the most benevolent (and therefore non-existent) totalitarian regimes. Some of his remedies, as in the case with his ideas on pain and his desire to abolish all control of both doctors and quacks, seem likely to intensify rather than to ameliorate the very problems he discerns. While complaining all the while about the use of mystifying language by doctors, he and his disciples consistently write and talk in ways which are often nearly incomprehensible. Sir Karl Popper's remarks about the philosophers of the Frankfurt school seem to fit Illich and his friends. They are in 'a tradition which accepts that something is profound when it cannot readily be understood and that the sign of a man who has had a university education is that he can write and speak in a manner which is both impressive and incomprehensible'.

Some tentative suggestions

My basic philosophy of the way to bring about political change at any level in any society consists of two propositions. The first is that we must start from where we are and we cannot do that unless we can see our present position with a reasonable degree of realism. The second is that, without any exceptions at all, the consequences of any proposed change are always different from those that the proposers predict. The gap between expected and actual consequences becomes greater the greater

the degree of change proposed. Since almost invariably the consequences are less favourable than expected, the greater the degree of sudden change, the greater is the shortfall between hope and reality.

At the moment I think that both Illich and the medical profession have an imperfect grasp of reality. Many doctors do not realize how serious the situation is and only partly understand the origins of those defects in the system which they do perceive. Illich has a better but exaggerated perception of the current situation but has almost no insight into its origins. He has performed a service by taking the writings of some concerned doctors and setting them out in such explosive and inflammatory language that the ideas must command some attention. It is up to the doctors, infuriated by Illich's rhetoric, not to condemn him unthinkingly but to consider seriously his thesis, to admit where he is right and then to set about doing something about it.

If a large enough number of doctors does become sufficiently roused to make a realistic assessment of the state of medicine, what is the best way of generating change? Illich's answer is essentially to remove most controls and to allow the public to decide what it wants. He does not believe that the profession will ever be able to make the decisions to move medicine towards what he sees as a more favourable state. I think he is totally wrong. The thirst for miraculous health is such that lay opinion is likely to be captured by effective publicists anxious to acquire more and more power. The last state will be worse than the first with a public dominated more than ever by health concerns and unable to make any rational assessments of the irrational complaints of competing healers.

My own belief is that most doctors are neither particularly humane nor particularly perceptive of the needs of society in general or of patients in particular. But one of the strengths of medicine is that it has repeatedly produced great healers who have seen the necessity for reform and who have dragged along their colleagues, grumbling and complaining furiously, but nevertheless ultimately being willing to change. Often the great men have been successful simply because they have pointed to the ideals of the Hippocratic Oath and have shamed their colleagues into agreement. The agreement has not come from the heart but the hypocritical head. However as C.D. Darlington has noted when speaking of the early Christians, 'Within the community, they established a stern uniformity of conduct, a deference to their own rules. Now although such public deference must always engender private hypocrisy, it is in practice the only weapon invented by man for raising the conduct of a heterogeneous society above the average genetic and instinctive level'. Because of their claims to be possessors of high ideals no matter how hypocritical such claims may be, if doctors are to retain public respect they will always be vulnerable to

those who demonstrate that the medical profession is not acting in the interests of society. Ultimately, if the idealists are persistent enough, they will always be able to force doctors to act hypocritically and grumbling and groaning, to surrender personal privilege and wealth in the interests of humane medical practice.

I therefore think that because of its supposed ethical basis the medical profession is vulnerable to enlightened pressure. But if it is to be fully successful such pressure should come from within and should be well informed. Ignorant outside pressure will always be angrily resisted.

Medicine is in a serious state and is in need of reform. But reform is likely to be effective only if the proposals are based on realistic information about the current situation and about its origins. I therefore think that such reform can be effected only by doctors themselves, by doctors sensitive to the criticism of laymen such as Illich. But doctors should not be under any illusions. There is a serious breakdown in the relationship between medicine and the public and unless doctors move to do something realistic about changing their behaviour themselves, heavy-handed attempts at reform will come from outside. Because of the vulnerability of lay opinion to all that is worst in medicine, the end result is likely to be much worse than before. Precisely contrary to what Illich hopes, there will be more bureaucracy, more waste, more meaningless control and the public will be even more firmly in the grip of those who want to remove its independence and control its destiny.

Simply in order to demonstrate that my approach to medicine is basically positive I shall conclude by presenting very briefly some possible solutions. These can be given in outline only here and I would not wish them to be regarded as more than tentative suggestions. There are four main issues which must be faced.

1. Is there too much or too little science in medicine?
2. Is there to much or too little technology in medicine?
3. Is there too much or too little administration?
4. Is it appropriate that a profession which claims to be a vocation and to offer a most important service to the community should also be the best rewarded financially?

Science in medicine

With 'love' being the only possible exception, 'science' is the word currently most misused in the English language. It ought to be a criminal offence punishable by at least seven years course-work in political science or social science, to use it without some definition. In the current context I mean by science the attempt, using reasonably reliable methodology, to ascertain the truth about situations in medicine. I am fully aware that any pedantic

philosopher – which I sometimes am when wearing another hat – can shoot that definition full of holes. I am also aware that anyone wearing an average man full of common sense hat will understand very well what I mean. The role of science in medicine is to attempt to get at the truth. When defined in this way it is difficult to see how anyone could object to scientific medicine.

But the fact is that many do object to scientific medicine. In the minds of many average men full of common sense there is a strangely illogical antithesis between a warm and humane approach and a cold, scientific one. I personally find it somewhat difficult to understand why falsehood and ignorance should be warm, while truth and knowledge should be cold. They seem to me to be very nearly independently variable qualities. However I happen to believe that what we want in medicine is not less science but more and so I had better explain a little further what I mean.

We do not know whether most of the things which we do to patients are better for the welfare of that patient than if we had done nothing at all. And on the whole we most of us prefer to remain warmly ignorant rather than coldly knowledgeable about the situation. It is I think obvious to anyone who looks at medical practice with anything like a critical eye that many of the things which are done to patients either have no influence on the outcome of the illness or may increase discomfort and hasten death. Much money would be saved and many patients would be better off if less medicine were practised. But which bits of medicine should be discarded? The only way to find out is by an effectively designed controlled trial in which the consequences of no treatment are compared to those of treatment. If more such well designed studies were performed, I have little doubt that many currently used treatments would be dropped and many proposed treatments, after careful trial in a limited number of centres, would never be widely introduced.

Unfortunately it is often difficult to persuade doctors – and in my experience much more difficult still to persuade most laymen – that to have a patient untreated may lead to an outcome more favourable than that resulting from any current treatment. The problem arises because of the illusion that in an untreated patient nothing is being done. Man's body is the product of hundreds of millions of years of refining evolution. Its survival depends on the ability of bodily control mechanisms to maintain the constancy of the physico-chemical features of the body fluids within which the cells are bathed. The potency of these mechanisms is extraordinary. It is only their superb effectiveness which prevents us from being continually surprised not that we get ill but that we ever remain well. In illness these internal control systems fight heroically against the

agents which would upset their equilibrium. With any disease a massive effort is therefore continuously being made to counter the disturbing forces. Any human intervention will alter the balance of power in this struggle between disturbance and equilibrium. It is just as likely to hinder the equilibrating forces as the disturbing ones and it is therefore by no means self evident that any treatment is better than none. Yet while most people, both medical and lay, can see the validity of this argument, most also have great difficulty in overcoming their emotional conviction that to do something must always be better than to do nothing. It is this warm emotional conviction which has done more than anything else to encourage the introduction into medicine of damaging and ineffective methods of diagnosis and treatment. Only more and better science will perform the humane function of eliminating the errors encouraged by warm emotion.

Technology in medicine

Technology is a word misused almost as much as science and so again I must begin by attempting to define what I mean. In this context what I mean by technology is simply the application of a technique to a situation, without any critical consideration of whether the outcome is likely to be favourable or not. And while there is too little science in medicine in the sense in which I have used the word there is unequivocally too much technology. There is a certain type of doctor who is very impressed by techniques particularly when they involve electronics, computers and oscilloscopes: such doctors love flashing lights, rolls of chart paper and pale green lines on screens. So mesmerised are they by the complexity and cost of the equipment that for the most part they do not even begin to entertain the possibility that the expenditure of large sums of money on such wonders might fail to benefit patients.And so expensive and complicated techniques are introduced without any properly controlled trials. Since the desire to have such techniques available in one's own hospital or unit seems highly infectious, once one has been acquired they tend to proliferate hugely at enormous cost and with no real benefit – or at the very least before anyone can be reasonably sure that any real benefits will accrue to the patients. Techniques should be subjected to controlled trials at least as rigorous as those which new drugs must undergo. Only if the outcomes of such trials are favourable should the techniques come into common use. This very simple device of the application of more rigorous scientific standards would stop at the outset the introduction of much useless new technology. But if such a reform comes about it will have to be pushed by doctors since laymen seem appallingly vulnerable to the megalomaniac intentions of

those members of the medical profession who are obsessed by the ideas that any innovation is good and that there is a strong positive correlation between the effectiveness of a technique and its cost.

Administration of medicine

One of the greatest paradoxes of the organisation of any modern profession or government department is that while most people instinctively understand what is required of an effective administrative machine, the administration machines actually constructed seem specifically designed to be both very costly and highly ineffective. An administrative structure whose function is to serve the public should be so constructed that the maximum number of decisions affecting individuals are made in the shortest possible time by other individuals in whom the public has confidence. Yet most administrative reforms seem to succeed in ensuring that members of the public almost never meet fact to face in the first instance with a courteous and competent person who has authority to make real decisions. Furthermore, the decision making process is so dominated by complex committee structures and tiers of organisation that even trivial questions may take months or years to sort out. The aim seems to be to set out a procedure which takes care of every possible circumstance and as far as possible eliminates individual error by eliminating individual responsibility. The result to the individual member of the public is a faceless and inhuman monster with which it is impossible to argue or fight. This leads to an apathy and a despair about the place of any individual in a modern bureaucratic state.

Medicine is no exception to this general picture. In all countries, irrespective of whether medicine is state or privately financed, the numbers of people with no technical role as health professionals but with purely administrative duties have increased. It is unfortunately true that the increases have been most dramatic in countries with state controlled systems and that the resulting administrative patterns have become labyrinthine and self defeating. It would be foolish to deny that changes in the pattern of administration have made some things better. But most of these things have been better for the professionals than for the public. There is an alarming tendency for improvements to be made purely for the benefits of administrators and to be in the interests of neither doctors nor patients. If our altruism has not been stirred by administrative monstrosities which obviously make things more difficult for the patients it is just possible that self interest may rouse the profession when the monstrosities make things more difficult for the doctors as well.

It is very easy to be uselessly generalised in one's comments on this situation so I shall try to be more specific.

1. It has several times been noted that the best administrators are those busy and competent people who hate administration. They are the ones who will make efficient decisions with the minimum of waffle and bumbling because they cannot afford to waste their time in unproductive ways. This means that as far as possible power should be in the hands of those people, whether lay or professional, who have no time to waste because their main function in life is not administrative. It also means that we should cease the ridiculous practice of defining promotion in a professional group as an opportunity to become an administrator. Once anyone becomes a full time administrator, no matter what their training, they cease to feel the same pressures to get things done quickly and effectively and they become infected by the administrative disease. As few decisions as possible should be in the hands of those whose function is purely administrative.

2. Attempts must be made to keep every medical institution as small as it is possible to be. The supposed increases in efficiency which come with centralisation and size have almost all proved either to be illusions or to have been gained by paying a price which ought to have been recognized as unacceptable. A good example is the closure of small hospitals in communities and the increasing centralisation of facilities in monster institutions. This has arisen because of a failure to recognize the extraordinarily simple fact that patients are in hospital for very different reasons. A surprising number are in hospital not because of any technical services which the hospital can provide but because, for reasons which have nothing to do with medicine, it is not possible for them to receive the minimal nursing care which in a well run 19th century middle class household they would normally have received at home. This sort of patient can readily be housed in an institution which essentially provides hotel facilities with no resident medical staff, no complex laboratory or radiological facilities, few professionals of any kind, but many people, often with no training at all, who are interested in looking after people. This sort of 'cottage hospital' is excellent for what it aims to do. It is cheap to run, it is usually close to the community it serves and it is often capable of generating a huge amount of community loyalty which is a major asset in helping to make it a humane place in which either to work or to be a patient. Above the cottage hospital should be another type of hospital whose function is to provide relatively simple technical services for those who are acutely ill. This requires simple operating theatres, radiological and laboratory facilities, resident medical staff and good trained nurses. Again because there are no facilities which most of the patients in hospital will never use, the institution can be kept small and can retain a good deal of community loyalty. Finally there should be specialist hospitals in big cities which will take only that tiny fraction of patients who can be cared for neither at home nor in the other types of hospital. Only in these units would the full range of complex techniques be available. Only these hospitals would cost to run per bed what many of our big general hospitals, most of whose patients could be in simpler institutions, cost today. The effect of this type of structure would be to return most hospital facilities and hospital patients to their own communities and to reduce costs sharply since the complex facilities instead of being provided for everyone in hospital would be used only for those who strictly needed them.

3. We must assess much more carefully the levels of training actually required to enable people to do jobs effectively. The greater parts of most courses for most health professionals cannot be justified either on grounds of technical or general education. All that most courses do is to delay the emergence from childhood to adulthood on the part of the students, to reduce the number of years a person can spend in productive work and to increase the distance between the haughty qualified professional and the poor bewildered patient.

In essence all I am doing is stressing that Schumacher's slogan 'Small is Beautiful' applies to things other than economics. Doctors, with their long traditions as independent individuals, able to take their own decisions, must resist vigorously attempts to make them cogs in a supposedly smooth running administrative machine.

Medicine and money

One of the most interesting features of *Medical Nemesis* is Illich's consistent refusal to make the most of the attitudes of doctors towards money. This is partly because he feels that the personal accumulation of wealth by doctors has an impact on the factors with which he is concerned which is relatively trivial. But it is also partly Machiavellian. Illich quite specifically and quite deliberately says that he does not want to control medical racketeering. Such obviously anti-social behaviour constantly reminds the public that their gods have feet of clay and seriously limits the power of the profession. If all doctors were humane and not particularly rich their power as a profession would be enormously increased.

I am antiquated and hypocritical enough to believe that a profession which is as satisfying as medicine, a profession which continually makes public pronouncements about caring, should not be, as it is in most countries, a certain road to wealth and security. There is something offensive in the fact that doctors are on the whole extremely rich by

any standards other than those of their immediate peer group. If Illich really wants to rouse the public against medicine, I personally believe he is being far too Machiavellian and that his strategy will fail. It is going to be very difficult to persuade laymen that doctors are as lacking in miraculous powers and even in competence as they in fact are. It will be much easier to arouse anger by pointing out the discrepancy between the high ideals which doctors often profess and their personal life styles.

But if Illich does not attack the groin in this way, others certainly will. Doctors must be made to realise the extent of their insensitivity on this issue and must stop being so greedy before it is too late. I am not optimistic of their ability to see that this really is an issue which could bring the whole pack of cards tumbling, and that if doctors do not reform themselves, someone from outside will most definitely do so. It should not prove impossible for professional bodies to set reasonable standards of fees and payments and to police these relatively simply. Unless something like this is done, the bureaucratic government machinery to carry it out will certainly be imposed in almost every country.

ACTIONS AT VARIOUS LEVELS

In all countries, while doctors are progressively losing to laymen their rights to make decisions they still have a good deal of power to regulate their own affairs. Possible reforms are legion and each country will have to devise its own. But I do not want to duck the issue of attempting to make specific recommendations concerning desirable changes. As I have stressed I believe that real improvements in the way we run a democratic society come from making small piecemeal changes in things which are obviously wrong and not from devising grand theoretical strategies for total revolutions whether bloodless or not. If the attitude of doctors is such that they are fully prepared to recognise problems and are eager to make effective changes, no matter how small those changes may be, the whole attitude of the profession towards the public and the public towards the profession will undergo a transformation.

I envisage changes being made at four main levels, of the individual doctor, of the organisation of the profession, of the relationship between government and medicine and medicine-related industries and of the medical school which is at least partly responsible for the face which medicine will bear in the future.

Individual doctors

The arrogance of some doctors faced with their patients is almost unbelievable. Yet alarming numbers of doctors are either unaware of how

arrogant they are or being aware are unconcerned. I am not sure how their attitudes can be changed, perhaps by a confrontation with an articulately angry patient, perhaps by an effective novel and perhaps not at all. It may be that fundamental change in the area will require a change in the sorts of people who are admitted to medical school. But one can always hope that with maturity will come an ability to treat as equals patients who do not happen to have specialised knowledge but who, because the illness is happening to them, deserve a full and unpatronising explanation of what is happening and what the alternatives are.

One very practical thing which in most countries would change the attitudes of people to doctors overnight would be a change of heart on home visits. I have recently moved from a country where home visits are a major, though declining, part of medical practice, to a continent where home visits are almost unknown. In Britain much of the residual affection which is attached to doctors depends on an experience with a competent and humane individual who came to see a sick person in his own home. In North America much of the growing resentment against doctors is related to their near total refusal to leave their offices to see any sick person. When two people have to meet, who travels to see whom is a statement about a number of things, but in part about who at that moment is the more important. In North America the view in the profession is near universal that the doctor is always the more important, that the doctor should waste as little time as possible in traffic jams, that there are no circumstances in which the patient is more important than the doctor and that therefore it should always be the patient who makes the journey, no matter how sick he may be. This surely is hubris of the worst possible sort and together with doctors' wealth may well be the issue which could bring nemesis. If they are not to be destroyed, if they are to retain their proud traditions of humanity and concern, doctors must change their attitudes to home visiting. Sometimes doctors may be more important and sometimes the patients must travel. But sometimes, and especially with the old and the very young, it is the doctor who should make the journey. Even if the direct clinical results may sometimes be scanty, even if the patient is not so ill as was imagined, home visits are very frequently gains for both doctor and patient. In my opinion one of the touchstones of the real motives of any doctor should be the attitude to home visiting. I feel uncomfortably sure that in North America at least most doctors would be found to be something less than pure gold.

The profession

The professional bodies in each country are in a position to make decisions and recommendations which can be enormously influential in changing professional attitudes for better or for worse. Unfortunately such influential decisions are rarely made by men and women who know what they are doing and who are fully aware of the enormous consequences. Decisions which later turn out to be of seminal significance are frequently made by incompetent small men with small concerns, only interested in balancing the personal power games in the organisation concerned. As a result medicine has drifted disastrously with few attempts at leadership and far sighted thought. It is certainly not hubris, but a total lack of it which has been the problem in many cases.

One major positive contribution which professional bodies could make is to stop assuming that anything which improves the personal financial position of their individual members is necessarily in the interests of the profession as a whole. What is good for General Motors is not always good for America and what is good for individual doctors is not always good for medicine in relation to society. If doctors as a group set out scales of fees and remuneration which were not legally binding but made publicly available and therefore carried a good degree of moral weight, and if those fees were such that doctors were adequately remunerated but not at a level which consistently made them the richest group in a nation, then, as Illich fears, the profession would gain enormously in respect and in its ability to influence the future direction of medical care systems. But if medicine consistently behaves as a purely self-seeking, money grabbing profession then sooner or later it will be recognized as such and treated accordingly.

Professional bodies should also be much more prepared to get involved in making hard hitting recommendations, as fully as possible based on hard science, as to the real values of treatments and diagnostic procedures. These should concentrate on demonstrating which techniques are useful, which are not and which are ones where more evidence is required. Some effort should be made to channel some research funds into effective testing of this type and some pressures should be devised to ensure that individual doctors at least take note of the research findings. The pressures should always be moral and never absolute since expert recommendations may sometimes and perhaps often be wrong but as far as possible doctors should be discouraged from using techniques or drugs whose value is uncertain or harmful. The profession must become less obsessed with technology and with innovation for innovation's sake and must try much harder to prevent fashionable and irresponsible misuse.

Governments and medicine

Since even in countries where medicine is basically privately financed, much of the cash flowing into medicine ultimately comes from government or is dependent upon government decisions, and decisions made by government can be enormously influential in determining which way medicine will go.

On the whole and this is perhaps a hopelessly optimistic concept, government should operate on the ideas that small is beautiful, that centralisation is very frequently inefficient, that administrative 'reforms' should never lead to an increase in the number of administrators relative to those of technical and professional staff and that costly high technology innovations should be fully evaluated scientifically. Clearly it would be silly in a book of this type to make specific suggestions for specific national situations. All I want to suggest are principles which should guide those who are trying to influence the relationships between medicine and government.

One interesting way in which governments could influence things would be to change patent laws in an imaginative manner. At the moment drug safety regulations and patent laws are such that it is impossible for a drug in most countries to enjoy more than a few years of patent protection while it is on sale to the public. Patent protection is given equally to drugs which are genuinely much better than existing ones and to those which are no better or even worse. Since the period for which patent protection operates is so short, it is frequently the marketing skill of the company rather than the real effectiveness of the drug which determines whether or not a product is a commercial success. I suggest that while the basic patent laws should operate as at present, patent protection should be withdrawn from any compound which is not unequivocally better in some clearly defined way than existing compounds, before the new compound is marketed. This would sharply reduce the number of competing products and the incentives to market effectively drugs which have little therapeutic advantage. Simultaneously, drugs which genuinely do provide an advance should be given perhaps 30 years full patent protection, not from the date of the original patent but from the date at which the relevant regulating body (such as the Food and Drug Administration in the United States) gave permission for the drug to be marketed. This would reduce the often unseemly haste to market a drug before it has been fully tested, haste which often stems from the knowledge that patent protected time is running out because it is dated from the time of filing of the original patent. It would also enormously increase the rewards offered to genuine innovation and would reduce the current drug company emphasis on the need to

market relatively ineffective products.

Medical schools

It is one of the illusions of both laymen and doctors that individuals are admitted to the medical profession at the time they receive their MD degree or its equivalent. The nature of the course followed and the examinations set are supposed to determine whether people will become doctors or not. This is an illusion because in most countries the failure rates of students going through medical school are now extremely low. For the most part people are selected to become doctors at the time they enter medical school.

Another illusion is that the quality of a doctor five years after graduation is related to the content of the courses that the doctor took during medical school and to the skill with which these courses were taught. It is my prejudice that this too is a fantasy. These factors may perhaps be important in the first year or two after graduation but by five years their influence has almost disappeared and thereafter it is non-existent.

What then is it which determines what sort of doctor a person becomes? Only two factors are of any real significance. The first is what sort of person *enters* the medical school. I do not believe that intelligence and personality traits can be much altered by education after the age of 20. The second is whether the philosophy of the medical school emphasizes teaching or learning as the key educational process. This is becoming almost an anachronistic consideration since those which used to emphasise learning have almost all been transformed into teaching orientated schools.

It is obvious to anyone who can see beyond the end of his nose that no matter how complete and valid are the facts taught in a medical school, those facts will be partly unknown to and partly forgotten by even the best students within a week of graduation, will themselves partly cease to be facts within a very short time and within 20 years of graduation will be of little value. After graduation, although occasional 'refresher' courses may be helpful, especially to morale, the only way in which a doctor is effectively able to keep up to date is if he personally seeks out selectively the information of value to him from a vast morass which is available. One might have thought therefore that a major aim of a medical school would be to help a student to prepare for a life time of this sort of study, of learning for oneself. In the great majority of the medical schools of the world nothing remotely like this happens. All day, every day, students are fed ephemeral facts by techniques, ranging from the traditional lecture to the modern computer, which will usually not be available to them in their lifetime of practice. Virtually no sustained

effort is made to offer a different approach in which the student is set objectives and then largely left to find and to learn the relevant material by himself. Lip service to the concept may be paid during a brief elective or project course but compared to the sustained weight of teaching the impact is trivial. The end result is a doctor whose education has most effectively atrophied the only characteristics which would enable him to remain competent throughout a lifetime.

Can anything be done to improve the education system? I have serious doubts because the schools are now so permeated by experts whose raison d'etre is the provision of teaching rather than the creation of opportunities for learning that the problems of generating change are likely to prove unsuperable. The sort of change I would like to see would be for a medical school to set out for its students the objectives of the course and then to leave its students to tackle these objectives themselves. Formal courses would be provided for those who wanted them but they would be drastically reduced and positive efforts would be made to ensure that no student imagined those courses to be compulsory. Students learn in many different ways and they should be given the opportunity to use the ways most appropriate for them. For some lectures are ideal, for others (myself included) there is nothing like a good book, for others learning is impossible without a practical experience. Few if any medical schools allow this diversity to be expressed. Everyone is forced into the common mode of following time consuming courses and time available for learning is almost non-existent.

As to assessment I regret to say – or rather am pleased to say – that I regard examinations as essential goads and guides for most students. Examinations have innumerable faults: in this they are like democracy. Both examinations and democracy can appear to be extremely unattractive ways of doing things until one looks at the alternatives. *All* alternative methods of assessment are less fair to someone, whether teachers, students or patients, than humanely conducted examinations. It does no one any harm to be forced to make a reasonably realistic assessment of his own abilities using a technique which incorporates the minimum of purely personal bias.

In short the only curricular reforms I would like to see are the introduction of clearly stated objectives which are not dependent upon the personal whims of a single teacher, a drastic reduction in formal tuition with an emphasis on forcing the student to find things for himself, and a reasonable emphasis on examinations as a method of assessment. I think that students emerging from such a system would be rather less like shell-shocked morons than some of those who now emerge from our medical schools with the grandiose title of 'Doctor'.

But I have no illusions that any revision of medical education of this sort would have any substantial reforming effect on the profession. The Medical Schools would still continue to choose the students with the very best grades for entry. And all over the world these grades are now very good indeed and most would agree that medical students, when assessed by conventional standards are the cleverest of all students in most universities. There has been a dramatic change in the last twenty years. Before that medical students were certainly not the brightest of students: their stereotype was that of the cheerful games playing oaf rather than the studious intellectual with straight As.

Most medical educators pride themselves on the quality of their students. In my opinion this pride is largely misplaced. The students have succeeded in distorting the pattern of medical education. Instead of trying to decide just what knowledge and skills most doctors need – and coming to the blinding realisation of the obvious, that on the whole the practice of medicine requires a very modest intelligence – educators have allowed the intellectual abilities of their students to determine the nature of the education offered. As a result all concerned, students particularly, and to a lesser extent teachers and laymen have been dazzled by the idea that competent medical practice requires great intelligence. It has become impossible for someone of moderate intelligence to become a doctor. Yet the great majority of jobs in medicine do require only moderate intelligence and this disparity between the intelligence available and the intelligence required becomes a major source of distress and unrest. It leads to pressure for the creation of more and more unnecessary high powered posts and to the demeaning of those necessary types of work which should make up the greater part of medical practice. It also leads to very clever doctors believing that their rewards are not commensurate with their intelligence and hence to an increasing lust for material reward.

The idea that medicine is a vocation seems to be disappearing from our medical schools. Students want to get into medical school because that is the ultimate accolade for smart city-bred kids and their parents: they want to get into medical school because that is a certain route to wealth: and only very rarely do they want to get into medical school for those old fashioned vocational reasons. It is therefore not surprising that we are increasingly breeding a profession whose major concerns are academic empire building on the one hand, and the rapid accumulation of wealth on the other.

The bright students who go to medical school are not even particularly interesting. Their concerns tend to be narrow, their lust to get into medical school at all costs all consuming. Since coming to North America I have learned that a high proportion of students who want to get into

medical school will stop at nothing at all in order to achieve their ends. Whatever the ability may be, it is inconceivable that those who will behave like this in order to get into medical school will ever make doctors who in any sensible meaning of the word could be described as 'good'.

I am therefore very gloomy about the current state of medical education. I see a cadre of narrowly intellectual, not very pleasant people, entering medical school and being herded through it in a way which is calculated to suppress any wider concerns they may have and to create a corps of brilliant morons, incapable of relating to their patients in any sensible way in spite of receiving more formal courses in sociology and psychology than ever before. Professor Stuart Sutherland of Sussex University in England recently wrote a book called 'Breakdown' in which he recounts in some detail his own breakdown and his encounters with those who profess to understand the working of the mind. In the end Sutherland concludes that most students would learn more about psychology and sociology by reading great novels than by going through any of the courses now available. This conclusion would perhaps be unremarkable if Sutherland were not himself one of the world's leading psychologists. Unfortunately I do not see many medical students reading great novels and their ability to relate to people in a sane and helpful way seems to be almost inversely proportional to their theoretical knowledge of psychology and sociology.

Is there any hope at all for medical education and therefore for medicine? The people now going through medical school seem to me to be more likely than ever to create Illich's nightmare world in which insanely applied medical power dominates individuals to a greater and greater extent. I have little optimism that any reform of the educational process itself will lead to much improvement given the present types of student entering medical school. As I see it the only hope is to change sharply the characteristics of the people entering medical school. In Machiavellian terms this seems to me to be a possibility because the number of people governing the choice of medical students in each medical school is very small. If only one or two of these people begin to adopt radically different ideas about who should be admitted to medical school they may well be able to exert an influence out of all proportion to their numbers on the future development of medicine. If change is to be a possibility it seems more feasible to change the sort of people entering medical school than to change those who are already in it. The change will take place slowly but it will be much more profound than any other sort of reform.

I suggest that the first point to be recognized is that while medicine requires a moderate degree of intelligence it does not require superb intelligence. Most posts in medical practice can be more than adequately carried out by ordinarily able people. The available pool of adequate

competence is enormously greater than the one which is now being tapped. For most of these posts an ability to get on with people in a reasonably sensible way, a determination to resist the wilder forms of academic idiocy, are much more important than very high intelligence. It therefore follows that what we should be looking for in medicine are moderately intelligent well-balanced people who want to be doctors not to prove their high academic ability, not to become rich but to fulfil what they feel as a vocation.

How are these people to be found? There is little doubt that at the age of 18 or 22 it is much easier to make a reliable assessment of academic ability than of personal qualities. The difficulties of making reliable assessments of people on the basis of a 30 minute interview have been emphasised again and again. Faced with these difficulties and obsessed with a desire to be fair to the candidates, medical schools have opted for the only route which offers any hope of any objectivity: they have selected those with the best academic records without for one moment asking whether in doing this they may be cheating not the candidates but the patients who will be treated by these super-intelligent doctors. It is at least arguable that medicine might in the long run be better served by deliberately and objectively selecting those with moderate academic records rather than those with the best. I am certainly not saying that no highly intelligent people are needed in medicine. Some certainly are required but this need could be met by taking far fewer into medical school than at present.

One way of being much more certain about personal qualities is to defer the selection process until much later, perhaps until the age of thirty after several years have been spent in jobs unrelated to medicine. What I would like to see is a sharp change in emphasis whereby at least half those selected for medical school are aged thirty or more and have had considerable experience of life outside the narrow confines of the medical profession. At this stage it is much easier to make a reasonably reliable assessment of personality and to select people who, while having more than adequate intelligence, have a genuine vocation and want to do medicine for reasons other than lust for academic power or a rich life.

What would be the advantages of recruiting a substantial number of medical students at this much later stage? The first, and by far the most important, would be to bring into medicine a group of people with a broad range of experience of life outside the medical profession. These people would bring to medicine perspectives quite different from those of the present doctors who on the whole have appallingly little experience of or interest in life outside medicine. They would have opinions of their own and would be far more resistant to attempts by their teachers

to mould their opinions.

The second advantage would be that it would be possible for those governing medical school admissions, without losing any objective assessment of academic ability, to use other criteria as well. By 30 most people have given some indication of their true worth in non-academic terms and it would be realistically possible to choose people whose common sense, moderate and equable approach to life would enable them to handle effectively the great majority of jobs in medicine.

Thirdly admission at around age 30 would ensure that most of those admitted were neither academic empire builders nor interested in riches. With rare exceptions the megalomaniac academics have to start much earlier than that – and are fully aware that they have to do so – if they are to realise their ambitions. Those who at 30 are prepared to commit themselves to being students for four or five years are almost equally unlikely to be motivated purely by lust for gold. Such entrants would come into medicine with a healthily diverse group of motives and would bring to it aims which are rarely seen with the present method of recruiting.

There are two obvious apparent disadvantages, that these entrants would on the whole have a decade less of life to give to medicine and that they would require substantial rethinking of the courses in most medical schools. Both disadvantages are largely illusory. In most Western countries there is by any sensible standard no overall shortage of doctors. There are serious problems of distribution both in terms of geography and speciality with some regions and some specialities having a substantial excess and some a substantial deficiency of doctors. I submit that these problems of distribution are at least in part a consequence of our recruitment of the city-bred super-intelligent into the profession. As we choose such people more and more exclusively I predict that no matter what the overall numbers going into medicine, the problems of distribution will become progressively worse. I suggest that people of moderate intelligence, entering medicine a decade later after a much wider experience of life, are in contrast much more likely to solve the problems of distribution. It may well be worth accepting the missing decade in order to correct the distribution problem which with our present type of medical student is likely to prove insuperable.

The second disadvantage, that the medical school curriculum would have to be substantially rethought in order to meet the needs and demands of those more mature students is one which I personally do not see as a disadvantage at all. If it produced deep thought about the fundamental philosophy of medical education as opposed to the trivia of curriculum development it could do nothing but good.

MEDICAL HUBRIS OR MEDICAL NEMESIS

Illich believes that the present state of medicine is disastrous because of its iatrogenic impact on individuals and society. He sees that state as having arisen from an overweening pride and lust for power, a longing to make decisions and perform miracles which should be the prerogative of the gods. This hubris is the cause of the present impending nemesis.

I also believe that the present condition of medicine in its relation to society is seriously defective. I do not think that the situation is as bad as Illich would have us believe, but it is certainly bad enough. All trends suggest that things will degenerate progressively and that Illich's faulty description of the present may not be far wrong as a true account of the future.

But I disagree strongly with Illich's understanding of the causes of our present disarray. Doctors have acquired an empire in a fit of absent mindedness. They have inherited the positions of both traditional healers and traditional priests. But the potential power is much greater because in spite of the weaknesses doctors can offer miracles which are consistent rather than capricious. When coupled with the desire of most people for health and long life, it is obvious that the influence of the profession is potentially far too great. That influence has been acquired because it has been and is being thrust upon doctors. With rare exceptions doctors have not actively sought it. Because of the real power of doctors they have repeatedly made decisions whose impace on society is incalculable. They have unleashed forces which it may not be possible to control. But on the whole these decisions have been made by small men with small concerns, shuffling papers while sitting bored around a table in some dingy committee room. Doctors have not realised that they have been making decisions which should be made by the gods. Because of the medical profession's ignorance and narrow concerns it has not been guilty of hubris.

I personally would have been happier had hubris been one of doctors' sins. The gods are not going to intervene in the organisation of medicine and so whether we like it or not doctors have to make the decisions. It is time the medical profession became aware of what it is doing. Conscious hubris, a knowing involvement in decisions which will affect the structure of society in the deepest possible way is what is required. If doctors abdicate their responsibilities in a headlong rush to become Everyman, Illich's prophesies will come true. It may well be too late but some at this hour must still try to snatch the fire from heaven.

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(Specially prepared for the Annual Meet of the Medico Friend Circle Sevagram, Wardha, December 27 to 29, 1995.

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"Sukarthah Sarvabutanam
Matah Sarvah Pravarthayah
Sukham ca na vina dharmat
Thasmad dharmaparo bhavet."

- Vegbhata in Astanga Hridaya.

(All activities of man are directed to the end of attaining happiness, whereas happiness is never achived without righteousness. It is the bounden duty of man to be righteous in his action.)

Prepared by: S.John.

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There are two types of physicians
- Those who promote life and attack diseases; those who promote diseases and attack life

Charaka Samhita

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ii) If you are interested in any of these papers (section 2 and 3) and are unable to access them from the sources mentioned, please write to CHC - Library and Documentation Unit. We will supply them at cost - for photocopying and postage.

- C.H.C., Bangalore.

ST. JOHN'S MEDICAL COLLEGE HOSPITAL
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✆ 55 307 24 Telegrams : SAINJOHNS

Ref. Date 8/8/96

Dear Ravi,

I am enclosing some material for your file on medical ethics. One is the country report submitted by Lalitha Nath .. SEARO and the 2nd is a brief report of the Kandy workshop that I prepared for the Principal/Director

All the best

Irene

CM 13/8

To Dr CMF/Dr VB
For information

8/8

SJ — Ethics File (ME Series)

MEP. 54. 27

Report on WHO sponsored Regional Workshop on Medical Ethics

The WHO, SEARO, sponsored a 5 day regional workshop on Medical Ethics in Kandy, Sri Lanka from June 26 - 30th, 1996. Paticipants came from Nepal, India, Bangladesh, Bhutan, Sri Lanka, Thailand and Indonesia. India was represented by 3 Institutions - AIIMS (Dr. L.M. Nath), KMC, Manipal (Dr. R.P. Pai) and St. John's National Academy of Health Sciences (Dr.Prem Pais)

Of all the Institution represented St. John's was the only one which systematically taught the subject. This fact was emphasized in the country report for India (copy enclosed). The workshop itself concerned the philosophy and theory of Medical Ethics and was interesting and thought provoking. There is a proposal to follow up the present workshop with another on teaching medical ethics. St. John's has been proposed as the venue, tentatively in January 1997. The workshop will be funded by the WHO.

Prem Pais
Professor of Medicine
and
Vice Principal

Received from Dr Prem Pais
RN
8/8/96
To Drs CMF/VB for information
↓
Then Ethics file

MEP 54-25

MP-2-A-18

MEDICAL TECHNOLOGY - ETHICAL ISSUES

- Anil Pilgaokar -

The practice of medicine by its very nature (a) invades the privacy of individuals (patients) and (b) is vulnerable to what may be best termed "rationalized misuse/illuse potential." It is in this context that ethical facets of Medical Practice become very important. "Technology" (described as the "science of industrial arts" - Consise Oxford Dictionary) by its very genesis lends itself to commercial exploitation. It is in this light that ethical issues of medical technology become of paramount importance but alas this is a neglected subject in the medical circles. It is with this at the back of the mind that we felt that it would be of pertinence that there is at least some sort of debate and discussion on the subject and hence this paper. It must be clarified at the outset that we are alive to the rather dismal prospects of putting before you a comprehensive paper before you but then that is neither our claim nor our aim to do so. There are limitations of data and more importantly our own limitations which prevent us from taking any firm position(s) in respect of many topics covered in the paper, but then it is our hope that vigourous (rigourous) deliberations at the MFC meeting would be helpful in (a) clarifying the grey areas on the one hand and (b) taking up some position(s) in respect of many aspects discussed in the paper; (which primarily is concerned with raising some questions for discussion).

Admittedly medical technology is a broad term and it would be purposeless to dwelve on every technology concerned with the practice of medicine; for that matter even commonplace 'injections' could be concieved as 'technology, and it would be quite pointless to discuss the ethical aspects of injections here. Rather it is our intention to restrict ourselves to newer sophisticated and/or pervasive medical technologies. In very crude terms, for the purpose of this paper we shall ignore the "first generation technologies" (to burrow the current 'in' expression) like say X-ray machines, and devote the discussion to "higher generation technologies" like CAT-scan or PET-scan.

Grouping/Catagorization of Technologies:

In our surrvey of literature we have not come across any grouping or catagorization of the various technologies harnessed in medical practice but for the purposes of this paper it is important to device one and so even at the risk of being challenged we have resorted to the following classification:

(i) Function replacement medical technologies eg. Heart-Lung machines or say renal dialysis units; cardiac pace-makers etc.

(ii) Investigational-aid medical technologies like CAT-scan; sonography; echo-cardiography; and its sub-class (ii-a) "Investigational-aid extendable (in some cases) to curative" medical technologies like some endoscopic instruments.

(iii) "Control technologies" like contraceptives, vaccines, and artificial life-support technologies, and of course genetic engineering and sex_preselection technologies.

Each as a class would have its own ethical considerations in addition to general ethical considerations. A priori, the above classification suggests a need for increasing stringency in ethical considerations with each class of the medical technology. Whereas the benifit: risk as also the cost: benefit evaluations vis-a-vis respective populations must form a base for assessing the relevence (in ethical terms) in all the three classes of technologies but it is evident that in the first class, the

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ethical considerations would mainly relate to 'operational' part i.e. use; mis-use; denial of use as also the fees for services etc. The ethical questions in this class mostly relate to the individual patient and the institution (investigating centre) policies. In the next class (ii), the ethical questions - all ethical questions relevent to the previous class are indeed pertinent but in addition, because of the enormous costs of some of the instruments involved ethical considerations in National priorities also must form important facets as many of the instruments lock up and siphon significant monetory resources, and thereby quite often affect (adversely) other medical facilities by depriving funds for these. In the last class, even more wider questions relating to demographic, individual rights vs rights of societies, right (?) to manipulate human systems and forms etc. could figure.

(i) Function replacement technologies: Admittedly most of these technologies are indeed 'life-saving' in critical conditions. But when the question such as whose life? become appearent (as in many cases in our setting do) then ethical issues do arise and these need to be debated in full measure. We shall take just two illustrations to initiate the debate.

(a) It is well-known that in a renal dialysis unit priority for dialysis service is given to acute cases rather than chronic renal failures. Again there is a long waiting list for routine dialysis of chronic renal failure patients (who have to be placed in a queue system because of the paucity of dialysis units. Even so when "J.P." needed dialysis (Jaslog Hospital) he got precedence over others. With all regards for the noble man, the question of whether life of other citizen is worth anyless needs to be taken up.

Again, the dialysis serves as a temparory respite until the organ teransplant arrangements are available, and it is at this juncture that further ethical issues arise. Should kindney of a young person be transfered to older person? The obvious answer is No. Yet one finds that kindney from a young woman (16) being transplanted on to MGR - knowing that the leader was close to his grave.

The "organ trade" racket with the conivance of the medical profession has been highlighted in lay press and yet the ethical questions have not been raised in relevant bodies.

It must be conceled that the examples quoted above, are not strictly ethical issues of medical technology, rather they are issues related to 'medical practice'. All the same these are so intimately connected with the technology usage that the mention made here would not be totally out of place.

(b) Cardiac pace - makers are fairly widely used in our country. And for harnessing this technology Intensive Cardiac Care Units (ICCU) are essential. The usefulness of these units is widely known and acknowledged. What is not generally appreciated is that in our settings is that a proliferation of such units could actually impede the quality of service (medical service) in other faculties of the hospital/ institution. A bed in ICCU could cost (to the institution)

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some 100 times more than the bed in say a general ward (of a public hospital). With relative crunches on the budget of the hospital, the pinch for resources is felt by other facilities. Any keen observer, who has observ the "progress" of some of our premier public hospital in last two decades, could not have failed to notice that with the advent of super-specialities (like ICCU, Artificial Kindly Units and the like), there is a steady degradation in the facilities in other departments. So we have a situation where the best of the facilities would be available in these highly specialized units and at the same time there would be acute dearth of common requirements like cotton, lint and linen in the general wards of the same hospital.

Even at the cost of increasing the length of the paper let us labour over this point a little more. It would not require statistical figures to state that the incedence of tuberculosis in the city of Bombay far, far exceeds that of CVDs. Dr. Amar Jesani (Economic & Political Weekly, Sept.24, 1988) has pointed out that the deaths due to TB in the city have increased over the years thus emphasising the increased requirement of hospital beds for TB in the city, but these have in fact been reduced by Bombay Municipal Corporation (paucity of funds) in the only hospital for tuberculosis in the city of Bombay; whereas there is a spurt in the ICCU beds in the city. (And mind you the ICCU beds cost some 100 times more) The number of ICCU beds in the city(in both public and private hospitals together) are some 30 to 35% that of the beds in the TB hospital.

Is this due to class biases ? CVD is a rich man's diseases and TB is a poor man's diseases. Is it 'ethical' to permit spurt in ICCU beds ?. At the cost of TB beds ?

(ii) Investigational-aid medical technologies:- In this group there are technologies that 'affordable' only to institutions as for example CAT-scan instrument and there the ones like sonography (ultrasound) which can be found with individuals too. What is peculiar, atleast as far as Bombay is considered is that none of the public hospitals have these as of today. And this brings out two possible reasons for this viz(a) the aquisition of these instruments is primarily for 'marketing' reasons - marketing of 'image' of the institution and(b) the law of diminishing returns impedes the aquisition of these instruments in public hospital i.e. the additional benefit in investigations with the aquisition of these instruments is not commensurate with the hugh cost of aquisition, operation and maintenence of the instrument.

It is true that public hospitals have little access to recovery of costs from the patients (even when these have resorted to collecting partial fees from the patients (in Maharashtra). But in private hospitals fees are levied for services, it would be unthinkable to operate these instruments (CAT-scan) if these are to be used solely used in well selected cases only. This is because the capital investment (around Rs.30 lacs) and allocation for operation and maintenence (another Rs.30 lacs) would work out in annual interest of Rs.10 to 12 lacs, which would have to be acrued from the patients, (i.e.Rs.1 lac per month). And considering that the time required for 'processing' a patient is 2 hrs and an 8 hr working period, it

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would mean to break even this Rs. 1 lac would have to be recovered from 120 patients or Rs.833/- per patient.

The question that one needs to consider is that would there be 120 truely well selected cases for such scan in a month, every month, every year ? If the answer is NO then it follows that patients who do not require such an investigation would also be enlisted for such investigation - which seems to be the case indeed. How does this stand on ethical grounds ? How does one ensure that such trend is checked ? reversed ? Could there be a well laid down norms for selecting cases ? Could there be an audit of such investigations ? Who would conduct such an audit ? These and many other questions will need to be answered.

Sonography : Ultrasound technology : This has been the domain of obstetricians and many obstetricians perhaps aquire this instrument for 'image' purposes. The premise that the technology is 'safe' (is it conclusively proved ?) has led to rampant ill-use or mis-use. Widespread (though unconfirmed) reports have indicated that this technology is used to detect pregnancy when cheaper, more accurate and non-invasive pregnancy tests are freely available. One reason behind this is to enable to charge fees (ususally exhorbitant) for the investigation. How ethical is this ? What does one do to prevent this ? What are the situations when use of this technology is rational ? Can there be an audit?

(iii) Control technologies :- These are perhaps the most 'impactful' and controversial technologies, and ethical as also philosophical must be discussed.

Contraceptives technology : There has been a shift in technology (ies) 'progressing' "user-safety" to "contraceptive duration of action" (from condoms & diapharms to 'implants'); there is a shift from "user-control" (condoms & diaphrams) to "doctor-control" (implants). The shift has been from birth control to population control. Is this ethical ?

In the case of doctor-control (and therefore state control) contraceptive if there is a contraception failure should it not merit compensation ? Is consent necessary ? imminent ? Is it sought to ?
The question also arises of 'doctored' results of field trials ? Should there be a third party audit of the field trials, particularly since there is an obsession to pushing these technologies.

Vaccines : These technologies being a part of Preventive Medicine are state mediated and at general population level some questions need to be raised. Is consent a necessary pre-requisit before vaccination ? In the event of vaccine failure should the patient not be compensated ? Can vaccination be forced in epidemics ?

Sex-preselection / selective foeticide : Sex-determination and selective foeticide and Sex-preselection technologies

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are the ones which have discriminitory and demographic-upset potential of the worst kind and yet these technologies are vigourously persued. In extremely small number of cases where a particular sex foetus could jeopardize the life of the pregnant woman can these be justified if at all. Even so there are no laid down ethical codes in respect of these at all. Apart from catering to individual passion for a particular sex of spring, scientific ego of achieving control over life processes, and a political handle to manipulate sex composition of a population, these technologies have little to offer to mankind. The basic premise in medical research is to improve the quality of human sustenence. These technologies have very little to offer in that direction (except perhaps cases mentioned above.) But they do have an enormously large adverse potential.

Should such technologies be allowed to be harnessed in the country ? Should not the medical comunity decrey these technologies on ethical grounds ?

Genetic Engineering : These technologies can have extremely widespread manifestations and carry with them dichotomous repurcussions. It is with this at the back of mind that there needs to be an extensive debate on the merits and demerits of these technologies to work out a rigid code of procedures.

The justifiable purpose of genetic engineering (we are restricting ourselves only to medical aspects of genetic engineering only) can be to rectify genetic aberrations (note the avoidence of the word abnormality) which can have disasterous or agonizing consequence and nothing more.

However as things stand today the commonly persued (and commonly percieved) goal of the technology is to rectify genetic abnormalities and improve the quality (of genes ?). Just what is abnormal? What is improvement in quality of genes ? On this there is no final word. What is more it is unlikely that there could be any final word on this. Allow us to elaborate this further.

Genetic aberrations like Down's syndrome; inborn errors of metabolism; juvenile diabetes (?) can have disasterous consequences and genetic rectification could possibly avoid these con-sequences and perhaps this technology could have credence in these areas. But say, if a person has six fingers on his/her hand, there is no reason to label him/her as ABNORMAL just because he/she does not conform to the commonly percieved frame of reference, since there is no physiological/physical agony or distress emanating. This line of argument can be extended to ridiculous but effective extent thus.

Blond hair, blue eyes and fair skin is normal to certain populations and a dark skinned, dark eyed and black haired person in this population would be ABNORMAL would genetic engineering experts like to 'improve' (?) this individual to fair skin, blue eyed and blond haired person. Decades

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earlier an 'engineer' attempted to do a similar exercise; his name was Hitler and his goal was called Fascism.

Can genetic engineering lead to camouflaged Fascism ? What are the ethical and philosophical positions one takes on genetic engineering ?

Life support technologies employed in lengthing 'vegitative' forms of human (inhuman) existence : Prolonging 'life' with total disregard to QUALITY of life is not uncommon these days Is this ethical ? Is it ethical to perpetuate incapacitation ? What is the position one takes on this issue ?

Research What are (should be) the priorities in research for developing technologies ? Who takes the decisions ? Whose needs (what needs) are given importance ? These are the crucial questions that need to be answered. The situation existing today is not one where 'independent' medical scientists engaged themselves in research and lead to discoveries. Today he or she is either employed directly by commercial corporation or if not is his research effort is heavily financed (and therefore controlled) by commercial corporations (for profits) in the name of 'service to humanity'. The commercial priorities invariably leed to secrecy, unethical conduct of research (witness the contraceptive research) and 'doctored results' and when scientific expertise and commercial power combine (as it is today) all this become ever so easy and free from challenge.

If there are strict laid down norms for drug research, why can their not be similar rigidity of conditions in research for developing technologies ? The question of consent in research & in practice is a virtual farce. Ethics of research and practice is evident by its absence. Use of technologies to serve defence medicine - whether right or otherwise - can be a matter of debate in United States but in India (today) does it have any place ?

Fears :

There can be no conclusions to a paper of this sort only FEARS. When one overviews the situations one distinctly gets the impression that the entire persuit is one of concentration of power, centralization of power - Medical Power; Contraceptive technology is shifting from end-user control to doctor-institution control. High priced instruments are phasing investigation pathology from individual doctor to institution. Function replacement technology vulnerably chains the patient to medical establishment. Artificial Life Support systems virtually confines the patient to institutions with very little else. Through selective foeticide and sex-preselection technology, medical establishment aquires a manipulative potential and this is further compounded with the emergence and proliferation of genetic engineering. We have had political leaders controlling populations, we have had religious leaders controlling populations. Will the Medical man : Commerce man combine also jump into the arena ?

NOTE : We appeal to your generosity and pardon us for stretching the point to ridiculous extent but believe us the intention is only to provoke discussion.

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Greed and the medical profession

Ralph Crawshaw

Organised medicine is not giving proper attention to the disturbing presence in the profession of a universal human trait: greed. Perhaps doctors' greed is less of a problem in Britain where an estimated 70% of the doctors are generalists, and reimbursement in the main is controlled by the national health system. Not so in the United States where 70% of doctors are specialists and an open health care market allows doctors to charge "reasonable and customary" fees. This is interpreted by some as "all the traffic will bear."

Despite considerable evidence at the other end of the generosity scale that 64% of US doctors give away considerable amounts of free service there is no end of opinion, verging on explicit protest, from patients, their families, insurance operators, legislators, and the general public that doctors are a greedy lot. In my opinion, which I discover I must leave my native land to voice, it behoves the medical profession to address any problem vexing its relationship with the public. Doctors' greed is just such a troubling problem.

"The income of specialty stars raises insurance premiums for all insured patients."

The profession is aware that greed best describes how some of its members place profit before patient wellbeing. Before addressing the 1991 annual meeting of the Federation of State Medical Boards of the United States I asked the solons of the profession to indulge me by responding directly to a question. "Do you believe the medical profession has a problem with greed?" Out of approximately 150, 90% raised their hands in assent.

The US medical profession as a whole nevertheless seems hesitant to move beyond acknowledging the greed problem and to comment on its scale. The profession has a curious propensity to avoid the issue by relegating possible doctor greed to the status of a non-problem. The subject seldom, if ever, appears in professional journals. The side stepping is accomplished by labelling any focused concern about greed as doctor bashing and thus beneath the profession's purview.

Little data exist for doctor greed. One rough approximation of the problem is implied in a bell curve for doctors' incomes postulated by the editor of *JAMA*, Dr George Lundberg. Heuristically he divides the profession into four categories along a continuum of reimbursement, starting with altruistic missionaries, moving to professionals, then business people, and finally money grubbers. The professional and business people form the vast majority under the curve. The money grubbers, the greedy ones, occupy about 3-5% of the area. Three per cent seems a fair beginning for considering those within the profession for whom "greed has become too dominant an ethic."

Some still ask, "What is the importance of the problem; greed among human beings is as common as fleas among dogs?" For the medical profession greed presents three fundamental problems.

Firstly, greed compromises quality of care. An egregious example is in the case of a doctor in the US whose yearly income exceeds $4m. Literally busloads of patients from nursing homes arrive at this doctor's office and without a sham of a physical examination undergo a surgical procedure with the postoperative care left entirely to a nurse.

Secondly, greed limits access to care for poor patients. The income of specialty stars raises insurance premiums for all insured patients. As the premiums go up increasing numbers of citizens with marginal incomes are forced to forgo insurance coverage; their access to health care evaporates.

Examples of greed can be found in all specialties. Imagine a hospital in a small city considering opening a service for coronary bypass operations. To secure a thoracic surgeon the hospital board is prepared to offer a base assured income beginning at $1·25m a year, including full office support. Simultaneously, the area suffers from a lack of family practitioners, who, at best, can expect to make $80 000 to $100 000 a year without any office support.

Consider my city of Portland, Oregon. It has one hospital offering organ transplant services and two other "non-profit" hospitals planning competitive services. All three hospitals expect to offer high if not exorbitant staff incomes, ultimately to come out of the existing health insurance pool that makes no provision for the health care of the homeless. An editorial in the local newspaper labels this health care business at its worst, "greed-driven nonsense."

Thirdly, the most corrosive effect of greed and the tacit approval of greed is to the profession's philosophy of service. Where most of us were trained to believe that our service is based solely on trust, with firstly avoiding harm as the ultimate measure of every medical action, an ethic of greed changes our elemental belief that the buyer is always responsible. With an ethic of greed doctors cease to base their motivation on compassion and caring to become merchants selling medical services to the highest bidder.

Given these reasons for concern the first and essential action for the profession is to undertake an open discussion of the problem. The consequences of continued side stepping by the profession of the problem of its greedy members is loss of authority, autonomy, and honour. The erosion of the profession's position of respect with the public is clear. Further erosion will aggravate all the problems which now diminish the delivery of health care while blurring the moral goal of the profession.

"The most corrosive effect of greed . . . is to the profession's philosophy of service."

Without question doctors should earn incomes which genuinely reflect the training, time, effort, and trust that goes with their care of the sick. It is malignantly counterproductive for soaring medical reimbursement to diminish the stature of the vast majority of doctors.

It is imperative for the medical profession to open its published journals and collegial forums to a candid appraisal of the existence of greed in its ranks. There is no need, in fact there is danger of exaggeration and mindless regulation, for the discussion to be taken up by the media. This is not to imply the discourse should be secretive but that it should have the serious attention and encouragement of the leaders of organised medicine, including the editors of all specialty journals, to insure a scholarly and objective appraisal. The discussion should strive to determine objectively sane and prudent limits for medical reimbursement, but not be confrontational, pitting one doctor against another, one specialty against another. Those that exceed considered limits should no longer have the tacit approval of the majority, the 97% who do not let a desire for money determine their service to the sick. Clearly, a serious problem with an exaggerated and misanthropic human trait, greed, challenges the medical profession to move to higher moral ground in the care of the sick.—RALPH CRAWSHAW *is a professor of psychiatry in Portland, Oregon*

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Frch NEWSLETTER

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MISUSE OF MEDICINE

N.H.Antia

There is no field of human endeavour where misuse of privileges, authority and funds can be entirely eliminated. Hence society devises methods for limiting such misuse in the form of rules, regulations and legal measures even though enlightened self monitoring and self restraints are ideal. What differentiates professions from trades is that the former not only possess special knowledge and skills but also evolve a code of conduct and ethics to monitor their own members. This is in order to ensure not only the level of technical competence but also the obligation to the society which has entrusted them with responsibility and has placed its trust in them. The medical profession has enjoyed a uniquely privileged position because of their technical skill as well as the intensely personal relationship which develops between a doctor and his patient, whereby the latter puts his/her entire faith in the doctor who not only cures but also cares and consoles the patient as well as the family. The epithet 'noble' is symbolic of the love and respect that this profession has enjoyed over the ages, which is somewhat akin to that of the priest.

It is unfortunate that there is now a rapid deterioration of this happy relationship between the profession and society at large and a degree of suspicion and mistrust pervades this relationship today. Before we blame the profession as a whole, let us not forget that there still exists the same relationship between the family physician and his clientele; only that this breed is rapidly diminishing as a result of the new, impersonal and materialistic trends which affect not only this profession but also the rest of society of which they are an integral part.

The wholesale adoption of the western model by our policy and decision makers after independence, based on an alien culture and its science and technology has shaken the entire social and economic fabric of our society and distorted age old values associated with our civilization and its culture. It has polarized our society with a small, wealthy, elite group marginalising the vast majority whose life is being increasingly degraded, as clearly observed by the burgeoning urban slums. While this western science and technology has given the knowledge and technology to provide for the basic needs of everyone on this planet, yet, because of its very materialistic nature and lack of a human and moral basis, it is used chiefly as a tool for aggrandizement and exploitation. Such misuse is not only restricted to the western nations where it has originated, but is also rampant in the poor countries, in the hands of those who have been able to obtain access to this technology. The gross misuse of such knowledge and technology in the field of medicine is demonstrated by the fact that the most simple, cheap and efficient aspects of the cure and control of communicable diseases (which still remain the major health problem for the vast majority of our people, especially the poor) are neglected and undue emphasis is paid to the most expensive, complex and cost ineffective diseases like cancer, heart-stroke which affect the small, affluent sections of our society. This clearly demonstrates that the dominant consideration in the import and use of such science and technology is dictated by the requirements of the rich and that of the medical profession rather than the needs of the vast majority. In the process, medicine is being converted from a profession to a lucrative trade in human suffering; an area where consumer resistance is at its lowest.

The gross overproduction of doctors, drugs and sophisticated medical instruments and that too of the wrong type has ensured that malpractice has been built into our present health system. Unfortunately, over the years, this has become an accepted form of medical practice by both the medical profession as well as the public. This is further compounded by the absence of any regulatory measures like public information and education on health and suing for malpractice, as exist in the USA and many other western nations.

In the case of the urban rich this is demonstrated by the unnecessary, excessive and even dangerous investigations and medications, inclusive of surgery, and the pressures to impose the latest and most expensive glamour technology imported from the West regardless of its appropriateness. Also, the patient or the public is seldom informed of the attendant dangers which are reported in Western journals, leave aside the far greater shortcomings in our own limited experience. Due to availability of easy money, the rich are unwittingly at the greatest peril of iatrogenic (doctor made) diseases, as is demonstrated by the mushrooming 'five star' urban hospitals with the latest specialities, the latest scanners and the latest drugs and operations. Intensive care units are indiscriminately used, even for terminal care patients, who now have to end their life in stark aseptic conditions monitored by the latest gadgets, rather than in an ordinary hospital bed or preferably in the home, surrounded in their last moments by loving and caring relatives and friends. Each one of these facilities have their specific limited use, but when unintelligently or deliberately pushed to their limits by

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those trained as technical robots or for satisfying their monetary greed, these "wonders" of modern science prove to be counter productive, if not actually harmful.

The growing middle class has now been caught in the cleft stick between providing the latest medical care like renal dialysis, kidney transplant and coronary bypass surgery for their loved ones and being pauperized in the bargain. Many search for a good, old fashioned family doctor, who is now in short supply, or turn to other cheaper and more acceptable alternative systems such as Ayurveda and Homeopathy. Without insurance and adequate financial resources, the thought of illness has become a source of anxiety and neurosis for this rapidly enlarging section of our society.

For the vast majority of the poor who live in villages and urban slums, this poses an entirely different problem. While the middle class are their role model they can hardly conceive of using the private hospital with its specialists or even the nursing home for their medical needs. And yet they too have been hooked by the medical profession, albeit by those in the lowest rungs, to the universal injection as a panacea for all ills. The 'blunderbuss' therapy of Rs. 20 or more for a so-called 'cocktail' injection consisting of an antibiotic, corticosteroid, vitamin B, anti-histaminic and analgesic is now familiar even to most villagers, leave aside the older 'heat' producing injection of calcium gluconate. The public hospital, whose mal-functioning was so starkly revealed by Justice Lentin, remains their last resort. Fear of these institutions now drives them to small, unhygienic private nursing homes, often after a preliminary visit to the moneylender. The government Primary Health Centre, which was designed to serve the preventive, promotive and basic curative health needs of the 70% of our population that lives in rural India, has ceased to undertake any of these functions as a result of its almost total devotion to Family Planning and its accessories like Immunization and MCH. Shrouded in secrecy, the PHC is unaccountable to the people for whom it is meant.

What is it that has lead to this lack of accountability of the public sector and the exploitative nature of the private one? The answer lies clearly in the inappropriate Western model that has been chosen for the development of this country. While we may forgive Nehru for being enchanted with the post-war euphoria for Western science, the continuation of the use of this model, that too in its worst aspects, despite ample experience to the contrary, can only be ascribed to the selfish and exploitative nature of those who continue to promote and operate this form of development.

The Hippocratic Oath

...I will prescribe regimen for the good of my patients according to my ability and my judgment and never do harm to anyone. To please no one will I prescribe a deadly drug nor give advice which may cause his death.....

.....If I keep this oath faithfully, may I enjoy my life and practice my art, respected by all men and in all times; but if I swerve from it or violate it, may the reverse be my lot.

Excerpt, as contained in "Medical Negligence", S.Raghavan, The *Free Press Journal*, Apr. 13, 1980.

Illness : A Lucrative Business

".....a common public opinion is that patients trust their physicians technically and personally but not economically,..... The harshest judgment comes from some medical economists who bluntly state that the ethical ideals of the Hippocratic Oath are out-moded and mythical..... The doctor-patient relationship is a commercial transaction that should be regulated by the rules of the marketplace,.....normal business activities such as aggressive advertising, paying in advance, and undertaking profit-making enterprises that are unrelated to direct provision of physicians services are all clearly legal and good business practice. But, are they ethical? Are they primarily in the spirit of what is best for the patient?"

Excerpted from the presidential address by Frank C. Spencer, (M.D., FACS, New York), to the American College of Surgeons, as carried in the *ACS Bulletin*, November, 1990.

It is regrettable that this type of medical practice now poses a threat to the health of our people. The public health colleges produce doctors who are mostly trained for, and work in, the private sector. It is inconceivable that any sane politician honestly believes that private medical colleges, which levy a capitation fee of several lakhs in declared and undeclared monies, are for the benefit of the rural masses. The mad rush for securing the highest marks for admission to government medical colleges, or paying high capitation fees by the rich, for their children who cannot get into the former colleges, does not demonstrate love for the health of the people but a clear indication of the extent of safe monetary returns that this profession ensures them. The type of medical education and even worse, the values inculcated in them are directly opposed to the health needs of our people. Permission to produce 60,000 drugs and formulations (costing Rs.3,600 crores), when the WHO lists only 258, is surely not for the benefit of the people but that of the pharmaceutical industry and those who give them licenses on the basis of kickbacks. The multinationals who control the major drug companies and increasingly, the medical instrumentation industry, do not come to India for the health of our people.

The medical profession and the associated health industry have the unique opportunity to trade in an area where consumer resistance is at its lowest, as a result of fear and ignorance. Public ignorance and absence of consumer resistance is demonstrated by the fact that malpractice insurance premium of doctors in India is Rs. 100 per annum, while that in the UK it is over 1200 Pounds sterling, and for certain specialities in the USA over $ 60,000 per annum. This is not to advocate legal action as the optimal way for improving the health services, but under the prevailing conditions of increasing material values and human greed, public awareness and threat of legal action remain

IRRATIONAL AND UNETHICAL MEDICAL PRACTICES

Mohan Deshpande

In recent years the press has been abundantly covering hitherto unreported and under reported cases of malpractice in the medical field. Undoubtedly, these and many more unreported cases will have to be fought in the legal courts, which in turn, will hopefully have a deterrent effect on the medical profession. This will also make people at large aware of their health rights to some extent.

Much goes under these press reports of overt malpractice and negligence. This consists of a bulk of irrational medical practices which are invisible and seldom brought to light owing largely to ignorance of people and a smart combination of tactics and the skills the profession possesses collectively. Moreover, to locate and to identify irrational practices needs quite a good knowledge of medicine and its practice. Since the effects of these irrationalities are neither immediate nor severe enough on the patients, they are rarely complained about. Even if a patient suspects an irrationality, he/she usually refrains from asking for clarification. He/she is simply a stupefied victim of so-called 'faith'.

Usually medical doctors, even those rational in their own practice, do not come forward to report such irrationalities even though in private they would express their dissatisfaction about the increasing commercialization in their profession. Some even try to protect fellow professionals under the pretext of protecting the medical fraternity. There is also a false notion prevailing amongst doctors that it is 'unethical' to divulge information on such matters to the 'lay' public. There are attempts even to justify the wide-scale unscientific and irrational practices on grounds such as, it is being unfair to isolate the medical profession to blame leaving untouched the general social atmosphere of rampant corruption at every level. Some tend to blame the professional (or business ?) competition or the dog-eat-dog health bazaar (too many doctors ?) as if these are entirely extraneous to their profession and thereby justify the so-called 'survival instinct'.

Irrational practices can be grouped in the following categories:

A) While actually treating/investigating patients,
B) While diagnosing the ailment,
C) Concerning the relationship with the drug industry,
D) Concerning other doctors,
E) Miscellaneous.

While actually treating/investigating patients

1) *'Injection' practice:* irrational or over use of this mode of drug administration, for profits.
2) *'Steroid' practice:* using steroids (reserved for life saving purposes and intractable diseases) for simpler ailments, for quick relief. The doctor also provides a (false) sense of well-being to the patients. This attracts more patients to him.
3) *Irrational use of antibiotics* notwithstanding their long term severe effects like tolerance cross-resistance etc.
4) *Using banned or bannable drugs:* the profession cannot absolve itself from its responsibility to update knowledge of recent research and government/legal decisions.
5) *Using sub-standard drugs for dispensing:* These drugs are usually available in local markets in bulk quantities produced by various ill-known companies.
6) *Prescribing tonics,* milk powders, protein powders.
7) *Injecting B complex* for a variety of ailments where injectable vitamins have no role to play.
8) *Using intravenous (I.V.) fluids* when not indicated. *Using I.V. calcium gluconate* for various non-specific indications.
9) *Use of anabolic steroids* (even injectables) for growth/gaining height etc.
10) *Using drugs (especially from other 'pathies)* without proper knowledge of their pharmacology. This applies not only to heteropathic practice but also to allopaths using allopathic drugs which are banned or bannable. The newer drugs and their information reach doctors sometimes through unethical and un-scientific literature from the drug industry with reports of contrived trials. There are also wide ranging empiricisms (e.g. 'no side effects') in the use of brand prescriptions from the Ayurvedic industry.
11) *Unnecessary investigations,* both invasive and non-invasive. This is not a 'defensive' practice. The sole aim is profit.
12) Unnecessary admissions/surgery.
13) Refusing to treat seriously ill/dying/leprosy/HIV positive patients/accident victims.

While diagnosing ailments

Usually the following diagnoses are thrown to patients:- Weakness, low blood pressure, backache, white discharge due to weakness, deficiencies, psychosomatic illness etc. Creating cardiac neurosis: patient is not a heart patient in reality but is made to believe she/he is.

Concerning drug industry

1) Accepting samples and gifts from drug industry causing both overt and unconscious obligation to prescribe.
2) Accepting and not verifying information coming from drug industry. One such example is the use of high potency combination B1 B6 B12 for a variety of illnesses ranging from weakness to serious nerve-brain disorders.
3) Engaging oneself in false, fabricated research for drug industry.

Continued on page 8

Mohan Deshpande is a medical practitioner who is also a researcher with FRCH, Bombay. The above is a slightly modified version of the paper presented in the workshop, *'Medical Malpractice; what it is and how to fight it"* organised by Medico Friend Circle (Bombay Group) in 1991.

EDUCATIONAL INTERVENTION IN MEDICAL MALPRACTICE

Amar Jesani.

The term Medical Malpractice (MM) encompasses a very broad (perhaps entire) area of inappropriate medical practices. The Bombay Group of Medico Friend Circle tentatively proposed a working definition (1990) of MM for its workshop on this topic as, 'a variation from the normally acceptable, scientific and average standard of medical practice at a given point of time'. There may be many shortcomings in this definition (readers are invited to suggest their alternatives) but, for the time being it will serve our purpose, because the subject of this article is to discuss the strengths and weaknesses of educational intervention intended to bring about appropriate changes in the doctors medical practice so that it becomes acceptable, rational, scientific of minimum average standard, ethical and free from possible negligence.

Why educational intervention?

We believe that there is a strong case for advocating continuous, scientific education of all practicing doctors. How can one object, in principle, that all doctors must be continuously educated so that the quality of medical care provided by them can be of optimum standard? In fact this is a truism universally accepted as an essential ingredient of medical ethics. Unfortunately in our country this component of medical ethics is violated by the profession as it has hardly any effective mechanism to provide systematic continuous education. As a result doctors' reading habits are found to be abysmally inadequate to do justice to their role in medical care.

There is another compelling reason for advocating educational intervention. Although there is no systematic study available on the medical 'competence' of Indian doctors, certain indirect indications show that 'incompetency' among Indian doctors is shockingly high. For instance, in two studies of prescription practices of private general practitioners in Bombay city by Uplekar (1989a, 1989b), for the FRCH, it was found that a majority of them had grossly inadequate knowledge of drug treatment for two highly prevalent diseases; leprosy and tuberculosis.

The structure and practices of the medical profession raise further doubts. In 1986 we had 7,63,437 qualified doctors of all systems of medicine. Of them about 42% were allopathic and 58% were non-allopathic. While in the developed countries, scientific criteria to assess competency of allopathic doctors are well developed, we have nothing to go by to judge the competency of non-allopathic doctors. In fact, we are almost sure that there will be divergent views about the methodology used to assess the competency of non-allopathic doctors. Secondly, cross system therapeutic practices are highly prevalent. It is generally accepted that a majority of non-allopathic doctors regularly use allopathic drugs and devices. With the ayurvedic drug industry coming of age, the use of ayurvedic drugs by allopathic doctors has also substantially increased. In this use of cross system therapeutics, it is obvious that the prescribing doctors have grossly inadequate scientific information on what they prescribe. Lastly, the problem of doctors' incompetency is a universal one. Even in countries where the profession is better organized, internally regulated, and has strong emphasis on continuous education, a significantly high proportion of doctors are found to be incompetent. For instance, in the UK, 10% to 15% of independently practicing doctors are estimated to be incompetent (Smith, 1989). A Canadian study in 1988, found that in their sample, 15% of family practitioners and 2% of specialists, had serious deficiencies in medical records or care (Smith, 1989). In our country, at least 3/4th, of all practising doctors are independent practitioners having no regular continuous medical education. Only a fraction of them subscribe to standard scientific journals. The prevalence of incompetency among them is, of course, anybody's guess.

In short, inspite of non-availability of hard data, the doctor's ignorance/lack of information on the scientific therapeutics need no further elaboration. The socially conscious doctors and others have therefore strongly argued that this ignorance or gap in information is greatly responsible for many irrational practices or malpractices by doctors. Due to lack of information, doctors also fail to critically evaluate information provided by commercially vested interests like pharmaceutical companies. As a result, many have suggested that malpractices be classified under two broad categories; intentional and unintentional. The former is deliberate MM indulged in with a motive, such as augmenting one's income. The latter is supposedly due to ignorance. A typical argument for the latter is, why should a private doctor prescribe wrong medicine for tuberculosis when it is not going to help him to hold the case. That is why educational intervention is considered useful, particularly to remedy unintentional MM.

Another strong argument advanced for educational intervention is that individuals in the profession have inflated egos and are very sensitive to criticism. Positive educational intervention would help some sensitive and ethical individuals to see reason and thus to change their behaviour. Also, since such intervention would not generate extreme negative reaction, it would help win over some to the cause of rational practice. After this is accomplished, it is believed that tactics can be used against those who refuse to 'shed their ignorance'.

Undisputedly, these arguments are highly logical, clear, and straightforward. However, these arguments are clinically too precise to explain the actual reality. It is indeed tempting to put high prevalence of MM and lack of continuous education into a one-to-one, direct relationship. But this relationship is highly complex with many other variables more crucial in determining the prevalence of MM. The need for continuous education is not only because the MMs are highly prevalent but that even if it fails to make a significant dent in the prevalence of MMs it is still badly needed for many other reasons. The point being emphasized here is that though educational intervention is necessary, its mere presence is not a sufficient condition to bring about a lasting change in the behaviour of doctors.

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Limits of educational intervention.

In our country some voluntary efforts have been made to change doctors' behaviour through education. Most of such efforts are in the field of drugs and pharmaceuticals. "Dear Doctor" letters, along with educational material on the rational use of drugs, information about hazardous, banned and bannable drugs, appeals against the use of drugs such as high dose estrogen-progesterone (EP), fixed dose combinations and so on have been circulated amongst doctors. In addition, certain categories of drugs (anti-diarrhoeals, tonics) have been studied for their rationality and reports have been compiled and circulated amongst doctors. These are highly commendable voluntary efforts and we have been participating in them in various ways.

However, to what extent do they make a dent in the MMs? Unfortunately, none of these efforts were adopted for experimental research by institutes. Most of these reports were by activists, done with the full conviction that such things ought to be done, irrespective of the extent of the immediate impact that they would make. Further, some important attempts were part of a wider campaign to get a particular drug banned, as the campaign against the high dose EP drugs. It was not a simple educational campaign but a definitive campaign to get the drugs banned on the ground that these are irrational and hazardous. Thus, there was no scope to wait for the results of the educational intervention. The ultimate ban on EP drugs was, in fact, brought about despite the lack of support from the profession!

Most systematic research on improving prescription practices through educational intervention is done in the developed countries, particularly in the USA, as the vagaries of the market in health care has made that country cost-conscious. But all experimental researches carried out there, on this subject, are also not scientifically rigorous. In a review of such services, Soumerai, McLaughlin and Avorn (1989) found that almost one third of them were inadequately controlled studies. They found that 85% of the inadequately controlled studies reported positive findings as compared to 55% of well controlled studies. They also found that in several studies, the control groups showed positive improvement due to the effects of other factors. (**Note:** in the control groups there was no educational intervention).

There are seven categories of educational approaches used in various studies reviewed by them. They are:

1) Dissemination of printed educational material,
2) Reports of patient-specific lists of prescribed medicines,
3) Group education including conferences, lectures, seminars, tutorials,
4) Feed back of physician specific prescribing patterns,
5) Reminders at the time of prescribing,
6) One-to-one education,
7) On going clinical pharmacy services.

Going through the above list we realize that:

(a) some of them are clearly suitable in the hospital set up and very difficult to implement in the case of independent private practitioners,
(b) some are very cumbersome, for instance, providing reminder at the time of prescribing may need a highly computerized set-up,
(c) some may be very costly such as providing one-to-one education by a visiting physician, and so on.

On scanning through some of the study reports we find that the method of providing doctors with mailed, printed material is the least effective method whereas the one-to-one education of the physician by a visiting physician is the most effective method. Perhaps this is the chief reason why the pharmaceutical industry uses an army of medical representatives who can change the doctor's prescription behaviour through one-to-one education. In any case, it will be the height of irrationality to create another army of visiting physicians for providing rational drug education.

Those who propagate the idea of rational prescribing most often depend on the method of providing doctors with print material. Studies of this method however, show disappointing results. At the same time it is found that the provision of printed material could create a necessary condition for trying other methods out. Further, studies using a patient care protocol to guide doctors at the time of examining and treating patients, show that the protocol makes a great difference in the behaviour of those doctors who participate in formulating such a protocol. That is, a participatory exercise in creating educational material is more important than in the use of the same educational material for other doctors.

What influences prescribing behaviour?

When we talk about alternative rational drug information, it is necessary for us to understand the role of such information, on the prescribing behaviour of doctors. A rational enquiry into the prescribing behaviour of doctors would reveal a very dominant phenomenon called 'the non-pharmacological basis of therapeutics', (Avorn et al, 1982). It is this phenomenon which makes educational intervention, which is chiefly centred around rational pharmacological information, less effective. Avorn et al (1982) argue that "irrational drug choices are made frequently, despite the availability of ample empirical evidence counseling otherwise". In a study of doctors they found that "although a vast majority of practitioners perceived themselves as paying little attention to drug advertisements and 'detail men' (commonly used term for medical representatives) as compared with papers in the scientific literature, their beliefs about the effectiveness of index drugs revealed quite the opposite pattern of influence in large segments of the sample".

Thus, in actuality, what a doctor normally does in treating patients is customary behaviour that is routinised, habitual and automatic. Such customary behaviour is formed with the influence of history, locality, peer groups and above all, environment and the system within which medicine is practised.

When sufficient weightage is given to the factors which actually condition prescribing behaviour of doctors, we find that the role of simple information dissemination or education is grossly limited. Kenhouse and Jacoby (1988), in an article reviewing the subject, argue that the 'customary behaviour' of doctors is likely to change only in the presence of a motivating trigger. Such information has a useful role only in conditions which are introduced to change the environment in which medicine is practised.

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PRIVATE HEALTH SECTOR
Regulation and Control

Ravi Duggal

Prevailing Situation.

The private health sector consisting of general practitioners, nursing homes and hospitals, employs two thirds of the medical manpower and is responsible for two thirds of the total expenditure on health in this country. Despite this there is hardly any regulation of the practice in this sector of health.

This is indeed surprising, because such activity cannot be carried out without registration. The medical professional has to be registered with the Medical Council, which is a statutory body that last set the standards of medical practice — 'discipline' the professionals, monitor their activities and check any malpractices. The doctors who decide to set up their own clinics as well as hospitals, nursing homes, polyclinics etc. have to register with the respective local body.

The problem with the above is that the controlling bodies are virtually non-functional. The reason for this is not only lack of interest but also weak provisions in the various acts. They are also heavily influenced by the private health sector.

Another agent in the private health sector which needs to be regulated further is the pharmaceutical industry. As a chemical industry, this agent is regulated to some extent but as a participant in the health sector, it operates virtually unregulated.

In view of the existing health situation and practices, regulation of those who provide the nation's health care is an urgent neccessity. Regulation exists in other sectors, so why not in health? This is especially needed as consumer resistance is at its lowest in this field and therefore lends easily to malpractice.

How to regulate

a). Medical practitioners:

Each medical practitioner is registered with the respective state Medical Council. Presently, beyond this registration the Medical Council does not concern itself with the practitioner, unless some complaint is made and a prima-facie case is established. The Medical Council and other related bodies, in consultation with the health ministry, must regulate the following areas of health practice: (This is only a selective list).

i Monitoring that only registered practitioners practice medicine.
ii Assuring that clinics have minimum standards of quality by setting standards for the same. (This should include X-ray, CT scan and pathology laboratories.)
iii Making maintenance of patient records compulsory and accessible to patients.
iv Auditing of prescriptions of the doctors in relation to the diagnosis.
v Determining a fixed tariff of charges that patients pay to doctors.
vi Providing continuing medical education to all those who practice medicine. For instance, a `summer' refresher course every three to five years should be compulsory for all practitioners and their license renewal should be dependent on this.
vii Regulation of geographical distribution of setting up practice to correct the urban-rural disparities. (We feel that as of present there is adequate medical humanpower in the country and it only needs redistribution.)
viii Annual return of patients treated; some minimum data to be maintained and filed with an appropriate authority.

b). Nursing homes and hospitals:

Similar to the practitioner, regulations need to made for setting-up and running of hospitals and nursing homes. Minimum quality standard, nurse:doctor ratio, patient:nurse ratio, proper location of premises, geographical distribution, fixed reasonable tariff charges, proper medical records, maintenance, filing of minimum data returns, properly qualified and adequately trained personnel for jobs assigned, prescription auditing, medical auditing etc.

c). Pharmaceutical industry:

i The pharmaceutical industry must be allowed to manufacture only rational drugs in required amounts with clear priorities in favour of essential drugs. All irrational and non-essential and dangerous drugs must be banned.
ii Branding of drugs must be prohibited.
iii There is every reason for a progressive nationalization of the pharmaceutical industry.
iv The regulatory body for the pharmaceutical industry must be the Health Ministry and not the Ministry of Chemicals.
v The practice of canvassing drugs through pharmaceutical (medical) representatives should be banned.
vi A National Formulary should be evolved with generic drug names becoming the basis of prescription writing.
vii Continuing pharmacological education of doctors should be through the Medical Council or other such statutory body.

d). General regulations:

i To prevent unnecessary concentration in urban especially metropolitan areas, state subsidies, soft loans, must not be given to those wanting to set up practice, or hospitals and nursing homes in these areas. Such loans should be restricted to rural areas and taluka towns.
ii A tax on private medical practice and private hospitals and nursing homes must be levied. This tax should be the highest in metropolitan areas and the lowest in rural areas. Private hospitals should not be allowed to be operated as

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Ravi Duggal is a researcher at FRCH, Bombay. The above formed a part of a larger note on the private health sector, presented by FRCH to the Planning Commission in April, '90.

MEDICAL MALPRACTICE AND THE LAW *

The issue of medical malpractice is dealt with by the rules governing medical negligence, which forms a sub-branch of the law of negligence. These come under the Law of Torts which offers civil redressal in the form of compensation. "A person is said to be negligent when s/he acts without due care in regard to the harmful consequences of her/his action". A physician surgeon or other member of the medical profession, if he has not exercised reasonable care in the treating of a patient, may be liable to a negligence suit. While the degree of care to be exercised depends on the facts of each case, it is generally presumed that the test is the standard of the ordinary skilled person, exercising and professing to have that special skill.

Duty of care

Once a doctor accepts a patient, the principle of exercising reasonable care becomes applicable, whether the doctor accepts fees or not, and whether the doctor is a private practitioner or public servant, general practitioner or specialist. A person who offers medical advice and treatment, impliedly undertakes that he/she has the requisite skill and knowledge. Such a person owes to the patient certain duties, of which the following are important:

a) Duty of care in deciding whether to take in a case.
b) Duty of care in deciding what treatment to give and in diagnosis.
c) Duty of care in administering the treatment.
d) Duty of care in answering a question put to him by a patient when he knows that the patient intends to rely on his answer.

A breach of any of these duties will support a suit by the patient.

Forms of medical negligence

Medical negligence may assume a variety of forms. These include:

a) negligent diagnosis,
b) negligence in operation,
c) failure to listen to a patient's complaint,
d) negligent administration of a wrong drug,
e) negligent exposure of the patient to risk of infection,
f) negligence in advice about the risk of an operation or negligent failure to warn the patient of such risks,
g) negligence in post-operative care,
h) inadequate supervision or inadequate staff in the nursing home.

Hospital/nursing home liability

Private as well as public hospitals (including charitable hospitals) are liable for the negligence of their employees. In a landmark American case, (Darling vs Charleston Community Hospital, 1966), the judges held:

"...The present day hospitals, as their manner of operation plainly demonstrates,do far more than furnish facilities for treatment. They regularly employ, on a salary basis, a large staff of physicians, nurses and interns, as well as administrative and manual workers....certainly the person who avails himself of the hospital facilities expects that the hospitals will act on their own responsibility".

Pleadings

In any suit claiming compensation for negligence, the plaintiff must plead and prove three things:

i) The defendant owed a duty of care to the plaintiff. (Exact situation must be mentioned).
ii) The defendant had committed a breach of that duty. (How such breach was committed must be clearly stated)
iii) The breach of duty resulted in an injury. (The cause effect relationship must be definitely brought out.)

As in the above, while the onus to prove guilt lies with the patient, in some cases, due to a number of reasons (such as incomplete information given by a doctor etc.) it becomes difficult for the patient to provide sufficient proof. In certain of these cases, when circumstances make it quite obvious that negligence, in fact, has been the cause, the doctrine of *Res Ipsa Loquita* (the thing speaks for itself) is applied. This doctrine has been extensively used in "swab cases" where after an operation, an instrument is left inside the patient's body.

Damages

Damages are classified as special andgeneral. Special damages include pain and suffering, loss of expectation of life, loss of amenities and the injury itself. General damages refer to pecuniary loss, such as loss of earnings, legal expenses, loss of pension rights, loss of marriage prospects, and loss of opportunities for gainful employment.

Conclusion

At present, litigation in case of medical malpractice is not widely prevalent. But the trend is catching on, especially in urban areas. While litigation in itself, may not serve to wipe out malpractice, the threat of legal recourse can certainly create conditions compelling accountability on the part of the medical profession. Needless to say, the extent of utilization of legal recourse would be pre-determined by its accessibility as well as the extent to which demystified information reaches the masses.

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*The article above has been compiled from the following:
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[Editor]

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Continued from page 3

Concerning other doctors

Accepting / offering 'cuts' (percentages) for referring / treating / investigating patients.

Miscellaneous

1) Giving false certificates,falsification of reports e.g. pathology, post mortem etc.
2) Advertising
3) Not preparing case papers records, not making them available to the patients.
4) Overcharging: There is no standard/prescribed price for medical care nor are there stipulated rules and regulations for monitoring. There are no grades given to dispensaries/nursing homes.The price of health care is guided by such factors as professional competition, crowding of doctors in a locality, patient's income and living standard, needs and greeds of doctors etc.

There is a minuscule section of doctors who are guided by ethics and rationale against the dominant market forces which usually control the attitude of doctors. It is necessary today to widen this circle of conscious,ethically motivated doctors and thus reverse the tide which threatens to wash away the noble principles on which this profession is supposed to be based. ●

The British Connection

About two-thirds of the world drug sales are controlled by big trans-national drug companies in West Germany (Hoechst, Bayer), Switzerland (Hoffman, La Roche, Ciba-Geigy, Sandoz), and USA (Merck, Pfizer, etc), all with subsidiaries in the U.K.

Source: Prescription for Change, Virginia Beardshaw, as carried in HAI's *Guide to Rational Health Projects*, pg.74

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In conclusion one can say that MMs exist not simply because there is a dearth of easily available rational and scientific literature but often inspite of it. The fight against MMs therefore, cannot be just an educational effort but must address to more fundamental factors which decisively shape the environment in which medicine is practised.

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trusts or societies which give them cover for tax relief. They should be treated as corporate bodies. Hospitals operating 'research centers' must be audited and their tax reliefs questioned.

iii A social audit of the health sector must be an ongoing activity of a statutory body which should be created for this purpose.
iv A tax on the international migration of doctors.
v Embargo on private practice of those receiving state financed medical education by part training at civil/rural hospitals or PHCs. This should be combined with a long term change of relocating medical colleges at the district centers.

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AMNESTY INTERNATIONAL MEDICAL POLICY

In the past few years, Amnesty International medical groups have discussed a number of questions which are relevant to the organization's work. These include:

- medical aspects of torture and its sequelae, and involvement of health professionals in torture.
- the abuse of psychiatry for political purposes.
- forcible feeding during hunger-strikes.
- floggings and amputations.
- medical involvement in the death penalty.
- international codes of medical ethics for health professionals.
- prison medicine.
- psychological effects of "disappearance" on families.

The views of medical groups have helped to shape Amnesty International policy in these areas and have contributed, in turn, to major Amnesty International campaigns against the death penalty and "disappearances".

CARE FOR REFUGEES

Victims of torture and those who are forced, for reasons of conscience, to flee their o country frequently need medical help for problems arising from their experiences. Amnesty International doctors can play a valuable role in this field either by treating the refugees themselves or by referring the patient to another sympathetic doctor. A number of Amnesty International doctors have played a part in the rehabilitation of former torture victims.

FOR FURTHER DETAILS CONTACT:
Amnesty International, International Secretariat, 1 Easton Street, London WC1X 8DJ, United Kingdom.
Telephone: 01-833 1771 Telegrams: Amnesty London WC1 Telex: 28502

INTERNATIONAL RECOGNITION

Amnesty International's work is based on the United Nations Universal Declaration of Human Rights. The organization has form relations with the United Nations (ECOSOC), UNESCO, the Council of Europe, and the Organization of American States.

On the occasion of the 30th anniversary of the Universal Declaration of Human Rights, Amnesty International was awarded the United Nations Human Rights Prize for "outstanding achievements in the field of human rights".

Amnesty International received the Nobel Peace Prize in 1977 for its contribution to "securing the ground for freedom, for justice, and thereby also for peace in the world".

In recognition of the medical work of Amnesty International, the Council of Europe awarded the organization the European Human Rights Prize in 1983.

Amnesty International Doctors & Health Workers for Human Rights

Thousands of people are in prison because of their beliefs. Many are held without charge or trial. Torture and the death penalty are widespread. In many countries men, women and children have "disappeared" after being taken into official custody. Still others have been put to death without any pretence of legality: selected and killed by governments and their agents.

These abuses—taking place in countries with widely differing ideologies—demand an international response. Founded in 1961, the Amnesty International movement, comprising members from all walks of life around the world, is working to expose and halt these violations of fundamental human rights—and to help the victims and their families. Doctors and other health workers are playing a vital role in this worldwide effort.

A MEDICAL PROGRAM FOR HUMAN RIGHTS

Health professionals working as members of Amnesty International focus particularly on prisoners with serious health concerns whose cases have been taken up under the organization's mandate (see box). Many of the prisoners are suffering as a result of torture, ill-treatment in custody or appalling prison conditions. Many of them will continue to suffer, physically and mentally, long after their release.

The need for medical attention is vital. Prompt action, supported by doctors in other countries simultaneously sending letters of concern in specific cases where prisoners are known to be in need of medical care, can save lives. There are now more than 4,000 doctors in nearly 30 countries involved in the work, ranging from letter writing campaigns to the care and rehabilitation of torture victims.

OUR MANDATE

Amnesty International's medical program is part of its contribution to the international protection of human rights. Its activities are focused strictly on prisoners:

- **It seeks the release of prisoners of conscience. These are people detained anywhere for their beliefs, colour, sex, ethnic origin, language or religion, who have not used or advocated violence.**
- **It works for fair and prompt trials for all political prisoners and on behalf of such people detained without charge or trial.**
- **It opposes the death penalty and torture or other cruel, inhuman or degrading treatment or punishment of all prisoners without reservation.**

Through its network of members and supporters Amnesty International takes up individual cases, mobilizes public opinion and seeks improved standards for the treatment of prisoners.

You can add to the campaign: you can become a subscriber, join a local group, send in a donation and inquire about the growing medical program which needs support from the medical profession for special interventions on behalf of prisoners and their families.

DIRECT ASSISTANCE

The clinical consequences of torture can be severe. Amnesty International doctors have been able to provide practical and invaluable assistance to people who have suffered unbearable physical and mental pain and the stress of isolation and exile. Using their professional skills to counteract the work of the torturers, these doctors have been able to improve the health of a number of former detainees. One such victim was a 38-year-old woman who had suffered temporary paralysis as a result of beatings sustained in police detention. "You have given me a new life", she wrote to doctors in Copenhagen after they had restored her ability to walk.

WHAT IS HUMAN RIGHTS MEDICAL WORK?

Members of Amnesty International medical groups and other health professionals who participate in the movement's activities are involved in a range of activities. They make appeals on behalf of prisoners of conscience who need medical attention. Appeals are sent as well on behalf of members of the medical profession who are detained solely because of their beliefs or origins. The work also includes promoting professional and public awareness about human rights. Refugees who have fled, often with their families, from political persecution are given medical and psychiatric care by doctors and other specialists working voluntarily with Amnesty International. This direct experience enables the medical groups to contribute to the organization's policy on medical questions and professional ethics related to the care of prisoners.

A LIFE-SAVING OPERATION

At the International Secretariat of Amnesty International careful research is carried out into the cases of prisoners needing attention. The secretariat's medical office relays requests for urgent appeals to a worldwide network of doctors and other health workers. They are asked to send letters or telegrams in cases where:

- prisoners of conscience are suffering from serious medical problems.
- medical or paramedical professionals are illegally detained or threatened with torture.
- provision of health service in places of detention is absent or inadequate or is abused as punishment.
- amputations or other cruel, inhuman or degrading treatment is inflicted with the help of doctors.
- doctors are involved in executions.

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INTERNATIONAL CONFERENCE
HEALTH POLICY : ETHICS & HUMAN VALUES NEW DELHI 1986

Artificial Insemination-Surrogate Parenthood Ethical, Moral, Legal Aspects

Dr. J.V. Bhatt, M.D.

Human mind is conditioned by a large number of factors. What is legal or illegal, what is ethical or unethical, what is good or bad, what is moral or immoral, what is sinful or otherwise are all determined by an individuals upbringing, his immediate social and cultural environment, his religious background and a host of such other factors. All of us tend to develop, what in transactional analysis are called "Scripts" resulting from Parent-Adult-Child interactions, within ourselves, and with the surroundings. Rapid scientific advances which are both as a result of and which result in information explosion are producing a positive feedback effect. We do not know where this accelerating cycle will lead us to. Any organism, organisation or system needs a strong and sensitive negative feedback component to maintain it in a state of homeostasis or equilibrium. Even if it is a forward moving accelerating system, it requires inbuilt mechanisms to check its progress and to absorb the shocks. It is also essential that all parts of the system move at the same speed, to maintain the integrity of this system. Most individuals are quick to accept newer techniques if they lead to monetory gains to them. Even an illiterate farmer in India readily accepts hybrid seeds, chemical fertilisers, pesticides, and newer methods of farming if he is convinced that he will get bigger financial returns. In fact at the back of his mind he has been looking for such inputs. Such inputs have in fact come up as a result of such a need. Most of us will also accept, though a little less readily, newer options in the field of health. In my field of rural health programme I find that the rural farmer accepts much more readily newer techniques which look after his animals than those which improve the health of his children. If the social system is slow in accepting newer health techniques, the legal system is still slower in accepting the facts if life as it were. If the legal system is slow, religious system is practically static. What may be acceptable socially and legally may still be considered intolerable from a religious point of view.

A.I.D. and surrogate parenting are problems, where medical science has advanced very rapidly. To-day it is possible for a woman to conceive without any sexual relationship with a man. The sperm could come from her husband or from any other man who may be miles away from her, or may be dead since long. It is now possible to collect the ovum (egg) from a woman, get it fertilised outside in vitro, get it embedded in the uterus of some other woman. Time is not far when it will be possible to produce an entire new individual by cloning from a single cell of any one of us. A sexual reproduction from a single cell was the earliest form of reproduction. With cloning the cycle will be complete.

Law in most countries has not yet taken cognizance of all these developments. An AID child is still illegitimate in many civilised countries

of the world. As is found in most instances those who want to do things legitimately face problems. One of the report states that in 30% of couples it is found on detailed examination that the father could not be the genetic father of the child in the family. Women seem to be finding their own means of attaining pregnancy. It has been rightly said that the results of AID can also be obtained by adultry. Seeing newspaper reports about surrogate parenting, physicians are approached by aspiring couples to help them out of their predicament. In India and also in many other countries, producing at least one or two children is not only an instinctual necessity or a socio-economic need but also a status symbol. A married couple is under great social pressure to conceive soon after marriage. A sterile woman is not only looked down upon but is considered inauspicious. This makes it obligatory to conceive by hook or by crook. Any scientific advance in the field of human reproduction is therefore not only appreciated but also demanded by the community. Such advances are eagerly looked forward to, and heartily welcomed by those in need.

Oxford dictionary defines Surrogate as "Substitute" or "deputy". The phrase surrogate parent would therefore mean a substitute parent. Surrogate father would be one who substitutes for the father or deputised to be the father. 12% of all married couples are faced with the problem of sterility. While some of them can be helped by simple means, most of them would have problems, where at least one of the partners is not in a position to produce the required gamete (sperm or ovum). In such cases it would be essential to obtain the gamete from a third party. In case of such a problem with the male partner, the biotechnical part is restricted to obtaining the gamete from a suitable fertile male and introducing it it into the fertile female. In case of inability of the female partner to produce the ovum, it is possible to obtain it from another female, and after fertilisation in vitro with the male partners sperm, implant it into the uterus of the female partner, after suitable preparation. In those cases where the female partner is not in a position to embed a fertilised ovum (either her own or of another female) it is possible to embed the ovum in the uterus of a suitable female for its growth and development. All of the above alternatives are not only possible but are likely to be generally available shortly.

In case both the partners are not producing gametes, inspite of medical interventions and where other alternatives also do not yield any results adoption is the only alternative. The parents of the adopted child would be substitute parents for that child. Adoption has been practiced since long. It is a well established custom. There are no ethical or moral issues, except when a child is sold for adoption or is purchased with an idea of subsequently using it for immoral or commercial purposes or for labour. Legal procedures for adoption are well established, but like all legal matters there will always be some loop holes lacunae. Interpretation of legal phraseology may also sometimes lead to some problems, but by and large the issue can be said to be as settled as any other legal matter. Other matters like AID, IVE, ET and hire-a-womb are matters with which law has not been able to keep pace with generally.

There are five or six characters in this drama.

1. *The doctor*: The medical man or the medical team would be well advised to take the following precautions.

(a) Take valid written consent of husband, wife and donor, for the procedures.

(b) Try to keep the identity of the donor a well guarded secret.

(c) Carefully select the donor to closely match the partner he or she is to substitute with the same blood group and without any bad genetic traits or transmissible diseases.

(d) If possible get a psychologists opinion about the couple's mental stability to accept the off-spring.

2. *The father*: He should be fully explained the procedure and be asked to remain present during AID, if possible. It is also possible to mix the semen of an oligospermic husband with that of the donor in order to give a chance to his sperm to fertilise the ovum. This combination procedure is known as AIC and can also be tried in suitable cases. For birth registration father's name should be left blank.

3. *The mother*: In case of AID the mother is very keen to be pregnant. So also in case of IVF and ET from another woman. There should be an unwritten pact that this matter will not be brought up during any domestic quarrels.

4. *The child*: In some countries or in some states of some countries such a child would be considered illegitimate. It is better to legally adopt the child as early as is legally possible. From medical point of view it is better if the child is informed, when it grows up, about its origin so that there is no confusion in medical history about genetic disorders.

5. *The donor*: He or she should give accurate and correct history about illnesses suffered and family history. They should not make attempts to find the outcome of their donation.

6. *Uterine mother*: In case of uterine mother it is better to find one who does not do this for money. It is better if she has two or three children—boys and girls, so she is not tempted to keep the child. Pregnancy even under best of circumstances can sometimes lead to mortality or morbidity. She should be explained about this. She should be fully instructed against consumption of alcohol, smoking and taking drugs which may be harmful to the foetus. The period for which she will be required to nurse the baby should be explained.

AID is already available as a eugenic measure. There is an attempt to produce a race of supermen by using sperms of intellectual giants. There is also demand from unmarried women to get pregnant through AID. Once it is possible to do IVF the day is not far when it would be possible

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AID: Artificial Insemination by Donor semen
IVF: In Vitro Fertilisation
ET : Embryo Transfer

to alter the genes prior to fertilisation by genetic engineering. Once a desired type of individual is produced he/she can be replicated by cloning. Though sexual reproduction by normal sexual intercourse is unlikely to lose its popularity for a long time for obvious reasons, some day in future it will be possible to totally separate the procreational and recreational aspects of sex. Whether this will be of benefit to mankind or not time alone will tell. Science keeps on producing deadliest weapons of destruction and also newer means of production and reproduction. At a micro level they can be of use but at a macro level their usefulness is questionable. Science, morals, ethic, religion and good sense will have to by synthesised, if a Frankenstein is not to let loose. □

INTERNATIONAL CONFERENCE
HEALTH POLICY : ETHICS & HUMAN VALUES NEW DELHI 1986

Demands of Few vs Needs of Many

Dr. V. Parameshvara
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"The right to health is a fundamental right"
W.H.O.
"A state of complete physical and mental and social well-being"
W.H.O.
"Complete freedom from disease and from struggle is almost incompatible with the process of living"
Rene Dubos

Health is different from pleasure and happiness. As opposed to health, in happiness there is hierachy. A happy man wants to be happier; getting one measure of happiness, he desires to get a greater measure of happiness; getting one kind of happiness, he longs for other kinds of happiness.

The highest value held out in Indian thought is not happiness or 'sukha' because happiness necessarily presupposes its invariable concomittant, unhappiness : the two constitute a pair. One cannot be there without the other. On the other hand, peace of mind (shanti) is freedon from all opposites and is therefore, the highest objective. Peace of mind (shanti) is defined as that, obtaining which, one does not seek to obtain anything else. It results, when there is no longing and thus no stress. There are no levels or kinds in peace of mind. A person who is content, does not aspire for more of it; if he does, he ceases to be content'. Thus it eliminates rivalry, strife and stress. It is an attitude of mind that is cultivated, in order to preserve and promote health and to prevent ill-health. Peace of mind is within easy reach and can be attained by a large majority of people, irrespective of caste, vocation, knowledge of philosophical truths and so on.

Health is possible only for mortal beings, for we are born with the twin inherited and inescapable 'diseases—ageing and mortality'. To lack health is a misfortune than misdeed. Health is more beauty than virtue, more an aesthetic than ethical term. One does not condemn some one for 'no longer being healthy'. Then, are our goals for attaining health or prolongation of life ? If we aim at the latter, we go after the diseases that are the leading causes of death, rather than the leading causes of ill-health. When we tend to evaluate in terms of mortality statistics, we invariably mean changing one set of fatal illnesses or conditions for another. Prevention and treatment of causes of ill-health may enable the prospective or actual victims to live longer.

Modern system of medicine, which is most widely respected of professions and which has never been more competent technically is in trouble.

Its health is not too well. The reasons are medical care is very costly and not equitably available. The average doctor sees may more patients than he should, yet many fewer than would like to be seen. In fact a modern doctor is overtrained for the job he is doing, yet undertrained for the job he is expected to do. On the other hand physicians powers and expectations from him have grown enormously, owing to explosion of knowledge and modes of diagnosis and treatment. His responsibility have grown as well. All kinds of problems now roll to the doctor's door from sagging anatomies to suicide, unwanted childlessness to unwanted pregnancy, marital maladjustment to learning difficulties, genetic councelling to drug addiction, from laziness to crimes. It is iromic but not accidental, that the great technical power of medicine is under confusion about its standards and goals for guiding its use. When its power was fewer its purpose was clearer. In fact, medicine was considered the very model of an art in the past. Today, although fully armed and eager to serve, its targets are no longer clear. Now health is not the only possible and reasonable goal of medicine. There are other goals as well Eg. removal of womens breast because it interferes with her golf swing, performing vasectomy, tubectomy as family planning for non-medical reasons, artificial insemenisation etc. Hence happiness is a false goal of medicine.

Without a clearly defined end views, medicine may prove to be only a set of means, and doctor being reduced to a technician and engineer, of selling his services on demads. This meands transforming the physicians into a helper for hire. 'Endless' profession is an 'ended profession'. A doctor should not be tyrant but neither must he be a servant. Doctor should remain as a leader and teacher. Public misperception of medicine is ultimately more dangerous than the doctors misperception of himself. The community must respect the fact that medicine is an 'art' and doctor is a 'docere'.

We need to advise better indices of healthiness than mortality and morbidity statistics. Thus the importance of epidemiological research in healthiness—about what promotes and what undermines health. Sophisticated studies in nutrition, exercise, rest, sleep, relaxation, response to stress are integral subjects of research. We need to identify and learn about health sub-groups in the community and to discover what accounts for their success Eg. change in eating habits, and new treatment for hypertension has shown a downtrend in death rate from heart attack in middle age groups. This approach would appear pedestrian in comparision with the dramatic style of high technology and therapeutics. One has the highest respect for noble prize winners, for the discovery of chemical wonder of enzyme structure, but surely he who suggested adding chlorine to drinking water or invented indoor plumbing system and closed drainage have contributed more to healthiness of human kind. What is actually important to note is that major improvements in mortality in Europe and USA occurred before the massive investment of the last few decades and before the advance of 'high technology' in medicine.

Mortality rates among children, young adults have continued to improve but not at an enhanced rate and gain in expectation of life at the age of 65 have been far from dramatic. It spite of enormous scientific development and availability of drugs and high technology machinery, the improvement in mortality has been disappointing. Complete eradication

of heart disease, cancer and stroke—currently the major mortal disease, would according to some calculations, extend the average life expectancy at birth only by approximately six or seven years, and at age 65 by more than one and a half to two years. Medicine's contribution to longer life has nearly reached its natural limits.

There are several countries, where spending on health services is not below 10 per cent of the gross national product (West Germany, Netherlands, Sweden, USA). People are now working for a five weeks year, simply to pay for their health services—less premature death, less illness and disability, less pain more comfort and support and care when disability cannot be further ameliorated. There is serious doubt, whether richer countries of the world have in fact gained any commensurate benefits. There is a point at which people want to keep their own money to spend in their own way. Bulk of the money in health care goes to a small minority who are seriously ill. There may well be a limit on what the healthy are prepared to spend on the unhealthy.

CT scanner is the greatest development in radiology and has enormous diagnostic potential but between 1973 and 1977, UK installed 30 brain and 11 body scanners. In USA in the same period, over 760 scanners including 200 body scanners were installed—if each of these machines did 2000 scanners a year, at average charge of US £300, the annual cost would be $456 millions. Being excessively impressed with the technological brilliance of big hospital medicine, mobilizing crusades and crash programmes against cancer and heart disease, the health politicians speak as if more money, more targeted research, better distribution of services, more doctors and hospitals, and bigger and better cobalt machines, lasers, and artificial organs should bring the medical millennium to every citizen.

Planning must not be vague, unless justified on economic grounds, increased efficiency or training, new and sophisticated equipments, and big hospitals can become 'white elephants', One approach to the problem of cost containment is to restrict the supply, both of hospital beds and of medical man power.

One view is that further preventive efforts may be more cost-effective than further investment in curative media. Equally important is the fact, that a section of intelligentia both in and out of medicine, have begun to wonder aloud, whether and to what extent medicines are doing good.

The countries that appear to spend the most on health services do not necessarily have the best health. Spread of free or nearly free health services to vast majority of the population does not seem to have narrowed relative social class difference in mortality risks. The 13 year increase in life expectancy from 1950 to 1970 for persons over 25 years old, who are non-smokers, is also most halved for those smoking more than 25 cigarettes a day. We are irrationally suspicious of any attempt to modify our personal behaviour, even if it kills us.

"A man who has built a fire to warm himself, but continues to fire it, until it begins to roast him"

Plato

Frankly he seeks ingenious devices to measure his discomfort accurately and to cool himself down, dazzled by the roaring success of his life, he fails to see, that the obvious remedy is to put less wood on it. Modern medicine is often pictured as a stunning breakthough. Technological revolution have evidently fostered this image. 'Technology' reign as the primary shaper of medical progress has been strongly challenged. not only in terms of the financial drain but also in terms of its outcome on the nation's health—its excessive use and the possible risks to patients and societies. Technological revolution has become a controversial issue. Now it is 'Technological Problem'. Therefore developed countries have a lesson to teach the developing countries from their experience—may be negative rather than positive 'Don't do it our way'.

The trend towards high technology evidently leads to a disequilibrium in type and distribution of services provided, with too much emphasis on acute institutional care and too little on more essential care, for huge segments of the population. In countries with more limited resources, it obstructs the development of priority health services, thus possibly contributing to a deterioration in the population health. The developing countries should not be mislead by developed countries. Gross attempts to transfer successful structures from one country to another, can lead to reactions out of proportions to the often minor adaptations needed to fit them to the recepient country's values.

Poverty is the key vector in the developing countries. Poverty creates illness and illness creates poverty. Health planning is a question of economic and social planning rather than medical planning. Industrial development would help a small urban elite. There is relatively high expenditare on health services in urban areas, concentration of resources, hospitals and trends towards physicians based security schemes. Usually training included doctors and specialists, medical education of the curriculum of more developed countries, heavy expenditure on imported gadgets and pharmaceuticals, service heirarchially controlled and at the same time vast majority are denied science based service and spend heavily on herbal remedies and traditional practitioners.

It is interesting the relatively low priority is given to health compared to other areas such as ornaments, hotels or air lines in developing countries. Health does not seem to be a priority.

Inadequate investment on the physical and mental well being of the people can only mean a proportionate decline in the economic development of the country. Putting greater pressure on its resources.

Pharmaceutical progress eliminated suffering and sadness, has benefitted modern medicine by the saving within the health service itself, saving from the reduction of loss of working days and savings from the elimination of premature death. For the vast majority of the rural population, it is now accepted, that basic and generally well established medicines are what is needed Eg. vaccines and antibiotics.

A case in point is that there are nine million blind persons in India—3 out of 200 persons and 3 million of them are preventable. 25 lakhs of children are estimated to go blind every year and 1.25 will need to be

protected annually with vitamin A—50,000 units costing Rs. 2 per child with a total cost of Rs. 25 lakhs as against Rs. 25 crores for feeding, educating and care of the blindand loss in terms of human happiness. Forty per cent of population are found to suffer some degree of iron deficiency anaemia which could be rectified by oral iron therapy, costing hardly Rs. 2 to 5 per person. Appropriate technology for health and rationing of services could lead to rational solutions. The need to eliminate waste and improve cost-effectiveness, and the principle of equal distribution of service in population.

In many areas of social life, policy and action still continued to be improved on the basis of prevailing beliefs rather than on informed appraisal of issues and alternatives. In meeting health needs, technology must be geared both to the problems to be solved and to local conditions. It should be scientifically sound, acceptable to those who apply it and to those for whom it is used and affordable to the nation.

Each country and each society has to decide its own health priorities. Good information is crucial to good decision making. Their use must justify the effect involved.

The stock of skill or human capital must be allocated in such a way as to reduce the cost of any particular treatment.

India has an abundance of men of intellect and aptitude for medical research, but they should be given all facilities and encouragement. The declaration of Alma Ata, proclaiming health for all by 2000 AD enjoins upon research, to gear its efforts to fulfil this goal. The challenges have to be met by appointing TASK Forces, comprising groups of experts in respective medical fields, who should formulate specific targets and time bound projects in the given fields and identify the priority areas with regard to their national relevance. IMA will also be happy to associate itself with this task and help the various medical research institutions with a proper feedback.

सर्वे जनाः सुखिनो भवन्तु

"*May the whole world be healthy and contented*".

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Man, Medicine and Law: Challenges of the 21st Century

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1. Introduction

Bio-medical and technological advances have forced not only a re-definition of some concepts in other disciplines, but also necessitated a widening of the perspectives of medical science. Science is no longer the concern of scientists only. It is no longer enough for the man of medicine to confine himself to the traditional learning of his own discipline. Whether he likes it or not, he has per force to expand the horizons of his mind and to take note of the points of view of other disciplines and to meet the demands of norms flowing from the principles evolved by other disciplines. Dramatic and frightening progress in knowledge, particularly in genetics and biology, and radical advances in techniques, especially in re-constructive surgery and in surgery connected with the process of reproduction, have raised issues of great consequence to humanity. Some of these issues are already of pressing interest, such as abortion. A few others, if not of pressing interest today, are bound to cry for answers tomorrow. It is only if we start thinking about them today, that the answers will be ready tomorrow.

It has been said that science often seems to thrust society into directions which society only partly understands and certainly has not chosen. This makes the task of social scientists and thinkers on ethical problems fairly difficut. They must first understand the directions of science and then offer guidance as to the implications of scientific advances, and elucidate to the best of their ability the choices open and the merits and demerits of each such choice. Knowledge must thus come first, but it has to be followed by wisdom, which a great jurist once described as the "elder sister of knowledge".

Both science and ethics have a common origin, as part of the process of civilisation which distinguished man from apes. In its earliest form, science was an attempt by man to understand the phenomena of nature and to exploit the resources of nature for satisfying his instinctive need for food, shelter and protection. The beginnings of science freed the man from the drudgery of hunting. Settling down in groups and cultivating his own food gave man the security and leisure needed for pursuing a life—style different from that of the ancestors of mankind. This inevitably led to the subtler things of life—language, writing, the arts, music, poetry, religion, ethics and law. In ancient civilisations, scientific thoughts flourished hand in hand with religion and ethics. Scientific discoveries were considered revelations. The great writer on the Indian science of medicine Charaka was an ascetic. Aryabhata (5th century A-D.) who propounded the revolutionary theory of rotation of the earth stated that

his knowledge owed itself to the grace of God. Al Biruni, the famous Arab mathematician, insisted that his experimental work was subject to the moral principles of Islam. When, in 1543, Vesulius, a physician from Belgium, published a book on human anatomy based on dissection and personal observation, he expressed his wonder at the "handiwork of the Almighty, by which the blood sweats from the right in the left ventricle through passages that escape human vision". The feeling of antipathy between science and religion was a later development, of which Copernicus and Galileo were the victims.

2. Nature of the issues

This paper does not seek to present an exhaustive treatment of the impact, on humanism, of medical advances or a comprehensive catalogue of the ethical and legal issues arising from such advances. But it seeks to point out some peculiar features of those issues that are very relevant to an understanding of their social significance, so as to facilitate the formulation of a correct approach.

Usually, such issues are seen as presenting a conflict between medical science and non-medical disciplines. However, this would be taking only a partial view of the matter. In a sense, science is neutral, because it does not take sides. The business of science is to discover the fund of knowledge, to organise it and to present it. What use to make of the knowledge, and whether to make use of it at all, is a question on which the scientist, speaking as a scientist, does not claim superiority and would not claim the privilege of his speciality. It is in this sense that science is neutral. When one speaks of a conflict between medicine and other disciplines, one should not imply that there is an antagonism or antipathy, as such, between what medicine demands and what society desires or ought to desire. The truth is, that the conflict really in here is in the conflict of interests, conflict of demands, conflict of desires and conflict of approaches between two individual members of society, or between society and its one or more individual members. For example, if one comes to questions of life and death and is concerned with the precise issue as to the determination of the exact moment of death, one finds, on a deep analysis, that two rival approaches are competing for recognition. It may be described as a conflict of values. The traditional concept of sanctity of life and of the peremptory moral obligation of society to maintain that sanctity at any cost, is one of the competing values. Pitted against this is the emerging movement for "dignity in death" and "the right to die". The latter movement has been regarded as an extension of individualism. It is an extension of the individualistic principles of self-determination, autonomy, integrity and self-realisation and the choice to exercise control over one's dying as well as over one's living.

3. The debate about abortion

The conflict of interest between two individual members of society is illustrated in the debate about abortion. The conflict here is between the mother and the yet unborn child. Of course, it is a conflict of a complex character, in which so many moral and scientific concepts or doctrines are entangled, though very few persons are able to perceive that the fabric is inter-woven with threads of an infinite variety and number

which criss-cross each other. Simply stated, the moral question is this: Whose desire or interest should prevail? Should the mother's desire prevail or should the interest of the unborn human being be given precedence? In a more complex form, the questions are really multiple. Should society recognise any right at all in the unborn? To put it in legal phraseology, should the zygote, the embryo or the foetus be regarded as a "human person" and, if so, from what point of time? When does the right of the embryo to protection begin? At implantation? At the end of the first trimester? At quickening? At viability? At the moment of birth? Assuming that the right of the foetus begins at one or other of the moments just now referred to, under what circumstances can the right of the unborn be overridden by the desire of the living and, at what point during gestation? If both the foetus and the pregnant woman have rights, the one to its survival and other to terminate her pregnancy, who is competent to adjudicate the conflicting claims, and what are the qualifications for such a role?

4. The right to live

The situation of abortion, mentioned above, involves a consideration of the two-fold obligation of the State towards the unborn life. (1) The obligation to refrain from all interference with unborn life, and (2) the obligation to prohibit an attack upon unborn life stemming from a private person. Obviously, any law which permits abortion upto a certain stage of pregnancy places unborn life at the disposal of society, though this decision is taken in the name of higher and more paramount demands. The conflict is seen in a more dramatic form when one comes to the right to life and the right to die. The right to live is at issue in the unending debate about the ethical aspects of prolongation of life by artificial means. In a deeply unconscious individual whose vital functions are maintained over a prolonged period only by extraordinary means, the question arises whether a time comes when it is no longer appropriate to continue the extra-ordinary means of support for the hopelessly unconscious patient. If man is regarded as being in the image of God (*imago dei*) then, theoretically, the duty to prolong life has no closing terminus. So long as the vital functions persist spontaneously or with the aid of artificial process, "life" survives and must be prolonged to preserve the 'image". This is one aspect of the matter. Apart from this religious aspect, there often comes to be presented a conflict of interests, though the conflict is not articulated. The family of the patient very often wants to terminate the agonising watch and may urge a discontinuance of extra-ordinary measures for prolonging life. Those who have an interest in organ transplantation might press for a new appraisal of what constitutes "death". The hospital authorities and society in general have a vested interest in terminating a costly procedure in a hopeless case. But the presence of these vested interests raises the possibility of selfish "rationalisation" of the course which the vested interests wish to adopt. It gives a warning of the need for a cautious approach. One may also remember that the termination of extra-ordinary care, even for just reasons, with death certain to ensue, can have a shocking effect on observers.

Some of the problems discussed here arise even out of the existing canons of medical ethics. The current code of ethics of the Indian Medical Council, in paragraph 3, provides[1]—

"I will maintain the utmost respect for human life from the time of conception."

In paragraph 7 it provides—
". . . I will respect the secrets that are confided in me."

5. Artificial insemination

Some of the techniques evolved by medical science give rise to legal as well as emotional problems. For example, there are emotional problems born of artificial insemination, which is now frequently used to help infertile fathers. Some fathers later resent children born as a result of A.I.D. Mothers have also been known to develop a romantic infatuation for the unknown biological father. The practice is to keep the donor's name secret from the parents. But legal problems may arise if the parents demand, say, a tall or vegetarian donor. There is also the question of legitimacy of the child born of A.I.D.

6. Genetic techniques, and IVF

Placed in the social context, any one genetic technique can be assessed from a number of different angles. The several frames of reference which apply, say, to a decision on abortion, include exploring it from the point of view of (i) the parents, who may or may not have a deformed child, or (ii) society, which may or may not wish to spend money on the care of children, or (iii) the child yet unborn, whose right to protection may require to be considered.

In vitro fertilisation is not simply a device to be marvelled at, as an instance of science fiction turning into science reality. It raises in our mind serious questions of ethical and social policy; for, genetic technology has the potential to take human heredity out of the realm of blind faith or chance into the realm of free will and choice. In the past, nature took the blame or the credit for genetic inheritance. This responsibility is increasingly becoming ours, because of expansion of the area of choice.

7. Coercive genetic and surrogate motherhood

This does not mean that "coercive genetics" (the prescribing of legal sanctions against the use of genetic techniques) should be readily resorted to, either to force the weeding out of undesirable genes or to prohibit the use of new techniques. Excessive intervention by the State would completely undermine the legitimacy and moral basis of Government. It is in this context that the most difficult issue is presented by surrogate motherhood. However morally shocking the practice may be, a legal prohibition may well remain unenforceable. What matters in such cases is the social feeling. As has been often pointed out, most new genetic techniques, once developed, would bring much joy to parents and cause little discernible harm to society. The State may, therefore, be well advised to guard itself against the urge to legislate in this field. Improvements in genetic technology may well excite the appetite of the State to interfere by legislation, but the tendency will have to be curbed.

8. **Inchoate rights: the question of privay**

The situations so far discussed concern themselves with legal or moral rights whose existence is undisputed. Besides these, however, sometimes there are involved rights which themselves suffer from obscurity, because of the prevailing uncertainty about their existence and recognition. Here the shadow on a correct appreciation of the ethical issues is not cast by any scientific advances as such, but arises from the hazy nature of the very rights themselves, whose existence and precise dimensions have not yet been demarcated in traditional legal and ethical thinking. Privacy is an example of such a right.

9. **Privacy and informed consent**

Of late, the doctrine of informed consent to medical treatment has come into prominence. This doctrine initially came to be premised on the patient's right of self-determination. This is instanced by the famous words of Judge Cardozo [*Schloendorff* v. *Society of New York Hospital* (1914) 105 N. E. 26]. The patient's right to information before consenting to treatment may also receive support from the principle of the right to privacy—being the principle of an "inviolate personality" which posits the individual's independence, dignity and integrity. It may be mentioned that of the several facets of this right as explained by Mr. Justice Douglas [*Roe* v. *Wade*, (1973) 93 Supreme Court 705], the third deals with the freedom to care for one's person and health.

10. **Bio-ethics**

All this naturally brings one to the new discipline of bio-ethics. Broadly, is a discipline dealing with the ethical implications of biological phenomena as manipulated or encountered by the science of medicine. It dwells on the frontiers of medicine and ethics, Because it dwells on the frontiers, it has its own excitement. Sir Ernest Gowers once said that the crossing of intellectual frontiers is always a thrilling experience, just as it is a thrilling experience to cross the physical frontiers of one's own country.

Bio-ethics is not a totally new subject. In some form or other, the medical profession has always had something to do with ethical issues. The celebrated works of Charaka (probably 100 A.D.) on the Indian system of medicine contain an elaborate code of ethics for physicians. Amongst the mandates that Code contains, is a direction to the physician to strive for the relief of the patient with heart and soul. It also directs the physician not to treat a female patient, unless a male relative is present.

Four goals may be concretely indicated in regard to the discipline of bio-ethics: (1) identifying the moral issues in a bio-medical context; (2) developing appropriate strategies for analysing moral problems; (3) relating moral principles to specific issues; and (4) training a small group in bio-ethics.

The first two goals imply that the physician is not a primary decision-maker, but rather one who assists the patient in coming to his own decision where a moral issue is involved. The physician must learn

how to distinguish technical questions of medicine (which are appropriately his own area of competence) from value dimensions (which are not exclusively his own area of competence).

A regards the third goal of bio-ethics (relating moral principles to specific cases), this will be for the patient, he being primarily the decision-maker. But some ethical issues can still remain for the physician—e.g. how much information is to be transmitted to the patient about a particular diagnosis.

11. **Conclusion**

To conclude, let me quote from Dr. A.S. Duncan's foreward to Alastair Campbell's *Moral Dilemmas in Medicine*: "Curricula have become so loaded with the very scientific and technical matters which lead to the dilemmas that little time is left for thought as to the dilemmas, themselves. As Harold Laski wrote, "expertise sacrifies the insight of common sense to intensity of experience." Where human problems are concerned, the expert fails to see that every judgment, which he makes, not factual in nature, brings with it a scheme of values which has no special validity about it. □

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1. See George Lobo Current Problems on Medical Ethics (Paul Publishers, Allahabad 1974) Pages 215-228.

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Teaching of Human and Moral Values in Postgraduate Medical Education

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A postgraduate medical student after completing his training is likely to work as a clinician, a medical teacher, a medical administrator and/or a medical researcher. During his professional career, he is likely to face many situations where he will have to take decisions not only on scientific basis but also on human and moral principles. His acts should reflect upon his character as a man of virtue and not as an a moral being. Intentionally or unintentionally he may speak ill of a professional colleague, be unkind to an anxious patient suffering from advanced cancer, recommend purchases from a particular firm which gives his gifts, select a student belonging to his region, award low marks to a student whom he does not like or steal ideas for research from a junior colleague. Although the present system of medical education imparts good theoretical and practical knowledge on scientific medicine, there is no formal and very little informal education on human and moral values during post-graduate medical training. Emphasis is being placed on learning operative acumen e.g. how to do prostatectomy but little importance is given to humanistic treatment of a poor old patient or the moral aspects involved in decision making of various real-life situations such as patient management, medical education (student selection, examination, etc.) medical administration and medical research.

The moral components are :

(i) *Attitude* : It is not simply an ability or a piece of knowledge. It is "regarding other people as equals", "thinking that other people's interest count", "taking notice of other people's wants and needs''. Attitudes are detected and verified by the way in which a person thinks in his everyday, practical living, and to some extent by the way in which he acts. On the cognitive side, it is a belief—the belief that other people have equal rights with onself. This can be tested by certain question or observations :

(a) Does he make some effort to find out what other people's wants and feelings actually are ?

(b) Does he listen to other's opinions and allow them to have their say ?

(c) How does he actually treat people belonging to a different ethnic origin/different region/different religion ?

(ii) Ability to know what other people are feeling, in particular situations. This may be described further as "awareness of other people's feelings", or "the ability to understand what other people's interest are", "knowledge of other's desires, emotions, etc.". This is concerned with awareness of the feelings of people with whom one actually comes into contact in one's everyday life! it also includes being able to predict the feelings of those whom he has never met. This can be tested as follows :

(a) Can the student give a reasonally good account of the feelings of the patient who is to undergo extirpative surgery e.g. total amputation of penis for penile carcinoma?

(b) Can he understand the feelings of the patient's wife and children when a diagnosis of advanced cancer of urinary bladder is made?

(c) Is he interested in other people's feelings and behaviour? Has he as a teacher, made any attempt to understand the feelings of his students? Has he as an administrator made any attempt to understand the feelings of his subordinates?

(iii) Actual knowledge of certain 'hard' facts—Knowledge of rules of the social system in general, knowledge of social conventions and social expectations.

(iv) Know-how to translate his moral decision into effective action. It is a kind of adeptness rather than a cognitive mastery of facts. This can be tested by :

(a) Is he capable of playing the roles of a leader and a follower, of issuing and obeying instructions?

(b) Can he behave efficiently in social situations involving people of various age groups, and different ethnic origins?

(c) Can he behave well in formal contexts as well as in less formal contexts?

(v) *Mode of thought*: Ability to face up to a moral situation and to consider that situation primarily in terms of other people's interests. A person with appropriate attitude, ability to discern other people's feelings, and knowledge of 'hard' facts will make a prescriptive moral decision dictated by other people's interests. Dimensions of this complex moral component are (a) right reasons. Not everybody makes, or even thinks he ought to make, his moral decision on the basis of other people's interests. Other modes of thought are regrettably common. Amongst these are: desire to please the boss, uncritical tendency to obey rules, a tendency to do what is most expedient for oneself, etc. The person with a high degree of this moral component will always consider other people's interests, and think in this mode rather than in others. (b) Sincerity of decision. There are people who may pay lip-service to a certain mode of moral thinking but who do not sincerely *commit* themselves in

making these judgements. This can be tested by the following questions :

(a) Does he think that moral values are 'just a matter of taste' or does he believe that there are right and wrong answers to moral questions?
(b) Do his principles include not only avoiding bad actions, but doing good ones (actively and positively helping other).

(vi) *Action or Behaviour*: When a person has reached a rational moral decision, he must have the motivation and resolution to translate that decision into action. There are all sorts of reasons why people fail to bring their abilities to bear on moral situations, or fail to translate their moral decisions into action. They may be forgetful, incompetent, lazy, frightened, tired cowardly, etc. A person should have sufficient sentiment or love for other people: this is atleast one kind of motivation which should enable him both to think and act rationally in the moral sphere. A person should also have good habits, or a settled disposition to think and act in a rational manner. A person must possess independence of judgement, the ability to think and act autonomously as opposed simply to following other people like sheep. A person must be reflective or thoughtful enough not to be carried away by particular situations, and not to be forgetful of other people.

Teaching of moral and human values

The spirit of the medical college and its teachers thus becomes the basic factor in developing moral values. There can be little contribution to moral and spiritual values from a college which resorts too easily to arbitrary authority; from an institution in which the chief mainspring of effort is rivalry; from an institution which fails to exhibit complete honesty; from a college in which each seeks only to satisfy his own selfish aims; from a college laden with intolerance, fear and suspicion. Only a medical college served by a faculty whose members are themselves sensitive and responsive to moral values; a college with a broad, humane, and flexible curriculum; a college steeped in a philosophy which commands respect for the personality of each teacher can hope for success. Medical colleges that exemplify moral values are better than lesson which preach them.

Human and moral values can be taught while discussing each patient's clinical problem. The teacher should be a 'role-model' in exhibiting human values while treating a patient. He should observe the students in the out-patient clinics, in the wards, and in the operation theatre, record resident-patient encounter and discuss it with the concerned resident later emphasising the need to adopt and practise humanistic approach and moral values. For example, the urology resident is often taught how to do urethral dilatation i.e. he should fellow aseptic principles, there should be no urethral bleeding, etc. Seldom is it emphasised that he should alleviate the anxiety of the patient before performing dilation, make an attempt to understand the feelings of the patient's family as regards patient's illness, check whether adequate urethral mucosal anesthesia has been produced before actually performing dilation. Not

infrequently it may be witnesses that the doctor scolds the patient when he complains of pain. Thus the human values should be integrated with the teaching and practice of clinical medicine. Often it may be observed that the teacher as well as the post-graduate student is kind to a VIP patient but forgets such human values while attending to a poor and illiterate patient.

The moral components mentioned above can be taught in the medical college during case discussion, structured lectures, informal coffee-club discussions, departmental seminars, interdisciplinary seminars and intensive workshops. At a national level, bibliography development, national workshops and national conferences on teaching of human and moral values can be organised.

Evaluation

Assessment of teaching of moral values, student's learning and student's behaviour in this regard should be periodically evaluated. Preferably, considerable weightage should be given to the above listed moral components in internal assessment of non-scholastic abilities. Self—assessment by the post-graduate students is the best method of evaluation to infuse motivation and self-analysis. He may be encouraged to record atleast one patient management every fortnight describing how he adopted human and moral principles. The teachers should act as facilitators of learning and directors of individually-prescribed instructional programmes. They should give immediate, positive feed-back to the student appreciating his good performance and encouraging him to make up his shortcoming if any. Peer assessment, and evaluation of recorded audiotapes of resident-patient encounter may also be useful. In the beginning, all groups may express some antagonism or unwillingness to admit to living by moral values. However, the teachers as role models, will be able to secure student's full participation in such programs. When the students are encouraged to think harder about these abstract ideas and given a little help with the terminology, they would quickly become adapt at analysing the moral issues involved in patient care, and in his professional career.

In conclusion, moral education involves both comprehension and apprehension, neither can be imposed. It is wholly open-ended, recognising that genuine morality requires free personal acceptance of values of that is, the goal is not the heteronomy of the slave, but the autonomy of the free man. □

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Human Values and Quality of Life

—A Personal Statement

Prem Kirpal

In 1969 while serving as a Senior Specialist at the East-West Centre at Honululu in the beautiful Island of Hawaii, and also unknown to myself at the time afflicted with malignant cancer inside my body to be operated shortly, I wandered at the blueness and vastness of the Pacific Ocean and the lovely beach of our tiny Earth. From this wander of the beauty of Nature and some surge of creation inside, I wrote the following poetic statement on the "Quality of Life":

I—QUALITY OF LIFE

Life's quality is comprised of: palatable food to digest well and enjoy; enough space and scope to contain and express the needs of body and soul in the full awareness and respect of other bodies and souls; robust health with abiding element of youthfulness; and, above all, the sheer love of life-the gift of friendship and love, the sense of wonder and endless curiosity, the perpetual thirst for giving and receiving, ceaseless strivings for new creations, and the capacity to accept any outcome in full understanding and with utmost serenity, cheerfulness and gratitude.

Life is as good as one can live it and it is as big as one can hope, imagine, aspire and dare!

Its quality depends a little on luck and chance, but much on what we value and search and how we go about it with courage, dedication and faith.

In this way one *can* never fail, because even failure becomes almost success when it is preceded by the right quest and effort.

To shoot at the stars and fail is better than a timid and faint-hearted venture which may satisfy or reward, but cannot thrill and exalt.

The spice of life and its meaning and scope determine its quality in the depth, breadth and extension of consciousness, from the earthly and the human to the spiritual, even the cosmic, dimension of man's perception, experience and vision. There is no limit to life's quest and quality, and often we become what we love. Being and becoming are great gifts of consciousness and these should be treasured and developed in all ways, dimensions and potentials of man's psyche and his cosmos. Remember always that in Life and its Beyond we are related and joined together to all Creations and the experience of this Great Harmony is the wonder and savour of Existence. Give full heed to the vastness of life's scope and its endless potentials and be grateful for the wonderful gift of life.

This Statement has been inscribed permanently on the inner wall of a Public School not far from the river Ganga and the massive machines of the Bharat Heavy Electric. Hopefully its young readers derive more practical meaning from it than what I have been able to practise. Since 1969 I have written and spoken a great deal on the Quality of Life and Human Values in the context of education and culture at home and abroad at several international meetings under the auspices of the United Nations, but the above Statement of life's quality abides in both the spirit and concrete attributes of life's quality, which is basically reflected in the health of mind, body and spirit and the inner life of the human psyche.

It is, of course, essential to achieve physical survival and a certain measure of material well-being before the quality of life is experienced and treasured in the world of the mind and the spirit. For physical existence we need food, health, housing, education, work, worship, sex and play. For man as a spiritual entity we must transcend along the path of security, freedom, identity, sense of belonging, joy, confidence, love and creativity. For both being and becoming we must now, in the emerging planetary order of Mankind, explore, identify and practise human values upon which will depend the attainment of the quality of life for all, and not only the privileged few.

From our past of many civilizations, diverse cultures, different religions and conflicting ideologies we are moving towards the unity of mankind. The formulation of a general statement on human values for our time could help the shaping of appropriate attitudes, common beliefs and suitable criteria and content of education for contemporary man. Such a statement can be based on the following important concerns and aspects of man, common to all civilizations and culture :

II—HUMAN VALUES

1. Man and his Own Self

In order to take charge of one's life in an uncertain and fast-changing world, the essentials of personality such as physical and mental health, right balance and poise of mind, and moral and spiritual qualities of character should be valued and cultivated. Education and Culture need to be directed to the enrichment of character and the pursuit of goodness, wisdom and transcendence. The development of the inner man by the fullest flowering of man's potentials and totality of being should be encouraged in an atmosphere of freedom and security. Man's care of his own self calls for measure for measure of austerity, self-discipline, pursuit of self-knowledge and cultivation of serenity as well as intensity. The luminuous and balanced self ceases to be vulnerable. The power of the inner self should be directed to love and service of fellow-beings.

2. Man and his Fellow-man

Man's relationship to Society should be governed by principles of humanistic morality acceptable to all and reflecting the quality and sensitivity of human relations, based upon compassionate love, mutual understanding and appreciation, and respect for justice and solidarity of

mankind.. The invocation to loving one's neighbour should extend to all inhabitants of the planet. Such a relationship between man and his fellow-man has to overcome the divisions and barriers of the past and the present attitudes of superiority and smugness arising from inequalities of wealth, power and knowledge. Man's common predicament and basic humanity should be planted firmly in his consciousness and conduct by the fullest and wisest use of the resources and potentialities of communications. The exploration and understanding of man's psyche should strengthen common humanity.

3. Man and his habitat

Contemporary man's habitat extends from his home and local environment to the entire planet, involving the care and nurture of nature and ecology from which he derives great benefits. The resources of the habitat must also be preserved for posterity for which he holds his habitat in trust. The sense of belonging and gratitude generate loyalty, prudence and austerity, and in the care and management of the habitat man learns to live in harmony with others. Narrower loyalities and nationalistic pride and egocentricity lead to conflict and war. These should give way to global loyalities.

4. Man and his work

To a large extent man lives in and for his work, and his mental health and happiness depend upon the choice of work, its scope for action, expression and initiative, its contribution to his creativity, decision-making, pursuit of excellence and sense of self-esteem and dedication. While work affords satisfaction, enjoyment and self-realization, it can also bring obsession for success and lust of power. We should avoid such temptation and work in a spirit of non-attachment and non-violence. Frustrations and alienations resulting from deprivations of work or its satisfactions warp the individual and distort society. Socio-economic systems and education should rectify these.

5. Man and Art

All men are endowed with artistic capabilities in varying forms and measure, and the flowering of these depends upon individual urge and social receptivity. The manifestations of beauty differ, but its essence and inspiration are the same. The pursuit of the beautiful strengthens man in his humanity and elevates his cultural life. In work, education and life we should recognise and enhance the importance of the arts and the artistic spirit. Respecting the diversity of art and culture, we can sense and share in the underlying unity of mankind. The quest of beauty and the joy of creation reveal life's meaning and enrich its quality. The artistic nature of man should be fed and nurtured all through the life span. People should have the opportunity of appreciating other people's arts and cultures.

6. Man and his Technology

Technological advance should be for human welfare and for the enrichment of man's humanity. Uncontrolled mechanisation for sheer power and de-humanisation needs to be checked. By controlling and

regulating technological advance and application of science we can improve human welfare and quality of life. Appropriate technologies should be chosen for practical relevance and efficient productivity, and also for their capacity to humanise life and spread culture. Technology should not be allowed to undermine or pervert the primacy of the human spirit which is the source of man's creations and the abiding values to live by. Technology must always be subservient to the ends of good life and humanism. As a significant reflection of man's relentless curiosity, inventiveness, perfection of methods and systems and mastery over the external world, technology projects important human values.

7. Man and his Ideology

Man cannot live by bread alone. Beyond the materials of economy, politics, science and industry, his restless mind and probing spirit need some beliefs to give meaning to life and its goals and purpose. Historical experience and human choice determine ideologies which are incentives to action in the present and guides to the making of the future. Ideology caters to emotional and mystical elements of man's consciousness as well as the quest of truth, faith and humanism. Ideologies are reflected in the diversities of cultures and choice of life-styles and systems. They can cause tensions and conflicts and lead to war and destruction. Ideology should be valued for its ennobling influence, its strength and integrity, its dedication to peace and harmony and its commitment to man's humanity.

8. Man and Time : The Stream of past, present and future

In his relationship with time man shares some compulsions and dreams not only with the fellow-man of his own time in life, but also with those who have gone before in history and those who have yet to come. The consciousness in time and the experience of the life-cycles contemplate the mysteries of life and death and the concept of eternity. Respect for the past with hope for the future strengthens man's care of his cultural heritage and pride in common endeavours and aspirations. Man's sense of history is a most precious source and guide to humanistic values, the understanding of human nature, deep humility and compassion; in the depressions and elections of the flux of history man recognises his eternal self and experiences the brotherhood of mankind.

9. Man and his Cosmos

Man has always pondered about the mystery of existence, the universe that lies beyond, and the larger scheme of life of which he is only a part. Imagination, intuition, mysticiam, and religion have all contributed to the quest of the Cosmos, the ultimate or the larger universe which may be glimpsed through worship, meditation, knowledge and poetry. Contemporary man has greater knowledge of the extent and nature of the universe than the past generations, and this knowledge brings us close to the life and unity of our own planet. We can all share in our common predicament of the planetary habitat, so small and insignificant in the vastness of space and time. The Cosmic dimension of life brings us closer to each other and gives a proper perspective to temporal existence. □

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Ethical and Legal Aspects of Family Planning

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I deem it a great privilege to have been asked to address this session of International Conference on Health Policy—Ethics and Human Values. The topic for this session is family planning—a National Priority. I would be speaking to you on the ethical and legal aspects.

It was 36 years ago that India became a republic and The Constitution of India came into force to secure, *inter alia*, to all its citizens social justice and dignity of individual. Part IV of the Constitution contains directive principles of state policy, which as mentioned in Art. 37 were fundamental in the governance of the country and were to be applicable, as duty of the state, in making laws, clause (f) of Art. 39 Contained in that part provided that. The state shall direct its policy towards securing that children are given opportunities and facilities to develop in a healthy manner and in conditions of freedom and dignity. According to Art. 47 the state shall regard raising of the level of nutrition and standard of living of its people and the improvement of public health as amongst its primary duties. These were great objectives, earnesty conceived and nobly worded, but even though a period of more than three and half decades has passed since then, the goals visualised by the founding fathers in these articles have remained elusive and more or less a tantalising illusion. Not that efforts have not been made towards attainment of those objectives. We have had a series of five year plans conceived primarily to bring about economic regeneration. We have had earnest, well-meaning persons who have striven in their own way and as best as they could to banish poverty and raise the living standards. We have made considerable headway in industry and technology as also in agricultural, dairy and poultry production. We have built dams and initiated river valley projects. We have spread network of roads and provided for Quick means of transport. We have also established a large number of educational institutions. But despite all these efforts, we still continue to be steeped in poverty and backwardness and our average standard of living is one of the lowest in the entire world with one of the lowest per capita income. If one were asked as to which has been the chief culprit and the main cause for frustrating and setting at naught all these efforts to raise the economic level of the people, the finger must pin-point in the direction of population explosion. The increase in population during the last four decades has upset all plans and frustrated all efforts to bring about betterment and amelioration in the living standards of the people. India's total population touched figure of 685 millions in the census of 1981. This represents an increase of 25% since 1971 when the population was 548 millions. It would be pertinent in this context to mention that India's population which was 238 millions in 1901 increased to 361 millions in

1951 and to 685 millions in 1981. Thus in the first half of the present century, i.e. during the years 1901—1951 India's population increased by about 51.5% whereas in the next 30 years from 1951 to 1981 it increased by 89.8%. The main cause of this increase can be attributed to fall in the death rate due to better health conditions and more efficient handling of epidemics. A sample survey revealed that the birth-rate in 1980 was 33.3% and the death rate was 12.4. The expectation is that the death rate would decline still further and be brought down to 10 per thousand by 1990.

The increase in world population during the year 1985 was 85 millions bringing it to a total of 4.9 billions. The population growth rate declined from 2% in 1970 to 1.7% in 1985. Even at this rate world population is expected to be 5 billions by middle of 1987 and 6 billions by the end of the century.

Unless therefore we can devise some measures to control the population growth, we can take it that all our plans for raising the living standards would go away and run into rough weather and the problem of poverty, backwardness and low living standards would haunt us and dog our steps for years to come. As it is the average increase per year of the population of India is more than the total population of Australia. It is in this context that the question of birth control has assumed tremendous importance,

So far as the ethical aspect is concerned I would say that it is inherently immoral to give birth to children if we cannot secure for them proper food, clothing and shelter and provide them with requisite education to grow into healthy, self-reliant adult-hood with prospects of decent standard of living. At the same time it would be unrealistic and plainly discriminatory to deny to the poor sections of the community the incident and satisfaction of a normal marital life. Begetting of children and the continuance of the family line is as such an important objective and desideratum of married life amongst the poor as amongst the affluent sections of the community. The difficulty, however, arises because the growth rate of family members amongst the poorer sections was and continues to be at a level higher than that of affluent sections who as a result of education have realised the desirability of restricting the number of children. It is in this context that some action is called for and some measures need to be adopted to bring about a state of small families in regard to poorer section of the community.

At the same time we have to bear in mind that in view of the consequences of resort to compulsory methods during the period of emergency the government would be reluctant to enforce compulsive measures. Faced with this situation all that we can do is to build a strong public opinion and create a General awareness of the need for and desirability of a small family. It has to be impressed upon every one that small family is a desideratum not merely because of any altruistic consideration or as a part of obligation to the society but much more than that as a matter of sheet enlightened self-interest of the individual concerned and for the benefit and welfare of his own children. Human nature being what it is, experience tells us that enlightened self interest is a much more potent motivating factor for an average person.

Coming to the legal aspect I may say that law does not prevent or impose a ban upon the procreation of children beyond a particular limit. Law, as was once said by trudeau, has no function in the bed-room of the married couple. Indeed attempt by law to impose restrictions upon the number of children might well be construed as an intrusion into the privacy of individuals' married life. At the same time law can provide incentives to couples to restrict the number of children. Such a law has been enacted in number of countries and it is a perfectly valid piece of legislation.

India adopted family planning as official programme in 1958 as it recognised that a timely check on population growth would in turn raise the living standards of the people. During the period of the first two plans from 1951 to 1961 the emphasis was mainly on research in the field of motivation, communication, demography, physiology of reproduction and extension of organisations for providing clinical services. Since then various ideas have been set afloat. The objective of family welfare in 1978 was to reduce the birth rate to 30 per thousand of population by the end of 1982-83 from the existing 33 per thousand population. At present the demographic goal is that the average woman should be replaced by one daughter and two child family as the normative pattern and to attain this objective by 1996.

Although section 312 which makes it an offence and provides for punishment for causing miscarriage, unless it be for the purpose of saving the life of a woman, still continues to be a part of our panel code, the parliament enacted in 1971 the medical termination of pregnancy Act. According to this act notwithstanding anything contained in the Indian penal code, A Registered Medical Practitioner shall not be guilty of any offence if any pregnancy of length not exceeding 12 weeks in terminated by him or where the length or pregnancy exceeds 12 weeks but does not exceed 20 weeks if two registered medical practitioners are of opinion formed in good faith that the continuance of the pregnancy would involve risk to the life of the pregnant woman or of grave injury to her physical or mental health. Likewise the law relating to abortion has been liberalised in other countries. In England notable part in this direction was played by Mrs. Margaret Sanger, while in the United States three connecticut women, one of whom was Mrs. Katharine Houghton Hepburn, mother of the famous Actress Katharine Hepburn, made significant contribution in starting birth control leagues. Some of the most interesting cases relating to birth control and abortion were decided by us Supreme Court. One of such cases, was Poe vs Ullman decided in 1961. In this case law relating to ban on clinics for birth control was challenged. The Supreme Court, however, turned down the request. Justice frankfurter who wrote the majority opinion said that the issue related to a dead letter and the court could not be umpire to debates concerning harmless empty shadows. According to him the fear of enforcement of that law was chimerical or imaginary because provisions of the law had gone unenforced. Justice Douglas who wrote the minority Judgement in a Scathing Criticism of the Majority view observed:

> "What are these people—Doctor and Patients— to do? Flout the law and go to prison? Violate the law surreptitiously and hope they will not get caught? . . . It is not a choice they need have under. . . our constitutional system."

Soon thereafter clinics started openly working in connecticut. A complaint was then filed and the Supreme Court was forced to decide this issue in 1965 in the case of griswold. This time Justice Douglas was on the side of the majority. The majority held that the impugned law trespassed into the zone of marital privacy, a realm of family life which the state cannot enter without substantial justification. The law was accordingly struck down. In a subsequent judgement in 1972 the Supreme Court extended the above principle to the case of single individuals. Ultimately in a decision given in 1973 in Poe's case the Supreme Court held that the right of abortion was not absolute and added a restriction. All abortions, the Court held, were not legal. A formula was evolved, according to which in the first three months of pregnancy the right of privacy prevails and the abortion decision was upto the woman and her doctor. During the second period of three months the state could regulate abortion in a way related to maternal health. In other words the state could require that operation be performed under certain conditions. During the last stage of pregnancy the court held the state laws could prohibit abortion except under circumstances in which the life or health of the mother was in danger.

One might discern a note of similarity between the view taken by the the U.S. Supreme Court and that which had been taken earlier in the law passed by The Indian Parliament in 1971.

Friends, I have been talking to you about the ethical and legal aspects of family planning, restricting the number of children and about the permissible limits of resorting to abortion. It would, however, be wrong to think that the matter has only ethical and legal aspects. More than anything else it is human problems and relates to some of the most intimate aspects of human life. This apart the issue has a vital bearing on the social equilibrium which is bound to get upset and disturbed by further increase in economic disparities. Unless we can somehow control the birth rate and introduce planned parenthood with small families the spectacle of vast areas of slums existing side by side with palatial multi-storied buildings would continue to mar at even a bigger scale the landscape of all big cities. They would also become focal points of social tensions. Experience tells us that a few island of richness in vast area of poverty, a few cases of affluences in a vast desert of penury and privation generate tensions and give rise to dangerous thoughts which portend ill for the smooth march forward of the society. Wisdom lies in forestalling such social convulsion and in taking timely steps to prevents occurrence. Family planning is one vital step for this purpose.

I think the organisers for asking me to address this August gathering on a vital issue. □

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Ethical Dilemmas in a Health Policy Points to Ponder

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"The enjoyment of the highest attainable standard of health is one of the fundamental rights of every human being without distinction of race, religion, political belief, economic or social condition." This cardinal principle enshrined in the Constitution of the World Health Organization has been the guiding light for health planners and administrators the world over as they have attempted to steer their national health policies in the turbulent seas of want, hunger and disease.

How successful we have been in achieving this laudable goal, is, of course, a debatable matter. What, however, is beyond any doubt is the fact that for vast number of people in the world, health remains an illusion, a dream.

What makes the problem more complex is that in an age of conflicting demands and limited resources, health unfortunately takes very low priority. The experience usually has been that when budgetary cuts become inevitable, the axe falls first on the health sector.

It is largely for the above mentioned reasons that we find ourselves in a situation where hundreds of millions of people in rural communities in the developing world have little or no access to health care. On the other hand, "disease palaces," as the Director-General of the World Health Organization, Dr. Halfdan Mahler, once described some ultra-modern hospitals, consume a sizeable portion of the country's health budget. We therefore find ourselves in the uneviable position of spending 80% of health budgets on 20% of the population, whereas 80% of the population living in rural areas has to make do with 20% of the budgetary allocations. If ever there was an ethical dilemma, this is it.

So, what does one do about it ? How can there be a more equitable distribution of available health resources ? How can the people be equipped to take care of themselves ? All these questions, and many more, have been raised in the past few years in international conferences as it has become increasingly obvious that in order to achieve a reasonable standard of health, the people themselves will have to do something about it.

Health for All

The beginning of this direction was made nearly a decade ago when, at the World Health Assembly held in 1977, the Member Countries of WHO adopted the historic resolution setting for themselves the goal of "Health for All by the year 200." The following year, WHO and UNICEF organized the first-ever international conference on Primary Health Care

at Alma-Ata, USSR. It was here that the vehicle through which health for all could be achieved, primary health care, was identified. Since then the momentum has grown with countries formulating their national strategies and plans of action to achieve the goal. Also, as a result of public debate on the issue, health has been recognized as an integral part of the development process. In fact, it is now acknowledged that without health there can be no development. What has also emerged recently is the understanding that health is not the responsibility of the health sector alone, and that in order to achieve common objectives, health development needs to be a multisectoral effort.

It is, for example, now an accepted fact that health depends on a number of supportive services, like health education, nutrition, water and sanitation, just to name a few. This aspect, of health development encompassing many disciplines was most forcefully emphasized in the Declaration of Alma-Ata. In spelling out what was meant by primary health care, the Declaration stated that this included at least: education concerning prevailing health problems and the methods of preventing and controlling them: promotion of food supply and proper nutrition; an adequate supply of safe water and basic sanitation; maternal and child health care, including family planning; immunization against the major infectious diseases; prevention and control of locally endemic diseases; appropriate treatment of common diseases and injuries; and provision of essential drugs.

If one examines these eight elements separately, it becomes obvious that in order to make primary health care available to all would mean active collaboration and coordination between various departments and ministries.

Policy-making Problems and Pressures

In order to make any objective assessments or set realistic targets, it is necessary to keep in mind that health development has to be viewed in the context of the prevailing socio-economic conditions. For example, it is impossible to expect any dramatic improvements in the health status of the people without a corresponding improvement in the agricultural or industrial production, literacy rates, status of women, and so on. I am purposely not going into the area of health statistics, of demographic profiles or disease patterns, because I wish only to differ some trigger points for discussion.

What is important to bear in mind is that many developing countries like ours find themselves in a very real predicament. The predicament of choice. Not because there are several choices, but because there are very few. Thus we find that while on the one hand there are millions without adequate medical care, on the other hand there are thousands of qualified doctors with nothing to do. Thus we find that whereas production of drugs is adequate, it never reaches the places it is most needed. Thus we find that simple, low-cost technologies that are available and acceptable to the people are not utilized. Here, it is not so much a matter of inadequate knowledge as the inability to take the necessary decisions at the policy-making levels. It is here that political commitment assumes a very significant role. For without such commitment, most ideas never get translated into action.

Community Involvement

Largely as a result of the movement set in motion by the resolution setting the goal of health for all and the subsequent actions taken at the country level, it is now realized that without the involvement of the community the goal of health for all can never be achieved. An active and self-reliant people can do a lot for their own health and the health of their fellow beings as well as prevent, control and treat diseases. But the real question that needs to be answered is how far do countries want their people to be self-reliant. This is not merely a rhetorical question, it has serious political undertones.

Even if one chooses to stay clear of political issues there is no denying the fact that many factors having a direct bearing on health are largely influenced by political decisions. To give just one example, one could cite the per capita expenditure on health. In most developing countries it can safely be said that expenditure on health is perhaps the lowest, compared to the other sectors. Here one need not draw comparisons between what is spent on defence, as compared to health. But the example is important to keep in mind because of its bearing on policy-making.

Another example in this context is the success achieved in some developing countries with regard to the provision and training of community health workers and the steps taken to rationalize the production and usage of drugs. Though the experience with community health workers has varied from country to country, the question of essential drugs has been most interesting. After WHO came out with the list of 200 essential drugs which an Expert Committee had recommended for use in primary health care, several countries set about to further refine the list. This was a political decision, taken at the highest levels as it very directly affected the interests of the multinational drug companies. But, here again, once the policy makers were convinced of the merits of the case, they were willing to take the decisions even though it meant going against well entrenched vested interests.

Similarly, once a country sets for itself the goal of health for all, the operative word becomes *all.* And when a country decides that the way it will achieve that goal is through primary health care and community involvement, then it also means that the country is prepared to take care of the consequent increased demands that will be made on existing health services.

As any one connected with the health services knows, it is one thing to create the right awareness and motivate the people to become self-reliant in health care, and quite another to cope with the demands. More damage is done to the credibility of a service if, having generated the demand, the health services finds itself incapable of coping. That is why it is essential to develop the necessary infrastructure before creating a demand.

These are all factors that have to be carefully examined, keeping in mind the special needs of the community. In a country as vast and diverse in its culture as India, no blanket norms can be applied to any situation. It requires inputs tailor-made to specific needs. And herein lies the biggest challenge, as well as the opportunity to provide the people with the basics in health care. It is only then that the cherished goal of health for all will be achieved. □

INTERNATIONAL CONFERENCE
HEALTH POLICY : ETHICS & HUMEN VALUES NEW DELHI 1986

Family Planning–A National Priority Social, Ethical, Cultural and Medical Aspects

Role of the Medical Profession

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The medical profession over the ages acquired two major roles in society. The first the more ancient one of ministering to the sick and sorry. Of providing medication, treatment and relief for illness and injury.

The second role evolved later and gradually. It was that of a mentor to the society on health matters. It carried out this role by organising and instituting measures for the prevention of sickness. By advising and suggesting measures for the promotion of health. This second role less dramatic and less spectacular has not the glamour associated with the provision of relief from suffering. But it is perhaps more substantive and important as it promotes and preserves the weal, welfare and integrity of the society. The two roles however are not exclusive but mutually supplementary.

It is in the ambit of the second role that the medical profession's commitment is invoked to tackle the current population growth and the health hazards arising thereof.

Let us do a quick review of the estimated momentum of the population growth since the oneset of the modern era.

It took several thousand year of man's existence on this planet to reach the world figures of 500 million by A.D. 1650. It took the next 175 years by A.D. 1825 to double the population to 1,000 million (that is one billion). 105 years more to again double to 2,000 million or 2 billion) by A.D. 1930, and the next 45 years by A.D. 1975 to double again to 4,000 million (4 billion). At this tempo it is estimated that the world population by the year A.D. 2000 will increase to 7,000 million or 7 billion (Table 1)

TABLE 1

Year	*Doubling Time*	*Population*
A.D. 1650		500 million (½ billion)
A.D. 1825	175 years	1,000 million (1 billion)
A.D. 1930	105 years	2,000 million (2 billion)
A.D. 1975	45 years	4,000 million 4 billion)

National Academy of Sciences U.S.A.

What are the penalties imposed on human existence and human health by this runaway population.

The first need of the people is that of food.

The problem is one of food and numbers. Can food production keep pace with the population pace.

The pattern of population expansion around the globe is not uniform. It ranges from zero growth to moderate in the affluent and developed countries. In the underdeveloped countries it is high. It seems that poorer the country the higher is the rate of its population growth. Resulting in the phenomenon that the countries least equipped to increase their food production are faced with high rise demand for food and nutrition.

It is estimated that two-thirds of the world's pre-school children suffer from one form or other of malnutrition. So does perhaps one-third of the world's population. Malnutrition may be one of low calorie intake or a more serious one of also low intake of proteins and other essential items. The resulting morbidity is of wide range.

A sensitive indicator of malnutrition in children is the slowing down of their growth and development. This may also be reflected in their later years by all round reduced capacity.

Infantile marasmus and kwashiorkar are not uncommon serious nutritional diseases. These are likely to occur when breast feeding is inadequate or terminates early due to one or another reason and the supplementary food given is deficient in calories and grossly so in proteins and other essential nutrients. These diseases have high mortality and are likely to leave permanent scars in the victims.

The classical nutritional diseases of beri-beri and pellagra are still quite common, Caused by deficiency of thiamine and niacin respectively in the diet and aggravated by protein deficiency, these may also leave permanent damages.

Anaemia is another wide-spread manifestation of nutritional deficiency occurring in all age groups. It is particularly harmful in mothers and children.

A number of other malnutrition morbidities like scurvy, rickets, goitre also occur but much less commonly.

Malnutrition directly contributes to lowered resistance to infections and inter-current diseases. The penalties on a nation from malnutrition are the decline in the general health of its population and the impairment of social and economic developments.

Let us look at our country. At the time of gaining our freedom our population was 350 million. Today it is nearing 800 million and by the year 2000 likely to cross 1000 million.

With 14 per cent of the world's population our geographical entity contains only 1.5 per cent of the world's arable land.

In the earlier post-independence years we had to import sizeable quantities of food. Today we are self-efficient. This is, however, a precarious situation. Apart from the growing demand from an enlarging population, the vagaries of the weather and climate can tilt the balance.

Our increased food production was achieved by a combination of inputs. By use of fertilisers and pesticides, by improved variety of seeds, by better management of land and water resources, by application of new technology and energy resources.

There is however, a biological limit to what can be produced by these special essential inputs from the small layer of about 10 to 12 inches of top soil that covers the earth's crust. In some parts of the world this limit has already been exploited.

The population imposes another burden on the land. To meet the pressure of increasing needs and demands the processes of development cause diversion of land to other uses. Like for the expanding network of roadways and rail-tracks, for dams and canals, for the construction of buildings for habitation, for industries and other institutes. It thus cuts away land to that extent and diminishes it for food production.

Another problem that the population creates is of deforestation arising from the mindless cutting of trees to fulfil pressing needs. This causes erosion of the soil, ecological imbalance and leads to climatic changes. The sequalae of such disturbances are harish. An example of such consequences are the recent occurrence of prolonged drought and widespread famine in Ethiopia.

Poverty is a high breeder of ill-health. The poor denied the resources and services essential for positive health exist under adverse and insanitary conditions. Their resistance is reduced and they are easy prey to infections and diseases.

Poverty is compounded by unemployment. The unemployed parasitic are not productive. Both poverty and unemployment expand as the population grows rapidly.

In India the jobless today are estimated at about 50 million. Every month another 130,000 new entrants swell their cadres.

Man tends to pollute his surroundings. He does it more at his growing numbers crowd the earth. The environmental deterioration is aggravated by the increasing discharge of industrial effluents and toxic by-products of technology onto the soil, the waterways and the atmosphere. The resultant environmental pollution has both direct and indirect effects deleterious to health.

The mounting pressure of high population growth imposes other penalties on the health of the people.

Man like other species requires a minimal space or elbow room in which he can function and lead a balanced existence. What may be labelled as his need of essential territorial exclusiveness. If the cordons of this territory are shrunk or intruded upon it causes his mental and physical disorientation and deterioration. Much of the social malaise and morbidity in the cities can be traced to the current fast trend of urban concentrations of high density.

The application of new health technologies in the developing countries has been comparatively facile. It has dramatically brought down their death rates. The professional cadres however have not been able to provide adequate level of individual health care in these regions. The doctor/population ratio there-in is low. So is that of the essential and supportive paraprofessional cadres. The fast population growth aggravates the deficiency. The training of these technical manpower groups is slow and time-consuming and their production cannot match the population pace. The demands for health services soon outrun the supply.

High fertility has a direct correlation with the health risks of women and children. In women besides causing a greater incidence of ill health associated with pregnancy and childbearing, it makes them more vulnerable to general health hazards and diseases. It reduces their reproductive efficiency and their capacity to give a good start and provide adequate maternal care and sustenance to their progeny. This is reflected in the occurrence of high fetal loss, more congenital malformations, low birth weights and raised infant mortality. The surviving children show more signs of malnutrition, impaired growth and retarded development. The adverse effects of high parity both in women and children are aggravated if the repeated pregnancies occur at short intervals. Uncontrolled and unregulated parity undoubtedly impose heavy penalties on women and their progeny.

High fertility rates are often associated with high rates of induced abortions. Often illegal and performed under most unsatisfactory conditions, these add to the health hazards of the women.

The communities which continue to have high birth rates show a profile of a young population and an age distribution of a pyramid with a wide base. In this pyramid O-14 years group forms a large cohort. The need of medical care for this group and the problems of its provision are more complex and difficult than for other age groups. This puts further pressure and strain on the medical network and its resources.

In cognition of the changing global pattern of human existence it is imperative that human fertility is controlled and regulated. The medical profession must take the prime responsibility to advise family planning as an essential health measure and propagate contraceptive practices.

Man stands apart from animal life. He is gifted with the power to think, to formulate, and pursue some enduring values. Amongst them is his capacity for compassion.

The raison d'etre of the medical profession is to demonstrate the quality of compassion in operation. It is in the compass of that aura that

the profession functions to prevent *unnecessary deaths*. To the objectives of reducing pain and suffering. Not for financial rewards, not for economic gains. But in the fulfilment of the humanistic traditions that inspires the professional ethos.

The same altruistic grace should move the medical profession to commit its resources to prevent *unnecessary births* which but add to the sprawling numbers condemned to an existence of hunger, want and degradation.

The atom bomb is man's brain-child. The population bomb his biological child. Both a threat to this survival. The first threatening his dissolution in an instant flash. The second to a slower end by choking up and dissipation of the earth's resources essential for his existence.

Man must control both diabolic creations. In that effort the medical profession must be in the vanguard. □

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The Right to Live and The Right to Die

Minoo Masani

President, World Federation of the Right to Die Societies

My good friend, Yusuf Meherally, whose useful life was cut short so cruelly, used to write in every autograph book which was placed before him by his many young admirers : "Live dangerously". In my young days I thought it was a rather good slogan and, by and large, I have tried to live up to it, and never regretted doing so. The idea of death has never worried or frightened me right from my young days. I would much rather be dead than red. What does, however, give me the creeps is the thought of being crippled and unable to function. I know a great many people who share this preference for a quick and dignified death to a long and humiliating existence as a cripple or a vegetable.

At a meeting I addressed on behalf of the Society For the Right To Die with Dignity, which was the first of its kind in India, I was asked by a gentleman who believed in *karma* what advice I would give him. I told him that, as far as he was concerned, he was altogether entitled to endure the sufferings to which he had referred as part of the cycle of karma. Since all we are arguing for was Voluntary Euthanasia, I hoped he would not mind my exercising my option the other way when the occasion arose, since I was not convinced of the reality of reincarnation or *karma.*

Some of my friends find it difficult to accept the thought that, when they die, it will be their final elimination and nothing will remain of them at any level of existence. I must confess that to me the idea of absolute destruction does not hold any terrors, while the idea of going through Purgatory and then facing whatever came afterwards does not appear to be particularly restful after a long and busy life on this earth. Why should one object to being blotted out at the end of this life ? Why should I have the conceit that I must go on forever ?

All this shows that our perceptions about the matter of life and death vary greatly and that to deny anyone the right to a different view from what one holds oneself would be not only dogmatic but stupid. We all know so little, about these matters, and it is best to keep an open mind, do the right thing, practice the golden rule, and leave the rest to Providence which, it has been aptly said, "shapes our ends, rough how them how we will".

I have always responded warmly to the English poet who wrote :

> "I am the master of my fate,
> I am the captan of my soul."

I was therefore greatly touched when Mr. Gopal Mandlik, a well-

known social worker of Poona, ended his own life in 1980 after waiting two years for the Government of India to amend the Indian Penal Code and to make it possible for him to do so legally. His only regret was that his eyes and his kidneys, which he had wished to donate for humane purpose by deleting Section 309 IPC could no longer be put to use in that manner. He was a true *satyagrahi* in the Gandhian sense. Gandhiji always urged that where one's conscience held a law to be wrong or immoral, the satyagrahi should break the law and take the consequences but not run away.

Mr. Mandlik's brave act was one of the factors that led some of us to establish The Society For the Right To Die with Dignity in May 1981. Another sad case of someone who was not in a position to imitate Mr. Mandlik was that of my good friend Norman Thomas, the American Socialist leader, who was in his old age completely paralysed and pleaded to be released, but was tormented by being kept alive for many years because it was not legal in that particular part of the United States to allow him to die.

When people tell me that public opinion is not ready for an amendment of the law which would make Voluntary Euthanasia easier to practice, under proper conditions and safeguards, I am inclined to wonder. Public opinion has been described as "a fickle jade" and indeed is very volatile and changeable. In the middle of the 60s, a well-known lady who was a champion of birth control in India, pleaded with me not to introduce a Private Member's Bill in Parliament for legalising abortion on the ground that, if I were to do so, it would create such a storm of opposition that the backlash would injure the cause of contraception. Lo and behold, four or five years later I found myself a member of a Joint Select Committee of Parliament which recommended to Parliament the legalising of abortion, and I noted that nobody in the Select Committee and nobody in Parliament opposed this change in principle. How do we then know what public opinion is or not in the case of Voluntary Euthanasia unless we first educate it and then test it ?

That is precisely what our Society has tried to do in the years that have passed since we took this pioneering step. There has recently been a great deal of public discussion on this issue.

Much of this is due to a Bill introduced by Prof. S.S. Varde in the Maharashtra Legislative Council to provide for immunity and protection to physicians and surgeons who withdraw life sustaining treatment from terminally ill patients at their wish. This Bill was ordered to be circulated by the Council to elicit public opinion and this led to a controversy in the course of which prominent doctors in Bombay including Dr. Praful R. Desai, Director, Tata Memorial Centre, Dr. N.H. Keswani, Medical Director, Jaslok Hospital and Research Centre, Dr. B.N. Colabawala, Dr. R.R. Soonawala. Dr. K.D. Desai, Dr. F. Soonawala, Dr. J.C.N. Joshipura, Dr. V. Talwalkar and others have written to the press welcoming the Bill.

The other helpful development is a judgement of a Division Bench of the Delhi High Court on March 31st 1985, which refused to punish a young man who attempted to commit suicide despite Section 309 of the Indian Panel Code which makes such an attempt punishable.

In an outspoken judgement, the Delhi High Court has held that Section 309 of the IPC is an anachronism unworthy of a humane society like ours. The High Court went on to observe that many penal offences were the offshoot of an "unjust" society. ',So long as society refuses to face this reality, its coercive machinery will invoke the provisions like Section 309 IPC which has no right to remain on the Statute Book". The Court said that "the young man (Sanjay Kumar Bhatia) who tried to commit suicide because of "over emotionalism" would have escaped human punishment if he had succeeded in taking his life but was now being hounded by the police, because the attempt failed."

By and large the response to our cause has been encouraging. This is particularly so in the case of the medical profession, many of whom have in their own practice faced the "Doctor's Dilemma". Most doctors are humane, compassionate human beings and many of them share Dr. Christian Barnard's regret that they are not able to give relief from pain and distress to those of their patients in whose case they consider it appropriate. Hundreds of letters have been received by us, many of them extremely touching, about the sad stories they have to tell and the welcome they have given to our Society.

Our Society has prepared a draft Declaration and a draft Power of Attorney which it has issued to members for their use if they so desire. These documents make clear the wish of a man or woman in sound mind that, in case he or she is terminally ill and unable to give expression to his or her wishes, artificial medical treatment should be withdrawn and pain killing drugs given to him or her. The Power of Attorney would nominate two persons who would be duly authorised to persuade the doctor and family to respect the patient's wish if the occasion does arise. The Power of Attorney could of course be revoked at any time. Such documents are widely used in the U.S.A. and in U.K., where the law in regard to the abetment of suicide is the same as in India. These documents do not legally bind anyone but are valid documents even under the law as it stands today and would carry a great deal of moral influence.

Our Society is the 28th of its kind in the world. I was very happy to hear from my good friend, Arthur Koesler, the well-known writer, who said in his letter : "I am glad to hear that you are starting EXIT in India. It will be a long and hard way until charity and commonsense will do their work."

The *Examiner* a Catholic Journal, dealt with this matter in two issues. In its first issue of August 15, 1981, it naturally came out in opposition. I was glad to see, however, that in the second issue of August 20, 1981, the paper conceded that passive euthanasia may be justified. It quoted from the declaration on Euthanasia by the Congregation for the Doctrine of the Faith :

> "When inevitable death is imminent inspite of the means used, it is permitted in conscience to take the decision to refuse forms of treatment that would only secure a precarious and burdensome prolongation of life so long as the normal care due to the sick person in similar cases is not interrupted".

The most common doubt that is expressed is the fear that any change in the law to make it more humane would make it easier for unscrupulous persons to bump off old and sick relatives. This is a genuine fear, but it relates to mercy killing with which we, as a Society, are not concerned, and not to Voluntary Euthanasia. The danger of 'bumping off' only arises when ore person can arrange for another person to die. It cannot arise when a man or woman in sound mind but terminally ill makes his or her own choice and asks for self-deliverance.

I believe that public opinion can be mobilised within the next few years when it has been made more aware of the issue. We in the Society believe in obeying the law, but we would like it to be amended so as to make it more humane and compassionate. □

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Terminal Care–Ethics and Cultural Aspects

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Mankind is subject to the experience of physical death. The death is a state or condition with an existence for man beyond the grave, difficult to describe or quantify. Terminally ill (dying) means that the patient has an illness has which been accurately diagnosed, and which seems certain to bring about his death within a relatively short period of time, since the illness is beyond both cure and palliation. Caring for dying patients and giving sympathetic support to breaved families are profoundly important parts of the work of doctors, nurses and other members of the caring professions. The care of patients during their terminal illness over various periods of time is a privilege, for they greatly appreciate the visits of the doctors and realise they are not forgotten. They may be cared for in hospitals, nursing homes, or family homes and is requires numerous medical and nursing skills according to the particular illness. Symptoms are treated so that the patient remains free from pain and in comfort. Much nursing care is required by some patients, especially those who are paralysed in various ways.

Guidelines for Delivering Bad News

Every physician derives satisfaction from delivering good news to a patient; and no physician enjoys delivering bad news. Still, there are rare occasions when it becomes necessary for the physician to disclose a crippling diagnosis and prognosis to the patient. There are some general guidelines for delivering bad news as follows:

1. *Keep it simple.*
2. *Don't deliver all the news at once.* It is good idea to try not to provide too much information at the first sitting.
3. *Educate the patient gradually and gently* regarding the diagnosis.
4. *Wait for questions from the patient.*
5. *Ask questions yourself*—Valuable clarifications can result from gentle, and clear questioning.
6. *Do not destroy all hope.* "Most people with this form of disease as chronic renal failure are living longer but are not cured of their disease" is a useful kind of statement.
7. *Do not say anything that is not true.* This would be the cruelest blow of all.

I have the responsibility of caring for many patients with various end stage renal diseases; this particular diagnosis understandably causes unrest and anxiety to the patient and family. Various questions require answering at all stages of these illnesses. An explanation about the treatment and prognosis is given to the family, with the assurance that every thing will be done to help the patient throughout the illness. The question

whether the patient should be told he or she has end stage renal disease needs some discussion. Information is given with sympathetic understanding of the situation and in the kindest way, in the presence of near relatives Words are chosen carefully to create faith and confidence, and nothing shall be said to take away a patient's hope. I believe we can work professionally in a more helpful way when patients are told about the terminal illness, and by understanding something about the problems to be solved they can cooperate usefully.

Emotional Aspects of Death and Dying

In a critically ill and dying patient, palliation and emotional support are the optimal strategies. A useful approach is to communicate the medical realities to the patient as skillfully, honestly, and clearly as possible and allow the patient with the help of his or her family to decide upon the preferred treatment. Health professionals must have the courage and willingness to acknowledge that the patient's wishes may take priority over their own.

Patient-Doctor Communications

Fundamental to the evolution of effective doctor-patient communications is the notion that physicians answer all questions honestly, giving as much information as is asked by the patient.

Ambiguous or dishonest communication imposes needless emotional pain on patients and families facing life-threatening illness.

A variety of information inputs that come to the patient:

1. Direct statements from the physician.
2. Overheard comments of the physician to others.
3. Direct statements from others including nurses, ward boys and technicians.
4. Statements from family, friends and clergy.
5. Changes in the medical care routines, procedures, behaviour of others towards patients and changes in physical location.
6, Self-diagnosis, including reading of magazines, newspapers, records, charts and books.

It is evident that the dying person is engaged in multiple communications with many people. If the messages are clear the dying person can make sense out of his experience. But if the messages are confused or contradictory, the result is needless apprehension and anxiety. Many patients, once they are aware and acknowledge the untreatable state of their disease, have less pain and discomfort in general and require a minimum of medical supervision.

It is very difficult to answer the questions about the length of time the patient is likely to live, except when the end is obviously neat and I explain that all our lives are in the hand of God. I respect the wishes of

the family relatives of non-mentioning of the diagnosis and prognosis to the patient to avoid any upset, although it made more difficult when a patient realises the gradual deterioration of health without a real explanation being given to him. During the final days of the illness, the family members have to be informed about the time becoming short for the patient and by that time majority of these patients know about their condition. Whole family require help at these times to ameliorate the strains and stresses caused by loss of family member.

Patients who are seriously ill and cannot recover by available recent mode of therapy and their families, appreciate the frequent visits of the doctor, who can give much sympathetic help and support to ameliorate the sorrow and suffering which become more intense as death approaches for the loved relations. The presence of the doctor who has become a trusted friend during the illness is a source of solace to them in their grief. A special, unhurried visit following soon after the patients death to take and discuss is greatly appreciated by the family and these visits to the breaved family should continue for a further period of time, until there is an amelioration of their grief and loneliness.

Community Approach to Psychological Support of Dying Patient

The awareness, tolerance and acceptance of the reality of dying is difficult for the patient and family. In order to provide emotional, social and spiritual support, a community-wide effort helps in achieving the maximum care for the patients comfort and psychosocial support. It is important to have people involved, whether social workers, trained volunteers, priests, etc., who can give supportive help to patient and family members.

Bereavement Follow-up

Bereavement leads to a period of crisis, for the family. The care of the terminally ill patient and family does not stop when the patient dies. The members of health team may attend the funeral. Home visits and telephone contact continues with the family within the first three weeks of bereavement and subsequently upto approximately one year. Opportunity for the spouse, parents and children to express their grief and talk about the illness and death does much to relieve guilt and depression. A memorial card is sent to the key person on the anniversary of the death.

Role of Clergy Man or Priest

Not all symptoms need medication in a terminally ill patient. Pain of isolation and inability to attend church and ring with the choir is helped immensely by the presence of clergy man or priest and with the relatives and friends at bed side.

Understanding Patient Depression

Frequently observed patient response to life-threatening illness is depression. It results from:

(i) Prolonged and painful hospitalization and treatment.
(ii) Emotional abandonment by family and friends.
(iii) The real or imagined insensitivity of hospital personnel.
(iv) Depletion of finances due to expensive medical care.

It is not helpful to interrupt this response with false promises of cure or positive response to treatment. Patients require emotional support. One can be extremely supportive by sitting with the patient, often in silence, in an attempt to convey willingness to share this emotionally demanding period.

The Patient's Family

The dying patient and his or her family constitute the optimal unit of health care. It is extremely important for patients to conclude family relationships in as emotionally satisfying a way as possible. It can be very distressing for critically ill persons and their families to be separated by the treatment milieu. Following suggestions are offered to health professionals:

1. Train family members to participate in treatment.
2. Encourage them to do such things as continue to cook special meals for the patient.
3. Allow unlimited visiting so that the total family, including children, can spend time with the patient.
4. Provide special social and educational programs for the family and patient.

Continue these programs, adding home visits for the family after the patient has died.

Despite the importance of care for all troublesome and common symptoms of terminal patients admitted in hospital (100 cases); it remains to be said again that good personal relationships and the prevention of loneliness are of paramount importance in providing high quality terminal care (Table I).

Pain	50%	Dyspnoea	17%
Incontinence	30%	Bed sores	15%
Confusion	20%	Vomiting	13%
Nausea	15%	Cough	5%
Anorexia	15%	Dysphagia	3%
Insomnia	15%		
Depression and anxiety	20%		

The importance of adequate fluid intake, bowel regulation without discomfort and the correction of electrolyte imbalance, must be stressed in the terminal patients as in others. In dealing with all these symptoms, the doctor's enthusiasm and confidence in his therapy will be, without doubt,

transmitted to the patient. He should have the same interest in the patient during this stage of life as in any other. It is stressed that whether patient is nursed at home, in an institution, or by intermittent hospital admission and discharge, it is essential to make certain that there is continuity of care.

The management of terminal illness by the family physician is in the exploration and development of the doctor/patient relationship where the feelings of patient and the doctor are fully expressed and understood. A good relationship is best established when the patient and doctor acknowledge, either overtly or covertly, their awareness of impending death and the patient is allowed to test out the relationship without any fear of the doctor withdrawing.

In hospital, the dying patient receives every attention, constant medical and nursing care, the advantages of modern palliatives, profusely planned drug administration for the control of pain and freedom from neglect and loneliness. Very little work has been done to estimate the numbers of patients who die at home compared to those who die in hospital. 90% of all episodes requiring medical and nursing care attentions are dealt with in the community, but it is unlikely that a similar percentage rate applies to death. Once the decision is made, the transfer from hospital to home care sbould be effectively planned, so that the home, family and the primary care doctors and nurses are all prepared. □

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Moral and Ethical Dilemmas in the Care of Critically ILL Patients

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The knowledge explosion in Science and Technology tends to overwhelm us and we get confused in a maze of technicalities and methods often forgetting the patient we are treating and who becomes a conglomerate of signs and symptoms instead of a person. Advances in resuscitative technology have enabled anaesthetists to almost indefinitely prolong the life-supporting systems of critically ill patients who would formerly have been pronounced as dead after simple traditional measures had failed. The dilemma lies in the moral and ethical necessity of providing maximal care for patients who are terminally or irrepairably ill but who have a chance to survive their present catastrophe (Declaration of Helsinki, 1964). It is agreed that permanent functional death of the brain stem constitutes brain death and further artificial support is fruitless and should be withdrawn (Honorary Secretary, 1976).

In a dilemma one is faced with two alternative choices, neither of which seems a satisfactory solution to the problem. They arise in situations of uncertainity and ambiguity when the general principles upon which one normally relies either offer no help or seem to contradict each other. Such decisions have to be distinguished from the many important clinical decisions which must also be taken by doctors. These decisions may present as dilemmas but their resolution is dependent solely on the doctor's knowledge, experience and intuitive abilities. All these factors are certainly helpful in a moral dilemma but are insufficient to unravel the moral conflict, because a different kind of decision has to be made. The more concerned the profession has become about the formulation of codes of ethics the more they have become aware of the complexity of the moral problems. The profession simply provides some generalised statements in everyday language and leaves it to the good sense and good will of its practitioners to deal with the ambiguous situations.

The individual conscience is thought of as a kind of inner voice warning you against wrong doing and creating remorse when the warnings have been disregarded. Following conscience is the most common way doctors seek to solve the moral dilemmas they encounter. Peoples' intuitions' about right and wrong often conflict sharply. It seems that conscience is a powerful force in controlling the actions of most individuals; but although powerful, it may not always be right.

There is confusion about what is useful and advantageous to the majority and what we feel all men ought to value. Treating every indivi-

dual justly usually does benefit society as a whole. Respect for the rights of individuals is a more fundamental moral value than the happiness of the majority. We are still primarily concerned with caring for people and the art of medicine should not be forgotten in the enthusiasm for scientific precision. Sympathy and understanding are just as important as diagnostic acumen (Payne 1978). However, in many dilemmas of personal and social morality the criterion of general happiness is a good corrective to personal bias and idealistic mounting of principles.

What we appear to be searching for is a set of absolute or fundamental values which will clearly and unambiguously inform our choices and decisions in any given situation. Such a calculus of human rights cannot and will not be done. Rule following, much of it habitual and unquestioned, characterizes a high proportion of our daily activities. Our behaviour is confined within the limits of the socially acceptable, the legally sanctioned and the routines of personal preference and conviction. A rule-governed approach to morality becomes a wholly depersonalised one. What is missing is any consideration of the persons who hold the principles and the persons to whose circumstances the principles are applied.

It is said that Hipprocrates forbade the administration of remedies to those who were past hope. This injection we may heed as advice not to make difficult the final stages when we recognise their finality. None can relieve us of the responsibility of judging when this moment shall have come. We should bring to the beside a great hopefulness, a determined optimism, but is the futility of the struggle is clearly evident, then we should put aside our remedies as cures, and make the patient easy with such solation as may offer (Gavey 1950). We are asked to give guidance, to judge dispassionately upon reasonable probabilities. The fact that many of our prognosis prove wrong should not detract from a genuine attempt at a correct forecast. As Osler said "Errors of judgement must occur in the practice of a art which consists largely in balancing probabilities".

The question: "should the doctor tell?" is guided in practice by the circumstances of each case which suggests the line that should be taken. In general, a guarded prognosis slowly revealed enables a patient to prepare himself, retaining a hopeful attitude in the background. In these matters few demand to know the truth and nothing but the truth and even if a direct question is asked the patient usually welcomes an answer which does not shut out all hope. The patient senses the true position far more accurately than one might imagine and any attempt to soften the blow is welcomed. There are occasions when it is best never to disclose the true position, even at the end. The human capacity for self deception is great and this characteristic needs to be promoted occasionally.

Intensive medical care is designed to diagnose, treat and maintain patients with immediate, acute but potentially reversible life-threatening impairements. It also aims at prophylactic management to avoid such catastrophes as cardiac arrest, respiratory arrest, shock, renal failure, and overwhelming sepsis. There is a growing beleif that medical and technological capabilities should not necessarily be used simply because they exist.

Is there an ethical imperative to preserve all patients in life threatening situations including those for whom existence seems only a fiction and others for whom it promises to be only severely diminished? On one view, it is justificable to moderate the therapy even though earlier death will occur, when this will result in relief from pain and suffering. Another view is that 'our training is to preserve life and functions whenever possible'. We are not trained to decide who "is better off dead". The patient who is alive has an overriding right to life and deserves the maximal possible therapy (Cohen, 1977).

This conflict has implications for the care of those who are not terminally ill, but who are potentially salvageable with the chance that survival will be accompanied by severe physical or mental impairement or both. It is these difficult cases concerning the level of salvageability that lead to the widest divergence of opinion. The problems are complicated by the fact that it is often not possible to evaluate the likely outcome of intensive care treatment until the patient has been monitored for some days and even then, predictions are open to revision in many cases (Cullen et al, 1976, Griner, 1973). It is also to be remembered that there is a moral difference between "Killing' and 'letting-die'. Dying is the final event of a valuable human being and no one else is morally empowered to initiate and transact. When a decision has been made that maximal treatment is inappropriate it is not an acceptable ethical alternative to kill the patient, but it is permissible to allow the patient to die (Mc Cormic, 1974).

Western ethical traditions have reached some general agreement that it is necessary to use 'ordinary' but not 'extraordinary' means to support and comfort patients in such cases (Pope Pius XXI, 1958). By 'ordinary' means is meant 'all medications, treatment and operations which offer a reasonable hope of benefit for the patient and which can be obtained and used without excessive expenses, pain or other inconvenience'. 'Extraordinary' means are those that do not offer such hope or cannot be obtained or use without those kinds of liabilities. There is a professional and moral relationship entered into with each patient admitted for intensive care in which it is understood the patient will receive appropriate care. Such care cannot be terminated later on the grounds that another patient with a higher potential for survival needs intensive care without violating the original obligation to the admitted patient and without violating the ethical principle that we cannot aid some by harming other (Report of Clinical Care Committee, 1976).

Survival though important, is not to be bought at any cost and that to attempt, but fail to achieve, may reduce so-called intensive care management merely to the level of prolonging the process of dying (Rabkin et al, 1976). It is of primary importance from an ethical perspective to determine whether the right to life is absolute or whether it can ever be overridden with justification. Our conclusions will not apply with absolute finality, like mathematical equations, to all cases as individuals have very different conceptions of how to exercise their right to the pursuit of happiness within the limits of the ethically possible. Reverence for life must be tempered by restraint and an equal respect for the dignity of death. In the last analysis, our choice is influenced by the way the personality regards it destiny and our own conception of death. □

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INTERNATIONAL CONFERENCE
HEALTH POLICY : ETHICS & HUMAN VALUES NEW DELHI 1986

Euthanasia

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Introduction

Euthanasia has its origins from a Greek word, the term 'Eu' means 'Well' and 'Thanatos' means death and it literally means an easy death. It is a form of peaceful or dignified death which is specially advocated when life become a punishment and dying comes as a pleasure to a patient, suffering from some incurable disease like cancer with severe intolerable and uncontrollable excruciating pain, who more often tearfully pleads to a doctor to relieve his suffering soul from bodily cage. The conflict is often stated to be between the doctor's duty to treat to the best of his ability and patient's right to be allowed to die quietly and in peace, when further medical measures appear meddlesome and only prolong suffering. Health Council of Netherlands has defined Euthanasia 'A deliberate life-shortening act or deliberate omission of a life lengthening act, in respect of an incurable patient and in his interest'. This definition includes both active (life shortening act) and passive (omission) euthanasia. The 'Declaration of Venice' at the meeting of the World Medical Association in Oct. 1983, has laid down that 'Physician may relieve suffering of a terminally ill patient by withholding the treatment with the consent of the patient or his immediate family member in case the patient is unable to express his will' and 'The physician may refrain from employing any extra-ordinary means which would prove of no benefit for the patient'.

In the light of above the present article endeavours to stress the role of Voluntary Passive Euthanasia in the Terminal Care, especially the withdrawing of life sustaining treatment according to wishes of patients suffering from Terminal Illness and withdrawal of life sustaining aids from a Terminally Injured patient after declaration of brain death. It will be in public interest for such a measure to be enacted as it would relieve a certain number of patients from suffering pain and torments which can be avoided.

Good death : Moral and Legal Challanges in Terminal Care

Law and medicine join a common pilgrimage towards protection, preservation, regulation, care, and all-pervasive welfare of human life. The Indian Constitution (Article 21) assures that 'No person shall be deprived of his life by the state except according to the procedure established by law'. The constitution can guarantee the 'Security' or 'Non-interference' in the enjoyment of life but no constitution in the world can ever assure its citizens that their life would remain always free from pain, disease and physical and mental agony. The right to life protected by Indian Constitution has not been judicially held to include 'Right to die'. The question is whether a person who has become a mere vegetable mass of protoplasm, who has worse than animal existence, who has no hope of recovery—

Should he be forced to live ? Should he be not allowed to die peacefully without suffering from further physical and mental agony ? Cannot he ask the state that while he has been given right to life, Can't he be endowed with a right to die in the event of a terminal illness or terminal injury ? The death sentence in India has been held to be constitutional under the very provision which protects the right to life of a person. Likewise state has legalised the Medical Termination of Pregnancy. Interaction of law and medicine is notable in cases of abortion. It is now perfectly legal though may not be perfectly moral or ethical. Man can choose to give life or death to the helpless unborn child then why should he not have similar right for his ownself ? The legislation of abortion means legislation of 'Death' of an unborn person. The purpose of abortion in most cases is to safe guard the health of a pregnant woman or it is for the convenience of the society and state as a measure of population control but the voluntary passive euthanasia is for the sake of suffering 'individual'. If law can permit 'killing' of an unborn child for the sake of 'others' Why should it not allow voluntary passive euthanasia for a willing and suffering patient.

Role of Voluntary Passive Euthanasia in Terminal Care

Terminal illness or Terminal Injury means any incurable illness or injury which will in all probabilities result in the expiration of life, regardless of use or discontinuance of medical or surgical treatment. To day cancer accounts for 15 per cent of deaths in the world. In U.S. alone more than 7 million unfortunates are in grip of this dreaded affliction. It is here that Voluntary Passive Euthanasia becomes relevant. Voluntary Passive Euthanasia advocates compassion in the preceding stages of terminal illness. These stages are process of dying which sometimes linger on for years. When a doctor prolongs the life of a dying patient by days, weeks, months or by years he merely prolongs his life of suffering. He simply promotes his vegetable existence or adds to his comatose condition in the name of preservation of life. No patient wants to put up with sufferings indefinitely. There is an innate desire in all living beings to terminate their sufferings as quickly as possible. When the intensity of suffering is beyond the pale of human indurance the urge to extinguish life is paramount. Prof. Elizabeth Ross recognises this final state of dying as a stage of acceptance, the patient is ready to accept loss of his life and beloved ones.

Withdrawing of Life Sustaining Treatment in Terminal Illness

The life sustaining treatment means all artificial means or measures of whatever kind administered as medical or surgical treatment designed solely to sustain life process. In developing nations health expenditure on the last few months of patient's lives rises to a crescendo, as might be expected but the consumer, the patient, often seems to derive little of real personal value from the money thus spent. Traditionally the medical ethics has been helped at this point by distinguishing 'ordinary' means of treatment which should be available to all patients, from 'extra-ordinary' which should not be employed as they cannot be used without excessive pain, cost or other inconvenience and which offer no reasonable hope of benefit.

Many people today have a fear that they will be kept alive artificially in this manner with consequent suffering and distress to them and members of their family. Since the decision to reject such treatment should be of patient alone and no one else in case of terminal illness as such provision of Voluntary Passive Euthanasia in terminal care will enable doctors, in the interest of compassion and humanity to respond to the patient's wishes in suitable cases but it should not provide for mercy killing of any kind.

Declaration for withdrawal of Life Sustaining Treatment

Any person of sound mind shall be entitled to make a declaration and give powers of Attorney duly executed by such person expressing the desire that if at any time in future he or she were to suffer from a terminal illness or terminal injury and be unable to express himself or herself, the wish embodied in the declaration and power of Attorney regarding withdrawal of life sustaining treatment, shall, if it has been in operation for 30 days and has not been duly revoked in writing be given effect to by his physician or surgeon and members of his or her family.

Withdrawal of life sustaining aids in patients of Terminal Injury

A person who can be declared dead under the law in U.S.A. and U.K. is considered to be alive in India. Though this may appear illogical, it is true because brain death is not legally recognised as death of a person and our law is silent on the issue of brain death. The main problem arises in road traffic accident victims who are being maintained on continuous artificial respiration by means of mechanical ventilators after sustaining irremediable structural brain damage. In such patients doctors are not lawfully authorised to switch off the respirator.

Legal recognition of brain death will enable doctors to withdraw life sustaining aids including the respirator, in patients suffering from terminal injury the moment brain death is diagnosed, especially in patients who failed to make any declaration in life time or execute powers of Attorney, expressing their wish for withdrawal of life sustaining aids in the event of terminal injury.

Diagnosis of Brain Death in Terminal Injury

The code of practice as agreed by Conference of Royal Medical Colleges and their Faculties of United Kingdom (1976) has advised the medical practitioners that before considering the diagnosis of Brain Death three conditions should be present altogether :—

1. Patient should be deeply comatose :

   (a) There should be no doubt that this state is due to depressant drugs.

   (b) Primary Hypothermia as a cause of coma should be excluded.

   (c) Metabolic and endoctrine disturbances that may cause or contribute to coma should also be excluded.

2. Patient should be maintained on continuous artificial respiration by means of a mechanical ventilator.

3. There should be no doubt that patient's condition is due to the irremediable structural brain damage for example severe head injury.

Tests for confirmation of brain death

(i) All brain stem reflexes should be absent.

(a) Pupils are fixed and dilated and do not respond to sharp changes in incident light.

(b) Corneal reflex absent.

(c) Vestibulo-ocular reflex absent.

(d) Carinal reflex absent.

(e) Gag reflex absent.

(f) No motor response within cranial nerve's distribution can be elicited by adequate stimulation of any somatic area.

(g) Spontaneous respirations—Absent with a normal P_aCo_2, in the absence of hypothermia.

(h) The oculo-cephalic reflex or doll's head eye movements must be absent.

Other Considerations

(i) Repetition of Testing—It is customary to repeat the tests to ensure that there has been no observer's error.

(ii) Integrity of Spinal Reflexes—It is well established that the spinal reflexes may perist after brain death (Ivan Smith 1973).

(iii) Confirmatory Investigations—It is now widely agreed that E.E.G. (Electro-encephalography) is not necessary for confirmation of brain death.

(iv) Body Temp.—It is recommended that body temp. should not be less than 35° C before the diagnostic tests are carried out.

Advantages of Legal Recognition of Brain Death in Terminal Injury

(A) *Responsibility of a Doctor* : Normally a doctor is not lawfully authorised to switch off a respirator sustaining the artificial respiration of a terminally injured patient, lying in a state of coma after sustaining the irremediable structural brain damage. If a doctor switches off the respirator at his own, he will be charged for causing death by an omission. The recognition of Brain Death legally as death of a person, will save the doctors from responsibility in such cases of terminal injury.

(B) *Organ transplantation* : The recognition of brain death of a terminally injured person in law will enable to the act legally and correctly

in the field of organ transplantation. After the confirmation of brain death if a surgeon has to keep on waiting for cardiac arrest to occur before removing organs for transplantation, a recipient may well receive a damaged organ and a recipient grafted with a damaged organ will have to undergo the pain, danger and suffering from two useless operations, namely one for the insertion of the graft and the second for its subsequent removal. The most suitable donors for organ transplantation are terminally injured patients, usually the road traffic accident victims who are being maintained on continuous artificial (IPPR) respiration by means of mechanical ventilators after sustaining irremediable structural brain damage. Such people have been organ donors either in their life times or consent has been obtained from their relatives. In U.S.A. such patients are also known as heart beating cadavers. Recognition of brain death as death of such terminally injured patients will enable doctors to remove the organs from such decerebrate donors. Normally transplants cannot be lawfully taken away from a living body if donor can not remain alive without the part being taken i.e. heart, so for a successful heart transplantation it is to be removed from a heart beating cadaver only. The most appropriate time for organ removal is before the vital life support system is withdrawn and organs are well perfused. Moreover heart has been kept alive and functional up to 56 hours after brain death, a duration of time which is long enough for operative exploration, tissue typing and search for a suitable recipient.

(C) *Economy of Intensive Care Resources* : Legal recognition of brain death as death of a person in case of a terminal injury will help in economising the intensive care unit's resources in the country, which are being strained by providing trained man power, intensive care unit beds and respirator for ventilating these brain dead people who have suffered from brain death after terminal injuries.

(D) *Property Rights* : Legal recognition of brain death as death of a person will have maximum impact in the matter of property rights, negligance claims, insurance, worker's compensation, probate law and taxes. A corpse cannot have property. Suppose that X is an old man who has left Y a large sum in his will. Y himself has suffered from a terminal injury and is in a state of coma, on artificial respiration at a hospital after sustaining irremediable structural brain damage. Here doctors are not lawfully authorised to switch off the respirator so they ask for consent of relatives but relatives see that Y is kept 'alive' on heart-lung machine because they want X's money. As soon as X dies the respirator off and Y is buried. In this example Y is being considered as still alive when X dies so that his family becomes entitled to property through him. This dodge will not be successful if Brain Death is legally accepted as death of a person.

The fact remains although the diagnosis of death is medical, its definition must be legal. The law protects the living but ceases to protect the dead (at any rate in the same way) and the line between the two must be drawn by law. The definition of death presented herein may suit both medical as well as legal requirements because it does not interfere with the existing procedure of declaration of death but at the same time it includes the concept of Brain Death in a terminally injured at the hospital level in the light of the current knowledge on the subject.

Definition of Death

'A person may be pronounced dead, whether inside or outside a hospital if based on usual and customary standards of medical practices, it is determined that the person has an irreversible cessation of cerebral, cardiac and pulmonary functions or a person inside a hospital only can be declared dead if having suffered from irreversible structural brain damage, his or her bodily functions cannot be maintained without continuous artificial support, provided the diagnosis of Brain Death in such a patient is based on diagnostic criteria as agreed by conference of Royal Medical Colleges and their Faculties of United Kingdom resolved in 1976'.

The above definition of death will be the most appropriate, not only for declaration of death in a terminally injured patient who has suffered brain death due is irremediable structural brain damage but will also pave the way for uniform determination of death in our country.

However it must be emphasised that for declaration of brain death opinion of two doctors must be obtained out of which one should be the consultant incharge of the case and the second may be any other doctor, incase the consultant is not available then his deputy who should have atleast five years of experience in dealing of such cases after his registration and none of the doctors who declare the brain death in such a patient should be the members of transplantation team in case the organ removal has been planned for transplantation.

Summary and Conclusion

Good medical care includes providing good death in a terminally ill or terminally injured patient. The dying patient must be considered competent in terms of capacity for autonomous choice unless proved otherwise. Medical science has now acquired life supporting systems and medications to extend life artificially for long periods even after loss of brain activities and control of bodily functions. Many people today have a fear of mind that they will be kept alive artificially for indefinite periods of time with consequent suffering and distress to them and members of their family. The conflict is often stated to be between doctor's duty to treat to the best of his ability and patient's right to die with dignity, quietly and in peace when further medical measures prove ineffective and only prolong suffering. Introduction of voluntary passive euthanasia in Terminal Care will not only relieve a certain number of patients from suffering pain and torment which can be avoided but will also enable the doctors to respond in the interest of compassion and humanity according to wishes of patients suffering from terminal illness and terminal injury. In case of a terminally injured patient who fails to make a declaration or execute powers of Attorney in advance expressing his wish to withdraw the life supporting treatment legal recognition of brain death will enable doctors to withdraw the life sustaining aid in a terminally injured patient after the declaration of brain death. Such a measure legalising brain death as death of a person in the event of terminal injury, will be in public interest, for such a measure to be enacted will not only protect doctors from needless prosecution and persecution but but will also have numerous other benefits i.e. It will help in the field of organ transplantation by permitting removal of organs either with the consent of their relatives or with their own consent in case they happened

to be organ donors in their life times, from these terminally injured patients at a time when they are being sustained on continuous artificial respiration after suffering from irremediable structural brain damage and their organs are well perfused; secondly it will help in economising intensive care unit's resources of the country which are being strained by providing trained manpower, beds and respirators for ventilating these heart beating cadavers, thirdly it will secure a doctor's right to switch off the respirator in a terminally injured patient after the confirmation of brain death in the light of current knowledge on the subject lastly it will help in the matter of property rights, negligence claims, insurance, worker's compensation, probate law and taxes. □

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HEALTH POLICY : ETHICS & HUMAN VALUES NEW DELHI 1986

To Tell or Not to Tell

Professional practices in the care of the dying

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Abstract

Sixty five responses of postgraduate doctors practising in India to a questionnaire on their beliefs and practice about telling the truth of inevitable death to their patients were studied. A majority (69.2%) favoured in telling the truth. Around 50% of their patients were suspected to be aware of their fate without being told. 40% of the doctors had had one or more occasion of feeling sorry later on because of their hiding the truth.

Introduction

Doctors differ in their approach about how much and when to tell the truth to the patient while caring for the dying. Some doctors have their own dogmas on this issue while others are guided by circumstances. Those who believe in telling the truth are usually critical of others who are evasive and use lies; but they themselves are considered unkind by the others.

There are few studies on medical perspective in the care of the dying from our country though in the West it has attracted both the professionals and the lay.[1,2] Issues and ethics while dealing with death in India may not be the same as in the Western countries in view of wide differences in social, cultural and religious beliefs. How do the doctors in India deal with patients facing inevitable and/or impending death ? We undertook a study with the help of a questionnaire on practicing doctors. One hundred ex-postgraduate students of the Postgraduate Institute of Medical Education and Research Chandigarh (PGI, Chandigarh), now practicing in the field and forty non PGI Alumni, Indian Medical Association members were sent the questionnaire. Since only three of the 2nd group responded we excluded them from the final analysis. Sixty five of the PGI alumni responded to the questionnaire.

Results

The responses were grouped into two categories depending upon their belief in telling the truth about the disease and its outcome to their patients :

Group I : Those who believed in telling the truth (45 : 69.2%).
Group II : Those who did not believe in telling the truth (20 : 30.8%).

The reasons favoured by those in favour of telling the truth were : (i) It pacifies the patient who can accept death more peacefully (61.5%); (ii) it helps in more effective palliative treatment (81.5%); (iii) the patient can put the family problems like marriages, transfer and division of assests etc. to order before death (90.8%); (iv) the patient can fulfil the last wishes (76.9%); (v) it stops their running around to seek treatment from different sources (93.8%). Other reasons included economic reasons (i.e. to give an expenditure versus result ratio to the patient), easier handling by the family and the patient's right to know the truth.

Those who were not in favour of telling the truth favoured the following reasons : (i) it frustrates and angers the patient (86%); (ii) it makes the family member's job more difficult (60%); (iii) it is difficult to tell the hard truth (60%); (iv) the patient may turn to quackery (50.8%).

Group I doctors (90.8%) felt that the truth should be told by the treating physician only. But 40% of group II doctors thought that if it has to be told it should be told by some one else eg. a close friend, relative or a priest.

About the awareness of the patient without being told 60.8% in group I and 72.3% in group II thought that over 50% of their patients knew of their fate.

Only 18.5% had ever felt sorry once or more afterwards about their decision of informing their patients. But 40.0% had one or more instances of feeling sorry afterwards when they did not inform the truth. This was because the patient kept wandering from place to place in search of cure and spent a lot of money (21.5%), could not settle worldly affairs (9.2%), or could not complete the last wishes (9.3%). Two doctors admitted of facing official and/or legal problems in view of their not telling the truth. However, none was ever charged in the court of law.

Discussion

It is generally believed that the knowledge of death takes away the charm of living. On the other hand, such a knowledge may dispel the uncertainty and may give the courage to face the situation. In the Western experience around 50% of the patients are already aware of their impending death.[3,4] In one study on the dying patients over 60% knew of this fact and none disapproved of open discussion.[3] Our results are similar to these findings. Most of our doctors have preferred a flexible policy of discussion guided by 'situation ethics' i.e. adapting the ethical standards to the situation. A majority of them would like to discuss the truth.

Involvement of the family members and the close relatives was favoured by most of the doctors. In view of the family structure and relatively closer ties amongst relatives in Indian set up, this aspect is of obvious importance.

It may also be worth recalling that 40% of the doctors had felt sorry at least once each about their hiding the truth from the patient. The most

important reason here was their failure in giving the patient an opportunity to put the worldly affairs in order. This point again needs to be stressed in our context especially when the head of the family who is often the sole bread earner of the family and usually the only knowledgeable person about family assets, debts, loans and other issues, is sick and dying. Many an official, procedural and legal complications can be avoided if these things are settled or atleast informed to the kith and kin before death. The patient also needs to know before hand about the utility of the expenditure involved in treatment versus the result as the family income may be meagre. Above all, a doctor is legally obliged to tell the patient the whole truth and nothing but the truth.

'The truth' of course 'has a broad spectrum with gentleness at one end and harshness at the other. Patients always appreciate gentle truth.[4]

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PROTECTION OF HUMAN SUBJECTS

CODE OF FEDERAL REGULATIONS

45 CFR 46

Revised as of March 8, 1983

NATIONAL RESEARCH ACT
PUBLIC LAW 93–348
JULY 12, 1974

INSTITUTIONAL REVIEW BOARDS; ETHICS GUIDANCE PROGRAM

SEC. 212. (a) Part I of title IV of the Public Health Service Act, as amended by section 103 of this Act, is amended by adding at the end the following new section:

"INSTITUTIONAL REVIEW BOARDS; ETHICS GUIDANCE PROGRAM

"SEC. 474. (a) The Secretary shall by regulation require that each entity which applies for a grant or contract under this Act for any project or program which involves the conduct of biomedical or behavioral research involving human subjects submit in or with its application for such grant or contract assurances satisfactory to the Secretary that it has established (in accordance with regulations which the Secretary shall prescribe) a board (to be known as an 'Institutional Review Board') to review biomedical and behavioral research involving human subjects conducted at or sponsored by such entity in order to protect the rights of the human subjects of such research.

"(b) The Secretary shall establish a program within the Department under which requests for clarification and guidance with respect to ethical issues raised in connection with biomedical or behavioral research involving human subjects are responded to promptly and appropriately."

(b) The Secretary of Health, Education, and Welfare shall within 240 days of the date of the enactment of this Act promulgate such regulations as may be required to carry out section 474(a) of the Public Health Service Act. Such regulations shall apply with respect to applications for grants and contracts under such Act submitted after promulgation of such regulations.

THE CODE OF FEDERAL REGULATIONS,
45 CFR 46, IMPLEMENTS THESE AMENDMENTS
TO THE PUBLIC HEALTH SERVICE ACT.

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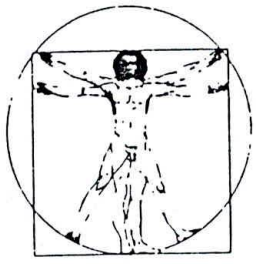
CODE OF FEDERAL REGULATIONS

TITLE 45
PUBLIC WELFARE

DEPARTMENT OF HEALTH AND HUMAN SERVICES
NATIONAL INSTITUTES OF HEALTH
OFFICE FOR PROTECTION FROM RESEARCH RISKS



PART 46—PROTECTION OF HUMAN SUBJECTS

REVISED AS OF MARCH 8, 1983

PART 46—PROTECTION OF HUMAN SUBJECTS

Subpart A—Basic HHS Policy for Protection of Human Research Subjects

Subpart B—Additional Protections Pertaining to Research, Development, and Related Activities Involving Fetuses, Pregnant Women, and Human In Vitro Fertilization

Subpart C—Additional Protections Pertaining to Biomedical and Behavioral Research Involving Prisoners as Subjects

Subpart D—Additional Protections for Children Involved as Subjects in Research

Authority: 5 U.S.C. 301; sec. 474(a), 88 Stat. 352 (42 U.S.C. 289l-3(a)).

Subpart A—Basic HHS Policy for Protection of Human Research Subjects

Source: 46 FR 8386, January 26, 1981, 48 FR 9269, March 4, 1983.

§ 46.101 To what do these regulations apply?

(a) Except as provided in paragraph (b) of this section, this subpart applies to all research involving human subjects conducted by the Department of Health and Human Services or funded in whole or in part by a Department grant, contract, cooperative agreement or fellowship.

(1) This includes research conducted by Department employees, except each Principal Operating Component head may adopt such nonsubstantive, procedural modifications as may be appropriate from an administrative standpoint.

(2) It also includes research conducted or funded by the Department of Health and Human Services outside the United States, but in appropriate circumstances, the Secretary may, under paragraph (e) of this section waive the applicability of some or all of the requirements of these regulations for research of this type.

(b) Research activities in which the only involvement of human subjects will be in one or more of the following categories are exempt from these regulations unless the research is covered by other subparts of this part:

(1) Research conducted in established or commonly accepted educational settings, involving normal educational practices, such as (i) research on regular and special education instructional strategies, or (ii) research on the effectiveness of or the comparison among instructional techniques, curricula, or classroom management methods.

(2) Research involving the use of educational tests (cognitive, diagnostic, aptitude, achievement), if

information taken from these sources is recorded in such a manner that subjects cannot be identified, directly or through identifiers linked to the subjects.

(3) Research involving survey or interview procedures, except where all of the following conditions exist: (i) responses are recorded in such a manner that the human subjects can be identified, directly or through identifiers linked to the subjects, (ii) the subject's responses, if they became known outside the research, could reasonably place the subject at risk of criminal or civil liability or be damaging to the subject's financial standing or employability, and (iii) the research deals with sensitive aspects of the subject's own behavior, such as illegal conduct, drug use, sexual behavior, or use of alcohol. All research involving survey or interview procedures is exempt, without exception, when the respondents are elected or appointed public officials or candidates for public office.

(4) Research involving the observation (including observation by participants) of public behavior, except where all of the following conditions exist: (i) observations are recorded in such a manner that the human subjects can be identified, directly or through identifiers linked to the subjects, (ii) the observations recorded about the individual, if they became known outside the research, could reasonably place the subject at risk of criminal or civil liability or be damaging to the subject's financial standing or employability, and (iii) the research deals with sensitive aspects of the subject's own behavior such as illegal conduct, drug use, sexual behavior, or use of alcohol.

(5) Research involving the collection or study of existing data, documents, records, pathological specimens, or diagnostic specimens, if these sources are publicly available or if the information is recorded by the investigator in such a manner that subjects cannot be identified, directly or through identifiers linked to the subjects.

(6) Unless specifically required by statute (and except to the extent specified in paragraph (i)), research and demonstration projects which are conducted by or subject to the approval of the Department of Health and Human Services, and which are designed to study, evaluate, or otherwise examine: (i) programs under the Social Security Act, or other public benefit or service programs; (ii) procedures for obtaining benefits or services under those programs; (iii) possible changes in or alternatives to those programs or procedures; or (iv) possible changes in methods or levels of payment for benefits or services under those programs.

(c) The Secretary has final authority to determine whether a particular activity is covered by these regulations.

(d) The Secretary may require that specific research activities or classes of research activities conducted or funded by the Department, but not otherwise covered by these regulations, comply with some or all of these regulations.

(e) The Secretary may also waive applicability of these regulations to specific research activities or classes of research activities, otherwise covered by these regulations. Notices of these actions will be published in the *Federal Register* as they occur.

(f) No individual may receive Department funding for research covered by these regulations unless the individual is affiliated with or sponsored by an institution which assumes responsibility for the research under an assurance satisfying the requirements of this part, or the individual makes other arrangements with the Department.

(g) Compliance with these regulations will in no way render inapplicable pertinent federal, state, or local laws or regulations.

(h) Each subpart of these regulations contains a separate section describing to what the subpart applies. Research which is covered by more than one subpart shall comply with all applicable subparts.

(i) If, following review of proposed research activities that are exempt from these regulations under paragraph (b)(6), the Secretary determines that a research or demonstration project presents a danger to the physical, mental, or emotional well-being of a participant or subject of the research or demonstration project, then federal funds may not be expended for such a project without the written, informed consent of each participant or subject.

§ 46.102 Definitions.

(a) "Secretary" means the Secretary of Health and Human Services and any other officer or employee of the Department of Health and Human Services to whom authority has been delegated.

(b) "Department" or "HHS" means the Department of Health and Human Services.

(c) "Institution" means any public or private entity or agency (including federal, state, and other agencies).

(d) "Legally authorized representative" means an individual or judicial or other body authorized under applicable law to consent on behalf of a prospective subject to the subject's participation in the procedure(s) involved in the research.

(e) "Research" means a systematic investigation designed to develop or contribute to generalizable knowledge. Activities which meet this definition constitute "research" for purposes of these regulations, whether or not they are supported or funded under a program which is considered research for other purposes. For example, some "demonstration" and "service" programs may include research activities.

(f) "Human subject" means a living individual about whom an investigator (whether professional or student) conducting research obtains (1) data through intervention or interaction with the individual, or (2) identifiable private information. "Intervention" includes both physical procedures by which data are gathered (for example, venipuncture) and manipulations of the subject or the subject's environment that are performed for research purposes. "Interaction" includes communication or interpersonal contact between investigator and subject. "Private information" includes information about behavior that occurs in a context in which an individual can reasonably expect that no observation or recording is taking place, and information which has been provided for specific purposes by an individual and which the individual can reasonably expect will not be made public (for example, a medical record). Private information must be individually identifiable (i.e., the identity of the subject is or may readily be ascertained by the investigator or associated with the information) in order for obtaining the information to constitute research involving human subjects.

(g) "Minimal risk" means that the risks of harm anticipated in the proposed research are not greater, considering probability and magnitude, than those ordinarily encountered in daily life or during the performance of routine physical or psychological examinations or tests.

(h) "Certification" means the official notification by the institution to the Department in accordance with the requirements of this part that a research project or activity involving human subjects has been reviewed and approved by the Institutional Review Board (IRB) in accordance with the approved assurance on file at HHS. (Certification is required when the research is funded by the Department and not otherwise exempt in accordance with § 46.101(b)).

§ 46.103 Assurances.

(a) Each institution engaged in research covered by these regulations shall provide written assurance satisfactory to the Secretary that it will comply with the requirements set forth in these regulations.

(b) The Department will conduct or fund research covered by these regulations only if the institution has an assurance approved as provided in this section, and only if the institution has certified to the Secretary that the research has been reviewed and approved by an IRB provided for in the assurance, and will be subject to continuing review by the IRB. This assurance shall at a minimum include:

(1) A statement of principles governing the institution in the discharge of its responsibilities for protecting the rights and welfare of human subjects of research conducted at or sponsored by the institution, regardless of source of funding. This may include an appropriate existing code, declaration, or statement of ethical principles, or a statement formulated by the institution itself. This requirement does not preempt provisions of these regulations applicable to Department-funded research and is not applicable to any research in an exempt category listed in § 46.101.

(2) Designation of one or more IRBs established in accordance with the requirements of this subpart, and for which provisions are made for meeting space and sufficient staff to support the IRB's review and recordkeeping duties.

(3) A list of the IRB members identified by name; earned degrees; representative capacity; indications of experience such as board certifications, licenses, etc., sufficient to describe each member's chief anticipated contributions to IRB deliberations; and any employment or other relationship between each member and the institution; for example: full-time employee, part-time employee, member of governing panel or board, stockholder, paid or unpaid consultant. Changes in IRB membership shall be reported to the Secretary.[1]

(4) Written procedures which the IRB will follow (i) for conducting its initial and continuing review of research and for reporting its findings and actions to the investigator and the institution; (ii) for determining which projects require review more often than annually and which projects need verification from sources other than the investigators that no material changes have occurred since previous IRB review; (iii) for insuring prompt reporting to the IRB of proposed changes in a research activity, and for insuring that changes in approved research, during the period for which IRB approval has already been given, may not be initiated without IRB review and approval except where necessary to eliminate apparent immediate hazards to the subject; and (iv) for insuring prompt reporting to the IRB and to the Secretary[1] of unanticipated problems involving risks to subjects or others.

(c) The assurance shall be executed by an individual authorized to act for the institution and to assume on behalf of the institution the obligations imposed by these regulations, and shall be filed in such form and manner as the Secretary may prescribe.

(d) The Secretary will evaluate all assurances submitted in accordance with these regulations through such officers and employees of the Department and such experts or consultants engaged for this purpose as the Secretary determines to be appropriate. The Secretary's evaluation will take into consideration the adequacy of the proposed IRB in light of the anticipated scope of the institution's research activities and the types of subject populations likely to be

[1] Reports should be filed with the Office for Protection from Research Risks, National Institutes of Health, Department of Health and Human Services, Bethesda, Maryland 20205.

involved, the appropriateness of the proposed initial and continuing review procedures in light of the probable risks, and the size and complexity of the institution.

(e) On the basis of this evaluation, the Secretary may approve or disapprove the assurance, or enter into negotiations to develop an approvable one. The Secretary may limit the period during which any particular approved assurance or class of approved assurances shall remain effective or otherwise condition or restrict approval.

(f) Within 60 days after the date of submission to HHS of an application or proposal, an institution with an approved assurance covering the proposed research shall certify that the application or proposal has been reviewed and approved by the IRB. Other institutions shall certify that the application or proposal has been approved by the IRB within 30 days after receipt of a request for such a certification from the Department. If the certification is not submitted within these time limits, the application or proposal may be returned to the institution.

§ 46.104 [Reserved]

§ 46.105 [Reserved]

§ 46.106 [Reserved]

§ 46.107 IRB membership.

(a) Each IRB shall have at least five members, with varying backgrounds to promote complete and adequate review of research activities commonly conducted by the institution. The IRB shall be sufficiently qualified through the experience and expertise of its members, and the diversity of the members' backgrounds including consideration of the racial and cultural backgrounds of members and sensitivity to such issues as community attitudes, to promote respect for its advice and counsel in safeguarding the rights and welfare of human subjects. In addition to possessing the professional competence necessary to review specific research activities, the IRB shall be able to ascertain the acceptability of proposed research in terms of institutional commitments and regulations, applicable law, and standards of professional conduct and practice. The IRB shall therefore include persons knowledgeable in these areas. If an IRB regularly reviews research that involves a vulnerable category of subjects, including but not limited to subjects covered by other subparts of this part, the IRB shall include one or more individuals who are primarily concerned with the welfare of these subjects.

(b) No IRB may consist entirely of men or entirely of women, or entirely of members of one profession.

(c) Each IRB shall include at least one member whose primary concerns are in nonscientific areas; for example: lawyers, ethicists, members of the clergy.

(d) Each IRB shall include at least one member who is not otherwise affiliated with the institution and who is not part of the immediate family of a person who is affiliated with the institution.

(e) No IRB may have a member participating in the IRB's initial or continuing review of any project in which the member has a conflicting interest, except to provide information requested by the IRB.

(f) An IRB may, in its discretion, invite individuals with competence in special areas to assist in the review of complex issues which require expertise beyond or in addition to that available on the IRB. These individuals may not vote with the IRB.

§ 46.108 IRB functions and operations.

In order to fulfill the requirements of these regulations each IRB shall:

(a) Follow written procedures as provided in § 46.103(b)(4).

(b) Except when an expedited review procedure is used (see § 46.110), review proposed research at convened meetings at which a majority of the members of the IRB are present, including at least one member whose primary concerns are in nonscientific areas. In order for the research to be approved, it shall receive the approval of a majority of those members present at the meeting.

(c) Be responsible for reporting to the appropriate institutional officials and the Secretary[1] any serious or continuing noncompliance by investigators with the requirements and determinations of the IRB.

§ 46.109 IRB review of research.

(a) An IRB shall review and have authority to approve, require modifications in (to secure approval), or disapprove all research activities covered by these regulations.

(b) An IRB shall require that information given to subjects as part of informed consent is in accordance with § 46.116. The IRB may require that information, in addition to that specifically mentioned in § 46.116, be given to the subjects when in the IRB's judgment the information would meaningfully add to the protection of the rights and welfare of subjects.

(c) An IRB shall require documentation of informed consent or may waive documentation in accordance with § 46.117.

(d) An IRB shall notify investigators and the institution in writing of its decision to approve or disapprove the proposed research activity, or of modifications required to secure IRB approval of the research activity. If the IRB decides to disapprove a research activity, it shall include in its written notificatio

[1] Reports should be filed with the Office for Protection from Research Risks, National Institutes of Health, Department of Health and Human Services, Bethesda, Maryland 20205.

a statement of the reasons for its decision and give the investigator an opportunity to respond in person or in writing.

(e) An IRB shall conduct continuing review of research covered by these regulations at intervals appropriate to the degree of risk, but not less than once per year, and shall have authority to observe or have a third party observe the consent process and the research.

§46.110 Expedited review procedures for certain kinds of research involving no more than minimal risk, and for minor changes in approved research.

(a) The Secretary has established, and published in the *Federal Register*, a list of categories of research that may be reviewed by the IRB through an expedited review procedure. The list will be amended, as appropriate, through periodic republication in the *Federal Register*.

(b) An IRB may review some or all of the research appearing on the list through an expedited review procedure, if the research involves no more than minimal risk. The IRB may also use the expedited review procedure to review minor changes in previously approved research during the period for which approval is authorized. Under an expedited review procedure, the review may be carried out by the IRB chairperson or by one or more experienced reviewers designated by the chairperson from among members of the IRB. In reviewing the research, the reviewers may exercise all of the authorities of the IRB except that the reviewers may not disapprove the research. A research activity may be disapproved only after review in accordance with the non-expedited procedure set forth in §46.108(b).

(c) Each IRB which uses an expedited review procedure shall adopt a method for keeping all members advised of research proposals which have been approved under the procedure.

(d) The Secretary may restrict, suspend, or terminate an institution's or IRB's use of the expedited review procedure when necessary to protect the rights or welfare of subjects.

§46.111 Criteria for IRB approval of research.

(a) In order to approve research covered by these regulations the IRB shall determine that all of the following requirements are satisfied:

(1) Risks to subjects are minimized: (i) By using procedures which are consistent with sound research design and which do not unnecessarily expose subjects to risk, and (ii) whenever appropriate, by using procedures already being performed on the subjects for diagnostic or treatment purposes.

(2) Risks to subjects are reasonable in relation to anticipated benefits, if any, to subjects, and the importance of the knowledge that may reasonably be expected to result. In evaluating risks and benefits, the IRB should consider only those risks and benefits that may result from the research (as distinguished from risks and benefits of therapies subjects would receive even if not participating in the research). The IRB should not consider possible long-range effects of applying knowledge gained in the research (for example, the possible effects of the research on public policy) as among those research risks that fall within the purview of its responsibility.

(3) Selection of subjects is equitable. In making this assessment the IRB should take into account the purposes of the research and the setting in which the research will be conducted.

(4) Informed consent will be sought from each prospective subject or the subject's legally authorized representative, in accordance with, and to the extent required by § 46.116.

(5) Informed consent will be appropriately documented, in accordance with, and to the extent required by § 46.117.

(6) Where appropriate, the research plan makes adequate provision for monitoring the data collected to insure the safety of subjects.

(7) Where appropriate, there are adequate provisions to protect the privacy of subjects and to maintain the confidentiality of data.

(b) Where some or all of the subjects are likely to be vulnerable to coercion or undue influence, such as persons with acute or severe physical or mental illness, or persons who are economically or educationally disadvantaged, appropriate additional safeguards have been included in the study to protect the rights and welfare of these subjects.

§ 46.112 Review by institution.

Research covered by these regulations that has been approved by an IRB may be subject to further appropriate review and approval or disapproval by officials of the institution. However, those officials may not approve the research if it has not been approved by an IRB.

§ 46.113 Suspension or termination of IRB approval of research.

An IRB shall have authority to suspend or terminate approval of research that is not being conducted in accordance with the IRB's requirements or that has been associated with unexpected serious harm to subjects. Any suspension or termination of approval shall include a statement of the reasons for the IRB's action and shall be reported promptly to the investigator, appropriate institutional officials, and the Secretary.[1]

[1] Reports should be filed with the Office for Protection from Research Risks, National Institutes of Health, Department of Health and Human Services, Bethesda, Maryland 20205.

§ 46.114 Cooperative research.

Cooperative research projects are those projects, normally supported through grants, contracts, or similar arrangements, which involve institutions in addition to the grantee or prime contractor (such as a contractor with the grantee, or a subcontractor with the prime contractor). In such instances, the grantee or prime contractor remains responsible to the Department for safeguarding the rights and welfare of human subjects. Also, when cooperating institutions conduct some or all of the research involving some or all of these subjects, each cooperating institution shall comply with these regulations as though it received funds for its participation in the project directly from the Department, except that in complying with these regulations institutions may use joint review, reliance upon the review of another qualified IRB, or similar arrangements aimed at avoidance of duplication of effort.

§ 46.115 IRB records.

(a) An institution, or where appropriate an IRB, shall prepare and maintain adequate documentation of IRB activities, including the following:

(1) Copies of all research proposals reviewed, scientific evaluations, if any, that accompany the proposals, approved sample consent documents, progress reports submitted by investigators, and reports of injuries to subjects.

(2) Minutes of IRB meetings which shall be in sufficient detail to show attendance at the meetings; actions taken by the IRB; the vote on these actions including the number of members voting for, against, and abstaining; the basis for requiring changes in or disapproving research; and a written summary of the discussion of controverted issues and their resolution.

(3) Records of continuing review activities.

(4) Copies of all correspondence between the IRB and the investigators.

(5) A list of IRB members as required by § 46.103(b)(3).

(6) Written procedures for the IRB as required by § 46.103(b)(4).

(7) Statements of significant new findings provided to subjects, as required by § 46.116(b)(5).

(b) The records required by this regulation shall be retained for at least 3 years after completion of the research, and the records shall be accessible for inspection and copying by authorized representatives of the Department at reasonable times and in a reasonable manner.

§ 46.116 General requirements for informed consent.

Except as provided elsewhere in this or other subparts, no investigator may involve a human being as a subject in research covered by these regulations unless the investigator has obtained the legally effective informed consent of the subject or the subject's legally authorized representative. An investigator shall seek such consent only under circumstances that provide the prospective subject or the representative sufficient opportunity to consider whether or not to participate and that minimize the possibility of coercion or undue influence. The information that is given to the subject or the representative shall be in language understandable to the subject or the representative. No informed consent, whether oral or written, may include any exculpatory language through which the subject or the representative is made to waive or appear to waive any of the subject's legal rights, or releases or appears to release the investigator, the sponsor, the institution or its agents from liability for negligence.

(a) Basic elements of informed consent. Except as provided in paragraph (c) or (d) of this section, in seeking informed consent the following information shall be provided to each subject:

(1) A statement that the study involves research, an explanation of the purposes of the research and the expected duration of the subject's participation, a description of the procedures to be followed, and identification of any procedures which are experimental;

(2) A description of any reasonably foreseeable risks or discomforts to the subject;

(3) A description of any benefits to the subject or to others which may reasonably be expected from the research;

(4) A disclosure of appropriate alternative procedures or courses of treatment, if any, that might be advantageous to the subject;

(5) A statement describing the extent, if any, to which confidentiality of records identifying the subject will be maintained;

(6) For research involving more than minimal risk, an explanation as to whether any compensation and an explanation as to whether any medical treatments are available if injury occurs and, if so, what they consist of, or where further information may be obtained;

(7) An explanation of whom to contact for answers to pertinent questions about the research and research subjects' rights, and whom to contact in the event of a research-related injury to the subject; and

(8) A statement that participation is voluntary, refusal to participate will involve no penalty or loss of benefits to which the subject is otherwise entitled, and the subject may discontinue participation at any time without penalty or loss of benefits to which the subject is otherwise entitled.

(b) Additional elements of informed consent. When appropriate, one or more of the following elements of information shall also be provided to each subject:

(1) A statement that the particular treatment or procedure may involve risks to the subject (or to the embryo or fetus, if the subject is or may become pregnant) which are currently unforeseeable;

(2) Anticipated circumstances under which the subject's participation may be terminated by the investigator without regard to the subject's consent;

(3) Any additional costs to the subject that may result from participation in the research;

(4) The consequences of a subject's decision to withdraw from the research and procedures for orderly termination of participation by the subject;

(5) A statement that significant new findings developed during the course of the research which may relate to the subject's willingness to continue participation will be provided to the subject; and

(6) The approximate number of subjects involved in the study.

(c) An IRB may approve a consent procedure which does not include, or which alters, some or all of the elements of informed consent set forth above, or waive the requirement to obtain informed consent provided the IRB finds and documents that:

(1) The research or demonstration project is to be conducted by or subject to the approval of state or local government officials and is designed to study, evaluate, or otherwise examine: (i) programs under the Social Security Act, or other public benefit or service programs; (ii) procedures for obtaining benefits or services under those programs; (iii) possible changes in or alternatives to those programs or procedures; or (iv) possible changes in methods or levels of payment for benefits or services under those programs; and

(2) The research could not practicably be carried out without the waiver or alteration.

(d) An IRB may approve a consent procedure which does not include, or which alters, some or all of the elements of informed consent set forth above, or waive the requirements to obtain informed consent provided the IRB finds and documents that:

(1) The research involves no more than minimal risk to the subjects;

(2) The waiver or alteration will not adversely affect the rights and welfare of the subjects;

(3) The research could not practicably be carried out without the waiver or alteration; and

(4) Whenever appropriate, the subjects will be provided with additional pertinent information after participation.

(e) The informed consent requirements in these regulations are not intended to preempt any applicable federal, state, or local laws which require additional information to be disclosed in order for informed consent to be legally effective.

(f) Nothing in these regulations is intended to limit the authority of a physician to provide emergency medical care, to the extent the physician is permitted to do so under applicable federal, state, or local law.

§ 46.117 Documentation of informed consent.

(a) Except as provided in paragraph (c) of this section, informed consent shall be documented by the use of a written consent form approved by the IRB and signed by the subject or the subject's legally authorized representative. A copy shall be given to the person signing the form.

(b) Except as provided in paragraph (c) of this section, the consent form may be either of the following:

(1) A written consent document that embodies the elements of informed consent required by § 46.116. This form may be read to the subject or the subject's legally authorized representative, but in any event, the investigator shall give either the subject or the representative adequate opportunity to read it before it is signed; or

(2) A "short form" written consent document stating that the elements of informed consent required by § 46.116 have been presented orally to the subject or the subject's legally authorized representative. When this method is used, there shall be a witness to the oral presentation. Also, the IRB shall approve a written summary of what is to be said to the subject or the representative. Only the short form itself is to be signed by the subject or the representative. However, the witness shall sign both the short form and a copy of the summary, and the person actually obtaining consent shall sign a copy of the summary. A copy of the summary shall be given to the subject or the representative, in addition to a copy of the "short form."

(c) An IRB may waive the requirement for the investigator to obtain a signed consent form for some or all subjects if it finds either:

(1) That the only record linking the subject and the research would be the consent document and the principal risk would be potential harm resulting from a breach of confidentiality. Each subject will be asked whether the subject wants documentation linking the subject with the research, and the subject's wishes will govern; or

(2) That the research presents no more than minimal risk of harm to subjects and involves no procedures for which written consent is normally required outside of the research context.

In cases where the documentation requirement is waived, the IRB may require the investigator to provide subjects with a written statement regarding the research.

§ 46.118 Applications and proposals lacking definite plans for involvement of human subjects.

Certain types of applications for grants, cooperative agreements, or contracts are submitted to the Department with the knowledge that subjects may be involved within the

period of funding, but definite plans would not normally be set forth in the application or proposal. These include activities such as institutional type grants (including bloc grants) where selection of specific projects is the institution's responsibility; research training grants where the activities involving subjects remain to be selected; and projects in which human subjects' involvement will depend upon completion of instruments, prior animal studies, or purification of compounds. These applications need not be reviewed by an IRB before an award may be made. However, except for research described in § 46.101(b), no human subjects may be involved in any project supported by these awards until the project has been reviewed and approved by the IRB, as provided in these regulations, and certification submitted to the Department.

§ 46.119 Research undertaken without the intention of involving human subjects.

In the event research (conducted or funded by the Department) is undertaken without the intention of involving human subjects, but it is later proposed to use human subjects in the research, the research shall first be reviewed and approved by an IRB, as provided in these regulations, a certification submitted to the Department, and final approval given to the proposed change by the Department.

§ 46.120 Evaluation and disposition of applications and proposals.

(a) The Secretary will evaluate all applications and proposals involving human subjects submitted to the Department through such officers and employees of the Department and such experts and consultants as the Secretary determines to be appropriate. This evaluation will take into consideration the risks to the subjects, the adequacy of protection against these risks, the potential benefits of the proposed research to the subjects and others, and the importance of the knowledge to be gained.

(b) On the basis of this evaluation, the Secretary may approve or disapprove the application or proposal, or enter into negotiations to develop an approvable one.

§ 46.121 Investigational new drug or device 30-day delay requirement.

When an institution is required to prepare or to submit a certification with an application or proposal under these regulations, and the application or proposal involves an investigational new drug (within the meaning of 21 U.S.C. 355(i) or 357(d)) or a significant risk device (as defined in 21 CFR 812.3(m)), the institution shall identify the drug or device in the certification. The institution shall also state whether the 30-day interval required for investigational new drugs by 21 CFR 312.1(a) and for significant risk devices by 21 CFR 812.30 has elapsed, or whether the Food and Drug Administration has waived that requirement. If the 30-day interval has expired, the institution shall state whether the Food and Drug Administration has requested that the sponsor continue to withhold or restrict the use of the drug or device in human subjects. If the 30-day interval has not expired, and a waiver has not been received, the institution shall send a statement to the Department upon expiration of the interval. The Department will not consider a certification acceptable until the institution has submitted a statement that the 30-day interval has elapsed, and the Food and Drug Administration has not requested it to limit the use of the drug or device, or that the Food and Drug Administration has waived the 30-day interval.

§ 46.122 Use of Federal funds.

Federal funds administered by the Department may not be expended for research involving human subjects unless the requirement of these regulations, including all subparts of these regulations, have been satisfied.

§ 46.123 Early termination of research funding; evaluation of subsequent applications and proposals.

(a) The Secretary may require that Department funding for any project be terminated or suspended in the manner prescribed in applicable program requirements, when the Secretary finds an institution has materially failed to comply with the terms of these regulations.

(b) In making decisions about funding applications or proposals covered by these regulations the Secretary may take into account, in addition to all other eligibility requirements and program criteria, factors such as whether the applicant has been subject to a termination or suspension under paragraph (a) of this section and whether the applicant or the person who would direct the scientific and technical aspects of an activity has in the judgment of the Secretary materially failed to discharge responsibility for the protection of the rights and welfare of human subjects (whether or not Department funds were involved).

§ 46.124 Conditions.

With respect to any research project or any class of research projects the Secretary may impose additional conditions prior to or at the time of funding when in the Secretary's judgment additional conditions are necessary for the protection of human subjects.

Subpart B—Additional Protections Pertaining to Research Development, and Related Activities Involving Fetuses, Pregnant Women, and Human in Vitro Fertilization

SOURCE: 40 FR 33528, Aug. 8, 1975, 43 FR 1758, January 11, 1978, 43 FR 51559, November 3, 1978

§ 46.201 Applicability.

(a) The regulations in this subpart are applicable to all Department of Health, Education, and Welfare

grants and contract supporting research, development, and related activities involving: (1) The fetus, (2) pregnant women, and (3) human *in vitro* fertilization.

(b) Nothing in this subpart shall be construed as indicating that compliance with the procedures set forth herein will in any way render inapplicable pertinent State or local laws bearing upon activities covered by this subpart.

(c) The requirements of this subpart are in addition to those imposed under the other subparts of this part.

§ 46.202 Purpose.

It is the purpose of this subpart to provide additional safeguards in reviewing activities to which this subpart is applicable to assure that ey conform to appropriate ethical standards and relate to important societal needs.

§ 46.203 Definitions.

As used in this subpart:

(a) "Secretary" means the Secretary of Health, Education, and Welfare and any other officer or employee of the Department of Health, Education, and Welfare to whom authority has been delegated.

(b) "Pregnancy" encompasses the period of time from confirmation of implantation (through any of the presumptive signs of pregnancy, such as missed menses, or by a medically acceptable pregnancy test), until expulsion or extraction of the fetus.

(c) "Fetus" means the product of conception from the time of implantation (as evidenced by any of the presumptive signs of pregnancy, such as missed menses, or a medically acceptable pregnancy test), until a determination is made, following explusion or extraction of the fetus, that it is viable.

(d) "Viable" as it pertains to the fetus means being able, after either spontaneous or induced delivery, to survive (given the benefit of available medical therapy) to the point of independently maintaining heart beat and respiration. The Secretary may from time to time, taking into account medical advances, publish in the FEDERAL REGISTER guidelines to assist in determining whether a fetus is viable for purposes of this subpart. If a fetus is viable after delivery, it is a premature infant.

(e) "Nonviable fetus" means a fetus *ex utero* which, although living, is not viable.

(f) "Dead fetus" means a fetus *ex utero* which exhibits neither heartbeat, spontaneous respiratory activity, spontaneous movement of voluntary muscles, nor pulsation of the umbilical cord (if still attached).

(g) "*In vitro* fertilization" means any fertilization of human ova which occurs outside the body of a female, either through admixture of donor human sperm and ova or by any other means.

§ 46.204 Ethical Advisory Boards.

(a) One or more Ethical Advisory Boards shall be established by the Secretary. Members of these board(s) shall be so selected that the board(s) will be competent to deal with medical, legal, social, ethical, and related issues and may include, for example, research scientists, physicians, psychologists, sociologists, educators, lawyers, and ethicists, as well as representatives of the general public. No board member may be a regular, full-time employee of the Department of Health, Education, and Welfare.

(b) At the request of the Secretary, the Ethical Advisory Board shall render advice consistent with the policies and requirements of this Part as to ethical issues, involving activities covered by this subpart, raised by individual applications or proposals. In addition, upon request by the Secretary, the Board shall render advice as to classes of applications or proposals and general policies, guidelines, and procedures.

(c) A Board may establish, with the approval of the Secretary, classes of applications or proposals which: (1) Must be submitted to the Board, or (2) need not be submitted to the Board. Where the Board so establishes a class of applications or proposals which must be submitted, no application or proposal within the class may be funded by the Department or any component thereof until the application or proposal has been reviewed by the Board and the Board has rendered advice as to its acceptability from an ethical standpoint.

(d) No application or proposal involving human *in vitro* fertilization may be funded by the Department or any component thereof until the application or proposal has been reviewed by the Ethical Advisory Board and the Board has rendered advice as to its acceptability from an ethical standpoint.

§ 46.205 Additional duties of the Institutional Review Boards in connection with activities involving fetuses, pregnant women, or human in vitro fertilization.

(a) In addition to the responsibilities prescribed for Institutional Review Boards under Subpart A of this part, the applicant's or offeror's Board shall, with respect to activities covered by this subpart, carry out the following additional duties:

(1) Determine that all aspects of the activity meet the requirements of this subpart;

(2) Determine that adequate consideration has been given to the manner in which potential subjects will be selected, and adequate provision has been made by the applicant or offeror for monitoring the actual informed consent process (e.g., through such mechanisms, when appropriate, as participation by the Institutional Review Board or subject advocates in: (i) Overseeing the actual process by which individual consents required by this subpart are secured either by approving induction of each individual into the activity or

verifying, perhaps through sampling, that approved procedures for induction of individuals into the activity are being followed, and (ii) monitoring the progress of the activity and intervening as necessary through such steps as visits to the activity site and continuing evaluation to determine if any unanticipated risks have arisen);

(3) Carry out such other responsibilities as may be assigned by the Secretary.

(b) No award may be issued until the applicant or offeror has certified to the Secretary that the Institutional Review Board has made the determinations required under paragraph (a) of this section and the Secretary has approved these determinations, as provided in § 46.120 of Subpart A of this part.

(c) Applicants or offerors seeking support for activities covered by this subpart must provide for the designation of an Institutional Review Board, subject to approval by the Secretary, where no such Board has been established under Subpart A of this part.

§ 46.206 General limitations.

(a) No activity to which this subpart is applicable may be undertaken unless:

(1) Appropriate studies on animals and nonpregnant individuals have been completed;

(2) Except where the purpose of the activity is to meet the health needs of the mother or the particular fetus, the risk to the fetus is minimal and, in all cases, is the least possible risk for achieving the objectives of the activity.

(3) Individuals engaged in the activity will have no part in: (i) Any decisions as to the timing, method, and procedures used to terminate the pregnancy, and (ii) determining the viability of the fetus at the termination of the pregnancy; and

(4) No procedural changes which may cause greater than minimal risk to the fetus or the pregnant woman will be introduced into the procedure for terminating the pregnancy solely in the interest of the activity.

(b) No inducements, monetary or otherwise, may be offered to terminate pregnancy for purposes of the activity.

[40 FR 33528, Aug. 8, 1975, as amended at 40 FR 51638, Nov. 6, 1975]

§ 46.207 Activities directed toward pregnant women as subjects.

(a) No pregnant woman may be involved as a subject in an activity covered by this subpart unless: (1) The purpose of the activity is to meet the health needs of the mother and the fetus will be placed at risk only to the minimum extent necessary to meet such needs, or (2) the risk to the fetus is minimal.

(b) An activity permitted under paragraph (a) of this section may be conducted only if the mother and father are legally competent and have given their informed consent after having been fully informed regarding possible impact on the fetus, except that the father's informed consent need not be secured if: (1) The purpose of the activity is to meet the health needs of the mother; (2) his identity or whereabouts cannot reasonably be ascertained; (3) he is not reasonably available; or (4) the pregnancy resulted from rape.

§ 46.208 Activities directed toward fetuses in utero as subjects.

(a) No fetus *in utero* may be involved as a subject in any activity covered by this subpart unless: (1) The purpose of the activity is to meet the health needs of the particular fetus and the fetus will be placed at risk only to the minimum extent necessary to meet such needs, or (2) the risk to the fetus imposed by the research is minimal and the purpose of the activity is the development of important biomedical knowledge which cannot be obtained by other means.

(b) An activity permitted under paragraph (a) of this section may be conducted only if the mother and father are legally competent and have given their informed consent, except that the father's consent need not be secured if: (1) His identity or whereabouts cannot reasonably be ascertained, (2) he is not reasonably available, or (3) the pregnancy resulted from rape.

§ 46.209 Activities directed toward fetuses ex utero, including nonviable fetuses, as subjects.

(a) Until it has been ascertained whether or not a fetus ex utero is viable, a fetus ex utero may not be involved as a subject in an activity covered by this subpart unless:

(1) There will be no added risk to the fetus resulting from the activity, and the purpose of the activity is the development of important biomedical knowledge which cannot be obtained by other means, or

(2) The purpose of the activity is to enhance the possibility of survival of the particular fetus to the point of viability.

(b) No nonviable fetus may be involved as a subject in an activity covered by this subpart unless:

(1) Vital functions of the fetus will not be artificially maintained,

(2) Experimental activities which of themselves would terminate the heartbeat or respiration of the fetus will not be employed, and

(3) The purpose of the activity is the development of important biomedical knowledge which cannot be obtained by other means.

(c) In the event the fetus *ex utero* is found to be viable, it may be included as a subject in the activity only to the extent permitted by and in accordance with the requirements of other subparts of this part.

(d) An activity permitted under paragraph (a) or (b) of this section may be conducted only if the mother and father are legally competent and have given their informed consent, except that the father's informed consent need not be secured if: (1) his identity or whereabouts cannot reasonably be ascertained, (2) he is

not reasonably available, or (3) the pregnancy resulted from rape.

§ 46.210 Activities involving the dead fetus, fetal material, or the placenta.

Activities involving the dead fetus, mascerated fetal material, or cells, tissue, or organs excised from a dead fetus shall be conducted only in accordance with any applicable State or local laws regarding such activities.

§ 46.211 Modification or waiver of specific requirements.

Upon the request of an applicant or offeror (with the approval of its Institutional Review Board), the Secretary may modify or waive specific requirements of this subpart, with the approval of the Ethical Advisory Board after such opportunity for public comment as the Ethical Advisory Board considers appropriate in the particular instance. In making such decisions, the Secretary will consider whether the risks to the subject are so outweighed by the sum of the benefit to the subject and the importance of the knowledge to be gained as to warrant such modification or waiver and that such benefits cannot be gained except through a modification or waiver. Any such modifications or waivers will be published as notices in the FEDERAL REGISTER.

Subpart C—Additional Protections Pertaining to Biomedical and Behavioral Research Involving Prisoners as Subjects

Source: 43 FR 53655, Nov 16, 1978

§ 46.301 Applicability.

(a) The regulations in this subpart are applicable to all biomedical and behavioral research conducted or supported by the Department of Health, Education, and Welfare involving prisoners as subjects.

(b) Nothing in this subpart shall be construed as indicating that compliance with the procedures set forth herein will authorize research involving prisoners as subjects, to the extent such research is limited or barred by applicable State or local law.

(c) The requirements of this subpart are in addition to those imposed under the other subparts of this part.

§ 46.302 Purpose.

Inasmuch as prisoners may be under constraints because of their incarceration which could affect their ability to make a truly voluntary and uncoerced decision whether or not to participate as subjects in research, it is the purpose of this subpart to provide additional safeguards for the protection of prisoners involved in activities to which this subpart is applicable.

§ 46.303 Definitions.

As used in this subpart:

(a) "Secretary" means the Secretary of Health, Education, and Welfare and any other officer or employee of the Department of Health, Education, and Welfare to whom authority has been delegated.

(b) "DHEW" means the Department of Health, Education, and Welfare.

(c) "Prisoner" means any individual involuntarily confined or detained in a penal institution. The term is intended to encompass individuals sentenced to such an institution under a criminal or civil statute, individuals detained in other facilities by virtue of statutes or commitment procedures which provide alternatives to criminal prosecution or incarceration in a penal institution, and individuals detained pending arraignment, trial, or sentencing.

(d) "Minimal risk" is the probability and magnitude of physical or psychological harm that is normally encountered in the daily lives, or in the routine medical, dental, or psychological examination of healthy persons.

§ 46.304 Composition of Institutional Review Boards where prisoners are involved.

In addition to satisfying the requirements in § 46.107 of this part, an Institutional Review Board, carrying out responsibilities under this part with respect to research covered by this subpart, shall also meet the following specific requirements:

(a) A majority of the Board (exclusive of prisoner members) shall have no association with the prison(s) involved, apart from their membership on the Board.

(b) At least one member of the Board shall be a prisoner, or a prisoner representative with appropriate background and experience to serve in that capacity, except that where a particular research project is reviewed by more than one Board only one Board need satisfy this requirement.

§ 46.305 Additional duties of the Institutional Review Boards where prisoners are involved.

(a) In addition to all other responsibilities prescribed for Institutional Review Boards under this part, the Board shall review research covered by this subpart and approve such research only if it finds that:

(1) The research under review represents one of the categories of research permissible under § 46.306(a)(2);

(2) Any possible advantages accruing to the prisoner through his or her participation in the research, when compared to the general living conditions, medical care, quality of food, amenities and opportunity for earnings in the prison, are not of such a magnitude that his or her ability to weigh the risks of the research against the value of such advantages in the limited choice environment of the prison is impaired;

(3) The risks involved in the research are commensurate with risks that would be accepted by nonprisoner volunteers;

(4) Procedures for the selection of subjects within the prison are fair to

all prisoners and immune from arbitrary intervention by prison authorities or prisoners. Unless the principal investigator provides to the Board justification in writing for following some other procedures, control subjects must be selected randomly from the group of available prisoners who meet the characteristics needed for that particular research project;

(5) The information is presented in language which is understandable to the subject population;

(6) Adequate assurance exists that parole boards will not take into account a prisoner's participation in the research in making decisions regarding parole, and each prisoner is clearly informed in advance that participation in the research will have no effect on his or her parole; and

(7) Where the Board finds there may be a need for follow-up examination or care of participants after the end of their participation, adequate provision has been made for such examination or care, taking into account the varying lengths of individual prisoners' sentences, and for informing participants of this fact.

(b) The Board shall carry out such other duties as may be assigned by the Secretary.

(c) The institution shall certify to the Secretary, in such form and manner as the Secretary may require, that the duties of the Board under this section have been fulfilled.

§ 46.306 Permitted research involving prisoners.

(a) Biomedical or behavioral research conducted or supported by DHEW may involve prisoners as subjects only if:

(1) The institution responsible for the conduct of the research has certified to the Secretary that the Institutional Review Board has approved the research under § 46.305 of this subpart; and

(2) In the judgment of the Secretary the proposed research involves solely the following:

(A) Study of the possible causes, effects, and processes of incarceration, and of criminal behavior, provided that the study presents no more than minimal risk and no more than inconvenience to the subjects;

(B) Study of prisons as institutional structures or of prisoners as incarcerated persons, provided that the study presents no more than minimal risk and no more than inconvenience to the subjects;

(C) Research on conditions particularly affecting prisoners as a class (for example, vaccine trials and other research on hepatitis which is much more prevalent in prisons than elsewhere; and research on social and psychological problems such as alcoholism, drug addiction and sexual assaults) provided that the study may proceed only after the Secretary has consulted with appropriate experts including experts in penology medicine and ethics, and published notice, in the FEDERAL REGISTER, of his intent to approve such research; or

(D) Research on practices, both innovative and accepted, which have the intent and reasonable probability of improving the health or well-being of the subject. In cases in which those studies require the assignment of prisoners in a manner consistent with protocols approved by the IRB to control groups which may not benefit from the research, the study may proceed only after the Secretary has consulted with appropriate experts, including experts in penology medicine and ethics, and published notice, in the FEDERAL REGISTER, of his intent to approve such research.

(b) Except as provided in paragraph (a) of this section, biomedical or behavioral research conducted or supported by DHEW shall not involve prisoners as subjects.

Subpart D—Additional Protections for Children Involved as Subjects in Research.

Source: 48 FR 9818, March 8, 1983

§ 46.401 To what do these regulations apply?

(a) This subpart applies to all research involving children as subjects, conducted or supported by the Department of Health and Human Services.

(1) This includes research conducted by Department employees, except that each head of an Operating Division of the Department may adopt such nonsubstantive, procedural modifications as may be appropriate from an administrative standpoint.

(2) It also includes research conducted or supported by the Department of Health and Human Services outside the United States, but in appropriate circumstances, the Secretary may, under paragraph (e) of § 46.101 of Subpart A, waive the applicability of some or all of the requirements of these regulations for research of this type.

(b) Exemptions (1), (2), (5) and (6) as listed in Subpart A at § 46.101(b) are applicable to this subpart. Exemption (4), research involving the observation of public behavior, listed at § 46.101(b), is applicable to this subpart where the investigator does not participate in the activities being observed. Exemption (3), research involving survey or interview procedures, listed at § 46.101(b) does not apply to research covered by this subpart.

(c) The exceptions, additions, and provisions for waiver as they appear in paragraphs (c) through (i) of § 46.101 of Subpart A are applicable to this subpart.

§ 46.402 Definitions.

The definitions in § 46.102 of Subpart A shall be applicable to this subpart as well. In addition, as used in this subpart:

(a) "Children" are persons who have not attained the legal age for consent to treatments or procedures involved in the research, under the applicable law of the jurisdiction in which the research will be conducted.

(b) "Assent" means a child's affirmative agreement to participate in research. Mere failure to object should not, absent affirmative agreement, be construed as assent.

(c) "Permission" means the agreement of parent(s) or guardian to the participation of their child or ward in research.

(d) "Parent" means a child's biological or adoptive parent.

(e) "Guardian" means an individual who is authorized under applicable state or local law to consent on behalf of a child to general medical care.

§ 46.403 IRB duties.

In addition to other responsibilities assigned to IRBs under this part, each IRB shall review research covered by this subpart and approve only research which satisfies the conditions of all applicable sections of this subpart.

§ 46.404 Research not involving greater than minimal risk.

HHS will conduct or fund research in which the IRB finds that no greater than minimal risk to children is presented, only if the IRB finds that adequate provisions are made for soliciting the assent of the children and the permission of their parents or guardians, as set forth in § 46.408.

§ 46.405 Research involving greater than minimal risk but presenting the prospect of direct benefit to the individual subjects.

HHS will conduct or fund research in which the IRB finds that more than minimal risk to children is presented by an intervention or procedure that holds out the prospect of direct benefit for the individual subject, or by a monitoring procedure that is likely to contribute to the subject's well-being only if the IRB finds that:

(a) The risk is justified by the anticipated benefit to the subjects;

(b) The relation of the anticipated benefit to the risk is at least as favorable to the subjects as that presented by available alternative approaches; and

(c) Adequate provisions are made for soliciting the assent of the children and permission of their parents or guardians, as set forth in § 46.408.

§ 46.406 Research involving greater than minimal risk and no prospect of direct benefit to individual subjects, but likely to yield generalizable knowledge about the subject's disorder or condition.

HHS will conduct or fund research in which the IRB finds that more than minimal risk to children is presented by an intervention or procedure that does not hold out the prospect of direct benefit for the individual subject, or by a monitoring procedure which is not likely to contribute to the well-being of the subject, only if the IRB finds that:

(a) The risk represents a minor increase over minimal risk;

(b) The intervention or procedure presents experiences to subjects that are reasonably commensurate with those inherent in their actual or expected medical, dental, psychological, social, or educational situations;

(c) The intervention or procedure is likely to yield generalizable knowledge about the subjects' disorder or condition which is of vital importance for the understanding or amelioration of the subjects' disorder or condition; and

(d) Adequate provisions are made for soliciting assent of the children and permission of their parents or guardians, as set forth in § 46.408.

§ 46.407 Research not otherwise approvable which presents an opportunity to understand, prevent, or alleviate a serious problem affecting the health or welfare of children.

HHS will conduct or fund research that the IRB does not believe meets the requirements of §§ 46.404, 46.405, or 46.406 only if:

(a) The IRB finds that the research presents a reasonable opportunity to further the understanding, prevention, or alleviation of a serious problem affecting the health or welfare of children; and

(b) The Secretary, after consultation with a panel of experts in pertinent disciplines (for example: science, medicine, education, ethics, law) and following opportunity for public review and comment, has determined either: (1) That the research in fact satisfies the conditions of §§ 46.404, 46.405, or 46.406, as applicable, or (2) the following:

(i) The research presents a reasonable opportunity to further the understanding, prevention, or alleviation of a serious problem affecting the health or welfare of children;

(ii) The research will be conducted in accordance with sound ethical principles;

(iii) Adequate provisions are made for soliciting the assent of children and the permission of their parents or guardians, as set forth in § 46.408.

§ 46.408 Requirements for permission by parents or guardians and for assent by children.

(a) In addition to the determinations required under other applicable sections of this subpart, the IRB shall determine that adequate provisions are made for soliciting the assent of the children, when in the judgment of the IRB the children are capable of providing assent. In determining whether children are capable of assenting, the IRB shall take into account the ages, maturity, and psychological state of the children involved. This judgment

may be made for all children to be involved in research under a particular protocol, or for each child, as the IRB deems appropriate. If the IRB determines that the capability of some or all of the children is so limited that they cannot reasonably be consulted or that the intervention or procedure involved in the research holds out a prospect of direct benefit that is important to the health or well-being of the children and is available only in the context of the research, the assent of the children is not a necessary condition for proceeding with the research. Even where the IRB determines that the subjects are capable of assenting, the IRB may still waive the assent requirement under circumstances in which consent may be waived in accord with § 46.116 of Subpart A.

(b) In addition to the determinations required under other applicable sections of this subpart, the IRB shall determine, in accordance with and to the extent that consent is required by § 46.116 of Subpart A, that adequate provisions are made for soliciting the permission of each child's parents or guardian. Where parental permission is to be obtained, the IRB may find that the permission of one parent is sufficient for research to be conducted under §§ 46.404 or 46.405. Where research is covered by §§ 46.406 and 46.407 and permission is to be obtained from parents, both parents must give their permission unless one parent is deceased, unknown, incompetent, or not reasonably available, or when only one parent has legal responsibility for the care and custody of the child.

(c) In addition to the provisions for waiver contained in § 46.116 of Subpart A, if the IRB determines that a research protocol is designed for conditions or for a subject population for which parental or guardian permission is not a reasonable requirement to protect the subjects (for example, neglected or abused children), it may waive the consent requirements in Subpart A of this part and paragraph (b) of this section, provided an appropriate mechanism for protecting the children who will participate as subjects in the research is substituted, and provided further that the waiver is not inconsistent with federal, state or local law. The choice of an appropriate mechanism would depend upon the nature and purpose of the activities described in the protocol, the risk and anticipated benefit to the research subjects, and their age, maturity, status, and condition.

(d) Permission by parents or guardians shall be documented in accordance with and to the extent required by § 46.117 of Subpart A.

(e) When the IRB determines that assent is required, it shall also determine whether and how assent must be documented.

§ 46.409 Wards.

(a) Children who are wards of the state or any other agency, institution, or entity can be included in research approved under §§ 46.406 or 46.407 only if such research is:

(1) Related to their status as wards; or

(2) Conducted in schools, camps, hospitals, institutions, or similar settings in which the majority of children involved as subjects are not wards.

(b) If the research is approved under paragraph (a) of this section, the IRB shall require appointment of an advocate for each child who is a ward, in addition to any other individual acting on behalf of the child as guardian or in loco parentis. One individual may serve as advocate for more than one child. The advocate shall be an individual who has the background and experience to act in, and agrees to act in, the best interests of the child for the duration of the child's participation in the research and who is not associated in any way (except in the role as advocate or member of the IRB) with the research, the investigator(s), or the guardian organization.

NOTICES

HUMAN SUBJECTS
Minimum Criteria Identifying the Viable Fetus

On March 13, 1975, regulations were published in the FEDERAL REGISTER (40 FR 11854) relating to the protection of human subjects in research, development, and related activities supported by Department of Health, Education, and Welfare grants and contracts. These regulations are codified at 45 CFR Part 46.

Elsewhere in this issue of the FEDERAL REGISTER, the Secretary is amending 45 CFR Part 46 by, among other things, adding a new Subpart B to provide additional protections pertaining to research, development, and related activities involving fetuses, pregnant women, and in vitro fertilization.

Section 46.203(d) of Subpart B provides inter alia as follows:

> The Secretary may from time to time, taking into account medical advances, publish in the FEDERAL REGISTER guidelines to assist in determining whether a fetus is viable for purposes of this subpart.

This notice is published in accordance with § 46.203(d). For purposes of Subpart B, the guidelines indicating that a fetus other than a dead fetus within the meaning of § 46.203(f) is viable include the following:

> an estimated gestational age of 20 weeks or more and a body weight of 500 grams or more.

RESEARCH ACTIVITIES WHICH MAY BE REVIEWED THROUGH EXPEDITED REVIEW PROCEDURES

Research activities involving no more than minimal risk and in which the only involvement of human subjects will be in one or more of the following categories (carried out through standard methods) may be reviewed by the Institutional Review Board through the expedited review procedure authorized in 46.110 of 45 CFR Part 46.

(1) Collection of: hair and nail clippings, in a nondisfiguring manner; deciduous teeth; and permanent teeth if patient care indicates a need for extraction.

(2) Collection of excreta and external secretions including sweat, uncannulated saliva, placenta removed at delivery, and amniotic fluid at the time of rupture of the membrane prior to or during labor.

(3) Recording of data from subjects 18 years of age or older using noninvasive procedures routinely employed in clinical practice. This includes the use of physical sensors that are applied either to the surface of the body or at a distance and do not involve input of matter or significant amounts of energy into the subject or an invasion of the subject's privacy. It also includes such procedures as weighing, testing sensory acuity, electrocardiography, electroencephalography, thermography, detection of naturally occurring radioactivity, diagnostic echography, and electroretinography. It does not include exposure to electromagnetic radiation outside the visible range (for example, x-rays, microwaves).

(4) Collection of blood samples by venipuncture, in amounts not exceeding 450 milliliters in an eight-week period and no more often than two times per week, from subjects 18 years of age or older and who are in good health and not pregnant.

(5) Collection of both supra- and subgingival dental plaque and calculus, provided the procedure is not more invasive than routine prophylactic scaling of the teeth and the process is accomplished in accordance with accepted prophylactic techniques.

(6) Voice recordings made for research purposes such as investigations of speech defects.

(7) Moderate exercise by healthy volunteers.

(8) The study of existing data, documents, records, pathological specimens, or diagnostic specimens.

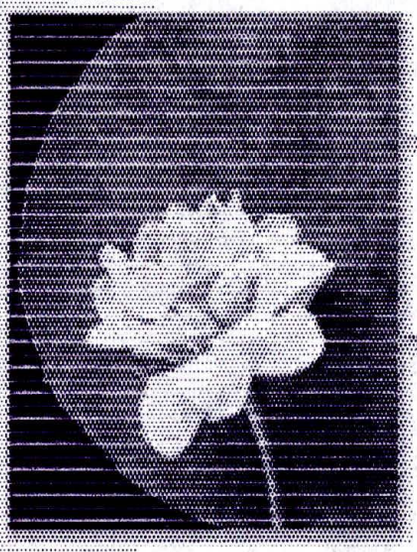
(9) Research on individual or group behavior or characteristics of individuals, such as studies of perception, cognition, game theory, or test development, where the investigator does not manipulate subjects' behavior and the research will not involve stress to subjects.

(10) Research on drugs or devices for which an investigational new drug exemption or an investigational device exemption is not required.

source: 46 FR 8392
1/26/81

* U.S. GOVERNMENT PRINTING OFFICE: 1984-421-132:4759

Research Ethics Training Curriculum



Self-Study

Presenter

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Self Study

Introduction to the Research Ethics Training Curriculum

It is essential that fundamental ethical principles be included in the design and implementation of research involving human participants. Ethical research principles are considered universal, transcending geographic, cultural, economic, legal and political boundaries.

Although these principles are universal, the availability of the resources needed to maintain these principles is not universal, and the procedures used for the ethical vigilance of research studies may not be optimal. For instance, no universal principle exists to monitor how research will be conducted.

Regardless of limitations, ethical research principles must guide those who plan, conduct and sponsor research that involves human participants. Human participation in research projects has contributed to better quality of life through the development of diagnostic tools and successful treatments.

This *Research Ethics Training Curriculum* has been developed for international researchers who:

- conduct research that includes human participants
- want to incorporate fundamental ethical considerations in design and implementation of their research

The Lotus Flower

The *Research Ethics Training Curriculum* uses the **lotus flower** to symbolize fundamental ethical elements. The lotus flower image represents **"purity and perfection"** in some cultures. The ethical considerations discussed in this curriculum aim for a pure and perfect research designÑthe foundation on which ethical research study is developed and implemented.

However, each research design will be unique in that it will be:

- specific to the studyÕs design and research outcomes
- important to the local research population
- intrinsic to the local culture

Because each research design will be unique, a different lotus flowerÑrepresenting the local culture and characteristics of each research studyÑis shown at the beginning of each section of the Contents section of the *Research Ethics Training Curriculum*.

The *Research Ethics Training Curriculum* offers international researchers:

- an overview to the development and philosophy of research ethics
- case studies so that the learner can consider real-world examples of ethical issues
- materials to assist researchers in designing studies that respect local regulations, cultures and expectations
- ancillary reference documents on modern perspectives that shape the research ethics field

The researcher sets as a primary goal the protection of research volunteers while at the same time incorporating ethical considerations for project design and implementation.

The principles of research ethics have grown out of abuses in the past. Today a great amount of attention is directed at research that involves human participants. International research ethics ensure that research conducted at the local level follows international expectations and standards. Following such international expectations validates the time and energy invested by the researcherÑas well as the good will and trust invested by the participants.

It is essential that local researchers familiarize themselves with the subject matter in this curriculum. Knowing current attitudes about research ethics will assist each researcher in aiming for the goal symbolized by the lotus flowerÑpurity and perfection in each research study.

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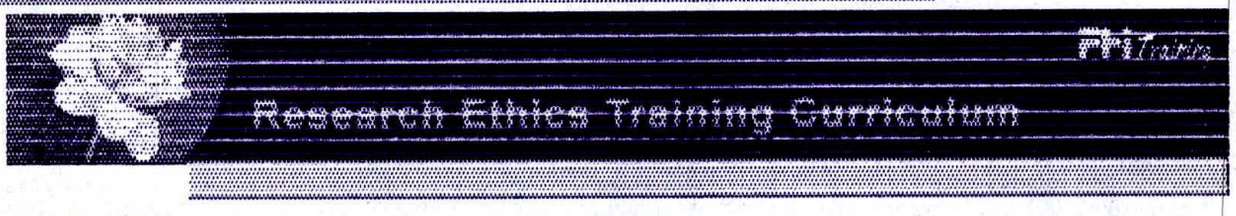

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Presenter

How to Use This Curriculum

This *Research Ethics Training Curriculum* is designed to engage the learner. Adult learning and retention improves when the learner participates actively in the learning process. The *Research Ethics Training Curriculum* can be used as either an interactive self-study program or as a participatory, group training experience. It is expected that completing this curriculum will take approximately 4 hours. **If you are a self-study user or a first time group presenter, please click your browser's back button twice and choose the Self Study option or use the Self Study Shortcut at the bottom left of this screen**. Note that while in the Self Study section, you will find a Presenter Shortcut link in this same location. **We recommend that group presenters work through the self-study version of the curriculum first, to prepare for the group training**. After completing the self-study version of the curriculum, group presenters should return to this point to prepare to lead a training session using the Presenter Tools.

The Presenter Tools contain print and projection tools in Adobe© Acrobat© format, including:

- Color Slides for Online Presentation
- Master Slides for Overhead Projection
- Presenter Notes
- Student Handouts
- Case Studies
- Evaluations

The *Color Slides for Online Presentation* section is for presentation on a computer screen or projection from a computer. If an overhead projector is your only available projection device, print the *Master Slides for Overhead Projection* and copy onto transparencies for presentation.

Use the *Presenter Notes* section to print speaker's notes for yourself, and review them before presenting. The *Presenter Notes* section is composed of grayscale summary slides followed by narrative text. At times, the narrative is followed by a shaded box labeled ÒLearner Note.Ó Learner notes contain interactive questions or activities. Ask the group to call out or write on flip chart paper some answers to the questions asked by the learner notes. This will help your participants retain the key messages.

Use the *Student Handouts* section to print note-taking handouts for your participants. Each page displays three slides with space for taking notes during the presentation. These can be printed in color or grayscale.

The *Case Studies* section provides 8 reproductive health case studies followed by thought-provoking questions. The case studies help anchor the curriculum to the reality of designing and implementing research studies. These case studies address reproductive health ethical considerations and are based on actual situations encountered by researchers at Family Health International (FHI).

Five of these case studies are found in the Narrative section of the curriculum; the other 3 case studies are found only in the *Case Studies* section. You will want to print a copy for yourself and photocopy the case studies for your participants to have available

during the training session.

The *Evaluations* section includes a Pre-Test, a Post Test, an answer key to the Pre and Post Test, and the Evaluation form. Please inform your participants that in order to receive their certificate of completion, they need to fill out the Evaluation form and send it to FHI at the address provided in the next section.

Note: If you have Microsoft® PowerPoint® installed on your computer, there is a fully functional version of the Color Slide Show with Presenter's Notes in a folder on the CD directory of the *Research Ethics Training Curriculum* CD.

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Improving Contraceptive Choices and Services

For nearly 30 years, FHI has focused on strengthening the capacity of partners in developing countries to improve contraceptive choices and services through contraceptive development, research, education and information programs.

FHI has worked to improve the safety, efficacy, acceptability and correct use of nearly every contraceptive method currently in use. We conduct studies on contraceptive methods and their use, the relationship between contraception and sexually transmitted diseases, health economics, maternal mortality and morbidity, and the reproductive health needs of special groups, including young adults and refugees.

Current and recent programs:

- The Contraceptive Technology and Family Planning Research Project, funded by the U.S. Agency for International Development, includes ongoing research, technical assistance and educational activities in more than 30 countries each year.

- Selected projects: Among our many ongoing family planning projects are efforts in collaboration with the World Association of Girl Guides and Girl Scouts to improve the health of female adolescent refugees; a multi-center study on the spermicide nonoxynol-9 (N-9) for the National Institute of Child Health and Human Development (NICHD); participation in a Cochrane Collaboration on fertility regulation; evaluation of the UNFPA-supported adolescent reproductive health program in Jamaica; training of reproductive health managers and providers in Haiti, and collaboration with the Population Council on the Frontiers Project.

- Fellowship: An FHI Fellowship in Contraceptive Technology Research brings outstanding scientists to the United States from developing countries. A year of advanced study in clinical trials design and implementation is followed by a fellowship-sponsored research project conducted in the participant's home country.

- Our recently completed Women's Studies Project (WSP) (1993-1999), funded by USAID, examined how women's family planning experiences -- their contraceptive use or non-use, pregnancies and childbearing, and experience with family planning and reproductive health programs -- affected women's lives in 14 countries.

Select key words on the drop-down list and hit "Enter" to launch a search, or click here to conduct a simple or advanced search using other terms.

Summaries of FHI contraceptive research

Network magazine on family planning and reproductive health.

The FamPlan Glossary: This collection of terminology provides translations in English,

Spanish and French of reproductive health terms. It was created in order to provide standardized translations for member organizations of the Population and Health Materials Working Group (PHMWG). The PHMWG is a group of cooperating agencies that work with USAID's Office of Population, Health and Nutrition and produce reproductive health materials for use around the world.

URL:http://www.fhi.org

If you experience problems browsing this page, please send e-mail to Webmaster

September 20, 2002

International leadership in HIV/AIDS prevention & care

Since 1986, Family Health International has pioneered ways to curtail the spread of HIV/AIDS. Many of the HIV prevention "best practices" in use today have emerged from FHI's work in more than 60 countries.

Interventions for HIV prevention

FHI's efforts range from clinical trials of promising HIV/AIDS prevention methods to managing and supporting prevention and care programs worldwide. These include:

- Behavior Change Interventions (BCIs)
- Blood safety and universal precautions
- Behavioral Surveillance Surveys
- Care and support for families, people with AIDS, and orphans
- Counseling and testing
- Evaluation and surveillance
- Policy support
- Prevention research
- Reproductive health service integration
- Sexually transmitted infection (STI) management
- Technical services
- Tools for prevention and care
- Tuberculosis prevention and management

FHI's HIV/AIDS programs

FHI began its AIDS prevention efforts with pilot AIDS prevention programs in West Africa. FHI's leadership role in the effort to slow the spread of HIV in the developing world has continued through our AIDSTECH, AIDSCAP, and HIVNET projects. Ongoing programs include our IMPACT Project, supported by USAID, and HPTN Project, supported by NIH.

Where we work

FHI currently conducts HIV/STI prevention and care programs in more than 30 countries in Africa and Near East, Asia, Eastern Europe, Latin America and the Caribbean and North America.

Publications

- **Workplace HIV/AIDS Programs: An Action Guide for Managers** (pdf 952K*)
- **HIV/AIDS Prevention and Care In Resource-Constrained Settings: A Handbook for the Design and Management of Programs**

This 28-chapter handbook offers state-of-the-art knowledge on designing and managing HIV/AIDS programs; reducing risk and vulnerability to HIV infection; strengthening STD management and services; reducing risk of HIV infection to infants; reducing risk of parenteral transmission; management and support of people infected and affected by HIV/AIDS; and prospects for the future. It is intended to be used by program managers, technical and programmatic field staff; staff of donor and international partner agencies; health care providers; and field researchers.

- **Strategies for an Expanded and Comprehensive Response (ECR) to a National HIV/AIDS Epidemic**
- **FHI/UNAIDS Best Practices in HIV/AIDS Prevention Collection** (pdf 11,914K*)

State of the Art Briefs on HIV/AIDS

Supporters and partners

FHI has worked with more than 500 organizations worldwide to support and improve HIV/AIDS prevention and care programs.

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Older Browsers: Help

Family Health International offers a range of technical services, publications and other materials focusing on contraceptive technology, HIV/AIDS and sexually transmitted diseases, and improving the health and well-being of women of reproductive age.

Advanced Search

Featured services:

Clinical research design and management

PharmaLink: Web-based data management

International Clinical Studies Support Center

Training Presentation Modules

Health economics research

HIV/AIDS prevention and care, capabilities and services

FHI publications

Education & training in reproductive health

Maternal Health Center, reducing mortality and morbidity

Major capabilities and areas of technical expertise

Applied research: FHI's experience conducting thousands of research studies in more than 100 countries since 1971 includes biomedical, programmatic and behavioral studies using a vast array of study methodologies and approaches: formative research, feasibility assessments, case studies, clinical trials, situation analyses, longitudinal studies, policy assessments and meta-analyses of existing data.

Research capacity building: Through collaborative research and educational activities, FHI strengthens skills for local ownership, management and implementation of health programs. FHI staff provide technical assistance to investigators around the world in various quantitative and qualitative data collection techniques, including focus groups, market analysis, clinical trials, surveys and questionnaires, as well as operations research and epidemiological, clinical, biomedical, demographic and economic studies.

HIV prevention programming: FHI designs, manages and evaluates comprehensive programs, providing documented accountability in both program impact and financial management. We offer the full range of technical services needed for effective efforts to control the epidemic, including behavior change interventions; prevention and management of sexually transmitted infections; voluntary HIV counseling and testing; support for people infected and affected by HIV; preventing mother-to-child transmission of HIV; blood safety; and evaluation and surveillance. FHI has pioneered programs to meet the complex needs of mobile populations and to provide peer education and other HIV prevention services in workplaces. We have also expanded efforts to reduce HIV risk behavior among marginalized groups to reach men who have sex with men and drug users. Our expertise in participatory strategic planning and community mobilization has helped create and nurture hundreds of grassroots prevention and care projects. This broad experience in community-based programs, which FHI developed by managing more than a thousand interventions in over 60 countries, is now being applied to improve tuberculosis treatment and prevention and to strengthen blood donor recruitment and retention.

Training and education: FHI strengthens the skills of developing country researchers, service providers, program managers and health communicators to ensure the highest quality work in our collaborative projects. Health organizations and donor agencies provide financial support to us to conduct training and continuing medical education programs which focus on: contraceptive technology; research

methods; research monitoring; clinical management; data analysis; epidemiology; clinical skills enhancement; program development; STD/HIV prevention and treatment; qualitative research; gender-sensitive research and programs; training materials development; provider counseling; training of trainers; and health journalism.

Scientific publishing: FHI publishes several periodicals, including *Network* (circ. 75,000 in English, French and Spanish) and *IMPACT on HIV* (circ. 5,000 in English). FHI publishes reports, case studies, monographs and training materials on a broad range of reproductive health topics, including in Arabic, English, French, Portuguese, Russian and Spanish.

Information dissemination: As part of its public health mandate, FHI is committed to disseminating research findings and helping developing country counterparts strengthen their own information dissemination capabilities. FHI works with organizations to assess communication skills and resources, prepare information campaigns and materials, strengthen media relations, write and disseminate scientific papers, produce publications, and plan strategic dissemination.

Maternal health: FHI works to reduce maternal mortality and morbidity. We develop strategies to improve maternal and neonatal care at all health system levels, and assist governments and other health organizations to assess their maternal health needs, plan for solutions and translate their plans into action. FHI designs, implements and evaluates innovative interventions, and disseminates information on maternal health to clinicians, consumers, policy-makers and the scientific community.

How to contact us

To learn more about technical services please contact Albert J. Siemens PhD, Chief Executive Officer, Family Health International, P.O. Box 13950, Research Triangle Park, NC 27709 USA. Email: services@fhi.org

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