New advances in medical knowledge and technology have created new treatment options for both patients and health care givers. Doctors are increasingly being confronted with challenges especially in the criteria by which they can make good clinical judgement. These judgements are often fraught with ethical dilemmas for medical personnel who are required to make decisions in the "best interest" of their patients whose wishes may not always be rational or even known. These decisions which are influenced by the doctor’s own values, should always be based on ethically acceptable principles.

The ethical objectives of medicine today include and emphasise the importance of relieving suffering. This is necessary because of the extraordinary capacity of modern medical technology not only to save lives but also to prolong the dying process.

Ethical dilemmas in medical practice nowadays are, however, not only limited to direct patient care. The advent of managed healthcare and medical entrepreneurial endeavours, have raised ethical questions for which there are no easy answers. The medical profession the world over is grappling with these changes.

The National Medical Ethics Committee (NMEC) was set up in January 1994 by the Ministry of Health to assist the medical profession in addressing ethical issues in medical practice and to ensure a high standard of ethical practice in Singapore. It aims to identify and study ethical issues relating to medical practice and research in Singapore and provide an ethical framework for medical practitioners to carry out their duties and responsibilities.

The principles that guide the NMEC when addressing these ethical issues are:

- Beneficence - the duty to promote good and prevent harm to patients
• Nonmaleficence - the duty to do no harm to patients
• Respect for patient’s autonomy - the duty to protect and foster an individual’s free and uncoerced choices
• Justice - the moral obligation to act on the basis of fair adjudication between competing claims

The NMEC has no statutory powers. Nevertheless, it serves as the national authority which provides advice to the Ministry of Health and other agencies on prevailing ethical issues. The ethical guidelines which have been drawn up for various clinical situations are intended to facilitate medical professionals in the process of making sound ethical decisions in clinical practice and medical research.
COMPOSITION OF THE NMEC

The members of the NMEC were drawn from diverse backgrounds; eminent medical and allied health professionals as well as lay persons of high public standing and who have interest and experience in medical ethics. There were also representatives from the ethnic minority groups in the community.

The members of the Committee were appointed on a 2-yearly term (Annex I). Dr Chew Chin Hin served as the Chairman during both the terms.

The Secretariat support to the Committee was provided by the Ministry (Annex II).

TERMS OF REFERENCE

The terms of reference for the Committee are as follows:

(a) Identify the prevailing ethical issues relating to public health, medical practice and research in Singapore;
(b) Develop ethical codes of conduct for doctors practising in Singapore;
(c) Advise the Ministry on the potential ethical issues which may occur in Singapore based on the trends in other developed countries; and
(d) Form Subcommittees to deal with special issues as and when necessary.
1994-1995

During the first two years, the Committee focussed its attention on three major issues. These were:

**Advance Medical Directive (AMD)**

The Committee reviewed the position of advance medical directives (AMD) or "living wills" which were practised in other countries as well as considered the merits of legislation for advance directives. Following the review, the Committee released a position paper in August 1994 proposing that legislation for advance directives be introduced in Singapore. Feedback from the public and views of the various professional and religious groups were invited. The Committee also held a series of dialogue sessions with the public and members of professional and religious organisations.

In May 1995, the Committee presented its findings and recommendations in a report - *Advance Medical Directives* - to the then Minister for Health, BG George Yeo. In this report, the Committee advocated among others:

(a) The definition and the use of AMD be limited to instructions on medical treatment. Based on the principle of patient autonomy, AMD would provide the legal means for patients to continue to exercise autonomy over their medical treatment even when they were incompetent and in their final stages of illness.

(b) The need for legislation on AMD in Singapore to provide the necessary substantive and procedural safeguards for AMD. This legislation should be an *enabling* one i.e. anyone who did not wish to execute an AMD should not be compelled or pressured to do so.
(c) The emphasis that appropriate palliative care must always be provided to the patient even after the AMD had been effected. The distinction between AMD and euthanasia was also made. Euthanasia was wrong and the Committee did not condone it under any circumstances.

The Minister accepted the recommendations made in the Report. The Advance Medical Directive Act (1996) was eventually passed in Parliament on 2 May 1996 and had been implemented since 1 Jul 97.

**Teaching of Medical Ethics to Medical Undergraduates**

Another issue reviewed by the Committee during this period was the teaching of medical ethics to medical undergraduates. This was necessary to ensure that the foundation for correct ethical behaviour for doctors was laid while they were still in medical school.

Consequent to the review, the Committee recommended that a more structured and formalised course in medical ethics be included in the medical undergraduate curriculum. This was to ensure that the young doctors were equipped to face the many complex ethical issues in their future medical practice.

These recommendations were accepted by the Ministry and the National University of Singapore. The teaching of medical ethics had been incorporated in the curriculum of medical undergraduates since 1995.

**Physician’s Pledge**

The Singapore Medical Council (SMC) sought the views of the NMEC on its proposal that newly qualified doctors take a pledge to remind them of their responsibilities and their duty to their patients, to mankind and the profession. The NMEC supported the proposal and
subsequently assisted in reviewing the Pledge to be affirmed by newly registered practitioners. The first Pledge Affirmation Ceremony for newly registered medical practitioners was held on 2 May 1995 and subsequently on an annual basis.

The Committee reviewed the ethical codes in other countries and produced a working document entitled "A Comparison of Ethical Codes for the Medical Profession in the UK, USA, Australia and Singapore". This was forwarded to SMC for its reference.

In addition, several ethical issues were referred to the NMEC for its advice. The Committee’s position on these issues were:

(a) **Do Not Resuscitate (DNR) Orders (May 95)**

A local hospital advocated the use of “Do Not Resuscitate” orders in the case records of patients whose illnesses had reached a stage where any attempt to resuscitate was clearly inappropriate. These orders were to guide doctors on call, who were not the patient’s own doctors, when alerted to treat a patient who had collapsed. The Committee’s position was that the written DNR order was not unethical under these circumstances.

(b) **Experiments to Alter Genes in Sperms (Jul 95)**

The Committee reviewed the available literature on the matter and concluded that as the technique was still at an experimental stage, it should not be carried out on humans yet. However, this position should be reviewed at a later stage when the technique was further developed. The Committee’s view was duly conveyed to the Ministry of Health.
The following two years saw the NMEC shifting its attention to drawing up several ethical guidelines to address specific current ethical problems faced by the medical profession. The objective was that these guidelines would serve as a reference for the hospital ethics committees as well as complement the SMC’s Ethical Code for the medical profession.

Subcommittees were formed to look into specific areas of ethical concern. External expertise was co-opted whenever necessary. A listing of the subcommittees and their members are at Annex III.

In preparing these guidelines, reference was taken from relevant medical ethics literature including those from the World Health Organisation, the professional colleges and organisations in UK, USA, Canada and Australasia, as well as legislation from these countries were studied. As at 31 Dec 97, the guidelines that had been prepared were:

(a) Ethical Guidelines on Human Organ and Tissue Transplantation (Oct 96)

This set of guidelines on organ and tissue transplantation provided for an orderly and acceptable framework for regulating the acquisition and transplantation of human organs/tissues for therapeutic purposes.

The Ministry has issued the Guidelines to all the hospitals where transplants were being carried out.

(b) Ethical Guidelines on Termination of Pregnancy for Mothers with Foetuses with Lethal Malformations (Sep 96)

The Committee recommended to the Ministry that termination of pregnancy be an option for mothers who have foetuses with
lethal malformations namely, trisomy 13, trisomy 18, anencephaly, acranium, bilateral renal agenesis and Barts’ hydrops foetalis. Foetuses with any of these 6 lethal malformations were likely to result in complications which would pose some risks to the mother’s health or life and psychological stress to the parents if the pregnancy was carried to full term.

The Ministry accepted the recommendation and would be incorporating this provision when the Termination of Pregnancy Act is reviewed.

(c) Ethical Guidelines on Medical Treatment of High-Risk Infants (Mar 97)

These guidelines promulgated the ethical issues involved in the medical treatment of high-risk infants to facilitate the decision making process for those involved in the care of such patients. These high-risk infants are infants around the threshold of viability such as very early premature newborns, those with major and/or multiple congenital malformations, or those severely damaged by complications of pregnancy and delivery.

These guidelines were forwarded to the Ministry which has since sent the guidelines to the neonatal, paediatric medicine and paediatric surgery units of the hospitals.

(d) Ethical Guidelines on Research Involving Human Subjects (Sep 97)

The objective of the guidelines was to ensure that the rights and the welfare of research subjects were protected. They were prepared to assist the ethics committees of the various
hospitals in assessing the ethical acceptability of research proposals.

The Guidelines were accepted by the Ministry and sent to all the hospital ethics committees and the National Medical Research Council for their reference.

(e)  

**Ethical Guidelines on the Practice of Psychiatry (Oct 97)**

These guidelines addressed the professional obligations of a psychiatrist with regard to safeguarding patient confidentiality, conducting himself with propriety and pursuing continuing medical education.

The Ministry has endorsed and issued the guidelines to all registered psychiatrists as well as hospital ethics committees in Singapore.

The above-mentioned guidelines are at Annex IV.

Besides preparing the guidelines, the Committee also deliberated on several areas of ethical concern. These were:

(i)  

**Foetal Tissue Transplantation (Jan 96)**

The Committee recommended that the use of foetal tissues or organs in medical research or therapy should not be done in Singapore unless specific permission has been obtained from the Ministry of Health. This was because foetal tissue transplantation was then still at an experimental stage and its use was limited to the treatment of Parkinson's disease. The Committee also recommended that the Ministry should selectively consider allowing the use of such treatment on a case to case basis.
(ii) Selective Termination of Pregnancy (Jan 96)

This was a case of a twin pregnancy conceived through IVF where one twin had been diagnosed antenatally to be genetically abnormal while the other twin was normal. The parents had requested for selective termination of pregnancy of the abnormal foetus. The NMEC advised that while the parents had the legal right to request for an abortion of the abnormal foetus it would be prudent for the hospital to counsel the parents regarding the possible complications arising from the procedure and the implications on future pregnancies. The Committee also recommended that informed consent should be documented in the case notes including details of the counselling given and that the procedure should be carried out by an experienced doctor.

(iii) Discontinuation of Mechanical Ventilation following Certification of Brain Death (Oct 96)

The advice of NMEC was sought by the ethics committee of a hospital on the need to seek the written consent of the next-of-kin before switching off the ventilator of a patient who had been certified brain dead.

The NMEC was of the opinion that it was not necessary to obtain the signed consent of the next-of-kin before switching off the ventilator under such circumstances. However, the Committee advised that the attending doctor must first properly explain the patient’s condition to the next-of-kin and that the necessary counselling be given by appropriately trained personnel before and after the ventilator was switched off.
(iv) **Cloning in Human Reproduction (Jun 97)**

This issue was referred to the NMEC for consideration following the announcement of the world’s first successful cloning of a sheep in Scotland in Feb 1997.

The NMEC’s stance was that there should currently be a total ban on the creation of human babies by cloning technology but there should be no prohibition against the cloning of DNA and human cells in culture. With regard to the cloning of human embryos for research which was a complex issue, NMEC would await the policy adopted by more advanced countries before making a decision on the matter.

(v) **Ethical Issues in Nursing (Nov 97)**

The NMEC recommended that as nurses were increasingly facing more ethical issues in the course of their daily work, it was advisable that their interests were represented in the hospital ethics committee by a senior nurse. In addition, a nursing resource group should be set up to support the hospital ethics committee as well as serve as a resource point to assist in resolving ethical issues faced by nurses. The Committee recommended that the Singapore Nursing Board (SNB) formulates and reviews the code of ethics for nurses and monitors its practice. This was conveyed to the Registrar, SNB.

vi) **Good Clinical Practice Guidelines (Nov 97)**

The NMEC endorsed the Ministry of Health’s proposed Good Clinical Practice (GCP) guidelines adapted from the GCP Guidelines of the International Conference on Harmonisation. This is an ethical and scientific quality standard for clinical
drug trials that involve human subjects. Comments from the Committee on the ethical aspects of the proposed guidelines were forwarded to the Ministry for incorporation when the Medicines (Clinical Trials) Regulations were amended.

Press cuttings related to the NMEC and activities of the NMEC are at Annex V.

It has been a fruitful four years for the Committee. The Committee will endeavour to continue to uphold the ethical standards as the health professionals in Singapore meet the new challenges that lie ahead in the next millennium.
Chairman:
Dr Chew Chin Hin - Consultant Physician
Dy Dir, Sch of Postgraduate Medical Studies, NUS

Members:
Dr Lawrence Chan - Sr Consultant, KK Women's and Children's Hospital
Prof Chao Tzee Cheng - Senior Forensic Pathologist
Institute of Science & Forensic Medicine
Dr Chen Ai Ju - Dy Director of Medical Services (Hospital)
Director of Medical Services (from Sep 96)
Ministry of Health, Singapore
Assoc Prof John Elliott - Psychologist, Dept of Social Work & Psychology
Faculty of Arts and Social Sciences, NUS
Prof Peter Hwang - Head, Dept of Physiology
Faculty of Medicine, NUS
Mr Terry Kaan - Senior Lecturer, Faculty of Law, NUS
Dr Alfred Loh Wee Tiong - President
College of Family Physicians, Singapore
Dr James Murugasu - Consultant Surgeon
Raffles SurgiCentre
Prof Edward Tock - Dean, Faculty of Medicine (up to Sep 94)
Head, Dept of Pathology, NUS
Prof Lenny Tan - Dean, Faculty of Medicine (w.e.f. Oct 94)
Head, Dept of Diagnostic Radiology, NUH
Miss Roselin Liew - Former Chief Nursing Officer, MOH
Prof A N Rao - Part-time Lecturer
Botany Dept, Faculty of Science, NUS
Mr Zainul Abidin Rasheed - Editor, Berita Harian (up to Dec 96)
General Manager (International)
NTUC Fairprice Cooperative Ltd/
MP for Cheng San GRC
Annex II

THE NMEC SECRETARIAT

Dr Clarence Tan (Jan 94 - Aug 96)
Dr Ng Chiu Wan (Jan 94 - May 95)
Dr Arthur Chern (Apr 95 - Dec 95)
Dr Theodor Wee (Jan 96 - Aug 96)
Dr U Bandara (from Sep 96)
Dr Chew Ling (from Sep 96)
Annex III

THE NMEC SUBCOMMITTEES

SUBCOMMITTEE ON GENERAL MEDICAL ETHICS RELATED TO THE MEDICAL PROFESSION

Dr Chew Chin Hin - Chairman
Dr Chen Ai Ju
Prof Peter Hwang
Dr Alfred Loh
Prof Lenny Tan

Dr Arthur Chern - Secretary (up to Aug 96)

Workgroup on Biomedical Research on Human Subjects

Prof Peter Hwang - Chairman
Dr Tan Chor Hiang
Prof Chan Heng Leong
A/Prof Goh Lee Gan

Work group on Guidelines on Mental Health and Neurosciences

Dr Chen Ai Ju - Chairman
Dr Rathi Mahendran
Dr Lionel Lim

Work Group on Guidelines on Organ and Tissue Transplantation

Dr Woo Keng Thye - Chairman
Ms Sally Kong
Dr Patrick Tan
Dr Li Man Kay
A/Prof Evan Lee
SUBCOMMITTEE ON ETHICAL ISSUES IN OBSTETRICS, GYNAECOLOGIC AND NEONATAL MEDICINE

Dr Lawrence Chan - Chairman
Dr J Murugasu
Dr Ho Lai Yun
Prof RL Tambyraja

Dr Arthur Chern - Secretary (up to Aug 96)
Dr Chew Ling - Secretary (from Sep 96)

SUBCOMMITTEE ON THE TEACHING OF MEDICAL ETHICS TO MEDICAL UNDERGRADUATES

Prof Peter Hwang - Chairman
Mr Terry Kaan
Prof Chao Tzee Cheng
Prof Chan Heng Leong
Prof Lee Hin Peng

Dr Ng Chiu Wan - Secretary
INTRODUCTION

The guiding principles are to provide an orderly, ethical and acceptable framework for regulating the acquisition and transplantation of human organs for therapeutic purposes. The guiding principles prohibit the sale of organs and are for the protection of minors and other vulnerable persons from becoming coerced into donating organs. The principles are only related to approved transplantations. Experimental projects are excluded from these principles.

The guidelines were drawn in consultation with the kidney, liver, heart, cornea, bone and bone marrow transplant teams.

GUIDING PRINCIPLE 1

Organs may be removed from the bodies of deceased persons for the purpose of transplantation when:

(a) consent has been obtained in accordance with the Medical (Therapy, Education and Research) Act 1972, and

(b) the deceased person had not objected to the removal of his kidneys under the Human Organ Transplant Act 1987.

GUIDING PRINCIPLE 2

Physicians determining the death of a potential donor should not be involved in the transplant team or in the treatment of potential recipients.

GUIDING PRINCIPLE 3

Adult living persons may donate organs, but they have to be genetically related to the recipients. Proof of kinship must be produced. Living unrelated transplants that can be considered are spouse to spouse or parents to legally adopted children or any other persons on a case to case basis.

Only when voluntary consent is given, will the organ be removed from the living donor. The donor must be free from any undue influence and pressure and must be well informed to be able to understand and weigh the risks, benefits and consequences of the transplant.

All living organ donors must undergo a psychiatric assessment.

This principle is not applicable to donors of regenerative tissues.
GUIDING PRINCIPLE 4

No organ should be removed from the body of a living minor for the purpose of transplantation. Exceptions may be made in the case of regenerative tissues.

GUIDING PRINCIPLE 5

There must be no trading or bartering of human body and parts. Giving or receiving payment for organs is prohibited.

GUIDING PRINCIPLE 6

Advertising the need for or availability of organs, with a view of seeking payment for commercialization purposes is prohibited.

GUIDING PRINCIPLE 7

Donated organs should be made available to patients on the basis of medical need and not on the basis of financial or other considerations, in accordance with existing law.

GUIDING PRINCIPLE 8

Except with the consent of the Director of Medical Services, all information pertaining to organ donations will be kept confidential by the relevant authorities.

GUIDING PRINCIPLE 9

All potential donors must be screened to ensure their medical suitability to donate organs for transplant.

GUIDING PRINCIPLE 10

Only transplants that are of proven medical benefit and have gone beyond the stage of experimentation can be carried out.

4 Mar 97
ETHICAL GUIDELINES ON TERMINATION OF PREGNANCY FOR MOTHERS WITH FOETUSES WITH LETHAL MALFORMATIONS

Background Information

1 With the advent of advances in medical technology, there is now a possibility of early diagnosis of foetal anomalies.

2 Presently, ultrasound imaging is utilised between 18 to 22 weeks of gestation to scan for foetal anomalies. When foetal anomalies are discovered, cytogenic studies are often made to determine whether there are associated chromosomal anomalies.

3 A Birth Defect Clinic is run on alternate weeks in SGH and KKH to review patients whose foetuses have been discovered to have anomalies. The Clinic is staffed by obstetricians, cytogeneticists, paediatric surgeons, neonatologists, pathologists, nurses and medical social workers. Cardiologists and neurologists are consulted when necessary. A definitive diagnosis of the foetal anomaly is arrived at, if possible.

Lethal Malformations

4 Based on the recommendations of the Center for Birth Defects Information Services, USA, the following conditions in foetuses have been recognised by the Birth Defect Clinic as lethal malformations or malformations that are not compatible with life:

(a) Trisomy 13;
(b) Trisomy 18;
(c) Anencephaly;
(d) Acranium;
(e) Bilateral renal agenesis; and
(f) Bart’s hydrops foetalis.

5 It is considered that termination of pregnancy for mothers with foetuses having any of these six lethal malformations is medically and ethically acceptable at whatever stage of gestation of the pregnancy. However, the following conditions must be fulfilled before the termination of pregnancy is carried out:

(a) A definitive diagnosis of the foetal anomaly has been reached by a multi-disciplinary medical team; and

(b) The informed consent of the patient has been obtained.
**Termination of Pregnancy Act**

6 The Termination of Pregnancy Act presently allows the termination of pregnancies which is less than 24 weeks of gestation. Termination of pregnancies beyond 24 weeks of gestation is legally permitted only when the mother’s life is threatened. As lethal foetal malformations per se do not threaten the life of the mother, it is therefore illegal to terminate such pregnancies if they are beyond 24 weeks of gestation.

**Recommendation**

7 It is recommended that termination of pregnancy should be an option available to the mother beyond 24 weeks of gestation if she has a foetus with any of the identified lethal malformations. This would require the Termination of Pregnancy Act to be reviewed and amended to provide for this.

*Sep 96*
1. The Treatment Dilemma

As medical technology has advanced, outcomes for high-risk newborn infants have greatly improved. If intensive treatment uniformly resulted in saving infants at risk, it would be the obvious choice for all severely ill infants. This outcome, of course, does not always occur. Intensive care has also been successful in rescuing infants with conditions where it can be predicted, with reasonable degree of certainty, that permanent and crippling disability will result. On the other hand, if intensive treatment is not provided to very ill infants, some of them will die, but some may survive with significant neuro-developmental disability, in part because specific treatments were withheld. The overall outcomes of failure to provide appropriate treatments or the indiscriminate use of technology are disappointing.

2. "Best Interest" of the Infant

The medical treatment of infants should be based on what is in their best interest. However, the infant’s ‘best interest’ is not always clear and his/her interest may be violated in a number of ways - through being allowed to die without sufficient reason, by being kept alive for a fate worse than death, or by prolonging the process of dying through insistence on futile treatment. It is perceived that the parents are most likely to have their infant’s best interest at heart and doctors are trusted to make decisions responsibly; but ignorance, prejudice, grief, eccentricity, self-interest and other considerations occasionally will intrude. As each infant in each family is unique and the circumstances of each case so complex, only general guidelines can be provided and much latitude in decision-making should be expected and tolerated.

3. The High-Risk Infants

Three groups of high-risk infants always present with difficult treatment decisions:

a. Infants around the threshold of viability (<25 weeks gestation or <700 grams birthweight)

b. Infants with major and/or multiple congenital abnormalities

c. Infants severely damaged by complications of pregnancy, delivery, or the early neonatal period.

4. Resuscitation at Birth - Initiation of Treatment

When it is clear that a high-risk infant will result, it is important to use the time before delivery for consultation with the family. The parents should be given some idea of the nature and extent of the problems, immediate and long-term. Sometimes, they may be totally unprepared for the situation, and they have to be much guided by the advice of their obstetrician, paediatrician and other relevant physicians. It is necessary, therefore, to take some stance and allow them to give agreement or disagreement rather than throwing the entire weight of decision in their laps.
If there is good reason to treat an infant and resuscitation becomes necessary, it should be started immediately to maximum efficiency and capacity. If death is inevitable or if it has been decided with the parents in advance that aggressive treatment is inappropriate, resuscitation should be withheld. It may not be possible to give an accurate prognosis at the time of birth. Therefore, the approach to this dilemma should be always to initiate maximum treatment, including endotracheal intubation and assisted ventilation if necessary, thereby favouring possible intact survival, until a more considered judgement can be made on the advisability of continuing life support. If further developments or later assessments indicate that there is a high likelihood of extensive brain damage, treatment will be stopped.

5. Continuation of Curative Treatment

Treatment of a curative nature should always be continued where there is a medical consensus that it would provide a net benefit to the infant. The infant’s medical condition should be the sole focus of any decision-making process. Decisions to continue, stop, or alter care must not be based on the financial status of the parents or the financial interests of the physicians, the hospitals, or the insurance carrier or other third-party payer. If there is any lack of clarity of whether curative treatment will be beneficial, the bias should always be in favour of its continuation. Only when the medical facts reveal the futility of further curative efforts should the difficult decision to discontinue life support and to provide palliative treatment be made.

6. Withdrawal of life-sustaining treatment

It will be easier to initiate treatment and begin intensive care if it is clear that this care can be withdrawn if it proves futile or ill-advised. When the burden of curative efforts lacks compensating benefit or such treatment is no longer of any avail, there is no need to continue or pursue it. Therapies lack compensating benefit when they merely prolong the dying process, when the infant suffers from severe pain which cannot be alleviated by medical treatment, or when the infant will be unable to participate even minimally in human experience.

Active measures to terminate life is not allowed, as it is equivalent to active euthanasia.

7. Palliative Treatment

Withdrawal of life-sustaining treatment is not tantamount to withdrawing care. When a firm decision has been made, it is not unethical, with parental agreement, to forgo all means of life-sustaining medical treatment if these measures are considered not appropriate and futile. Medical treatments include medication and artificially or technologically supplied respiration.

Since every infant is unique, the specifics of palliative treatment must be individualised. The infant and the family should be treated with dignity and compassion. Measures for the comfort of the baby, the avoidance of unnecessary and painful interventions, opportunity for interaction of the family with the infant, baptism when appropriate, swaddling and holding, presence and support by the medical team: these are vital aspects of care that cushion the impact of an unavoidable death.
8. The Decision-Making Process: Physician's Role

There is no distinction between initiation or withdrawal of life-sustaining treatment. An individualised prognostic strategy is recommended. In this setting, care is provided for the individual infant at the appropriate level based on the expected outcome at the time care is initiated. This approach places significant responsibility on the attending physician and health care team to evaluate the infant accurately and continuously. He/She should consult with colleagues and other appropriate sub-specialists and employ all available technologies to thoroughly assess and confirm the diagnosis and prognosis of the infant - good ethical decisions begin with good facts. Together, they attempt to define the issues, outline options and decide on the nature of treatment. By following this course, the risk of placing undue reliance on a single person's judgement is avoided.

As an individual with an overall perspective of the medical realities of the case and who also is in close contact with the family, the attending physician is in the best position to make a sound recommendation of the preferred treatment option to the parents, based on the projected benefits and burdens of treatment, recognising that parents may perceive and value these benefits and burdens differently from medical professionals. The decisions should be made openly and documented so that doctors are seen to be accountable for their actions. They should be prepared to defend them in court if necessary.


The effectiveness of the medical team depends on the extent to which the relationship between it and the parents is based on frank and open discussion and trust from the outset. The parents of the infant must be kept informed of the infant's current status and prognosis. In this way, the parents would have been in close communication and by the time a medical consensus is reached for discontinuation of curative efforts, they would appreciate that all reasonable hope has been exhausted.

Parents should be actively involved in major decisions that ultimately could alter the infant's outcome. The parents bear the principal moral responsibility for the well-being of their infant and should therefore be the surrogates for their infants. The pre-eminence of the parents' decision does not preclude the attending physician's responsibility to make a definite recommendation on the preferred treatment option. It is incorrect to provide a mass of medical facts and leave the parents adrift without specific guidance. The attending physician may have to guide parents towards what is acceptable not only medically but morally and socially, and what is within the law. He/She must also be sensitive to the parents' concerns and desires, which are often based on a complex combination of values and influences derived from their cultural, religious, educational, and ethnic backgrounds.

10. Resolving Differences

The decisions involved in shifting the emphasis from curative to palliative treatments are difficult and come about gradually as the infant's physical condition deteriorates. Sometimes a waiting period is required when the worsening condition becomes more evident before a time comes when discontinuation of curative efforts can be jointly resolved.

The rights and decision of the parents should always be respected. However, physicians should not be forced to under-treat or over-treat an infant if, in their best medical judgement, the treatment is not in compliance with the standards of care for that
infant. Although it rarely ever happens, when there is a conflict or disagreement between the recommendations of the physician and the desires of the parents, one option is to consult with the hospital ethics committee. Another option is for the physician and family to seek another physician willing to provide care for the infant in the manner desired by the family. In rare instances, it may be necessary to invoke established child protective mechanisms if parents wish to forgo life-sustaining treatment, physicians disagree, and the parties cannot resolve their differences with help from sub-specialists or ethics committees. In that case, the physician should continue to serve as advocate for the infant.

11. Ethics Committees

The decision-making process between the doctors and the parents is an intensely private affair and interference by outsiders like the ethics committees may cause confusions and complications. The role and objective of the Ethics Committee should be well-defined.

Ethics committees can be effective in an advisory capacity. They provide a good mechanism to review decisions for critically ill infants to ensure the best care for them and to assure the public that ethically sound decisions are being made in the Intensive Care Units. It can also assist in resolving differences in opinion among those involved in decision-making. Furthermore, by increasing discussion and deliberation of the complex issues, the professional staff will be better able to deal with exigent situations and to provide thoughtful decision making in difficult cases. Finally, the role of the ethics committee will be to provide ‘ethical comfort’ and give some legal protection for staff and family alike in carrying out these difficult decisions for some of the most critically ill patients in the hospital.

12. Aftercare and Support

Support should be provided to the family by physicians, nurses, and other staff beyond the time of the infant’s death. Support groups, intermittent contact by phone, and a later conference with the family to review the medical events surrounding the infant’s death and to evaluate the grieving response of the parents may be considered.

9 Feb 98
REFERENCES


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Annex IV/D

ETHICAL GUIDELINES
ON RESEARCH INVOLVING HUMAN SUBJECTS

Introduction

Principles

The need for human research
Definitions
Fundamental principles
Assessment of risk and benefit
Consent
Confidentiality

Implementation

Areas of responsibility
The Research Ethics Committee
  responsibility and objectives
  composition
  operations
  assessing research proposals
  continuing review
  accessibility

Other issues

Reference Materials

Acknowledgements

Appendices

I  Example of Consent Form
II  Members of the Working Group on Human Research

Aug 97
INTRODUCTION

1.1 Although it is now generally accepted that research on human subjects should adhere to codes such as those of the Helsinki Declaration, there is a need to establish more detailed guidelines to help investigators conform to generally accepted principles.

1.2 Currently, individual medical institutions in Singapore have ad hoc ethics committees to review the ethical acceptability of research proposals involving human subjects. In the absence of general guidelines with broad community support, differences of opinion between the investigators and ethics committees are often difficult to resolve. The lack of clear guidelines may either hinder useful research or result in inadequate protection of potential experimental subjects.

1.3 The objective of these guidelines is not to tell those responsible for making ethical decisions what course of action they should take. Rather, the purpose is to provide a broad framework of ethical principles which local ethics committees should take into consideration in their deliberations and to suggest procedures which these committees should follow in the decision-making process. The ultimate goal is to encourage awareness among research workers of the ethical values which are acceptable to the community, bearing in mind that ethical principles may change with time and with changes in public perception.

PRINCIPLES

2.1 The need for human research

It is clear that research on human subjects has resulted in significant medical advances. The discovery of the smallpox vaccine by Edward Jenner in 1796 is a good example. Animal or other models of biomedical research cannot entirely replace human studies. The careful study of human disease is a necessary part of the continuing process of improving diagnosis and treatment.

2.2 Definitions

2.2.1 Research. Human research can be broadly defined as studies which generate data about human subjects which go beyond what is needed for the individual's well-being. The primary purpose of research activity is the generation of new information or the testing of a hypothesis. The individual patient may or may not benefit directly. The fact that some benefit may result from the activity does not alter its status as "research". Defined in this manner, human research includes not only studies which involve human subjects directly, but also epidemiological surveys and reviews of patient records, for purposes not related to the patient's immediate health care.
2.2.2 *Distinction between research and therapy.* When an activity is undertaken with the sole intention of benefiting the patient, the activity may be considered to be part of "therapy". The progressive modification of methods of diagnosis and treatment in the light of experience is a normal feature of medical practice and should not be considered as research. There could be potential conflicts between research (intended to generate new information) and therapy (intended to benefit the individual patient directly). Their resolution rests on the integrity of the physician/investigator. The patient is always entitled to the best clinical management, and research considerations must never override this.

2.3 *Fundamental principles*

2.3.1 The fundamental principle of research involving human subjects is respect for life. From this principle, others follow: that of beneficence, justice, and autonomy. Beneficence concerns the benefits and risks of participating in research. Justice relates to the fair distribution of risks in research in relation to the anticipated benefits for research subjects. Autonomy refers to the right of individuals to decide for themselves what is good for them.

2.3.2 With respect to beneficence, the benefits and risks of research must always be carefully assessed. Research on human subjects should only be undertaken if the potential benefits arising from the expected new knowledge are of sufficient importance to outweigh any risk or harm inherent in the research, bearing in mind that risks and benefits may not be measurable on the same scale.

2.3.3 Since risks and benefits may accrue to different people, the question of justice must be considered. Mankind may benefit, but individuals participating in research put themselves at risk. Justice must be exercised in the allocation of the anticipated risks and the anticipated benefits. The ethical challenge is to decide, in the light of principle, what risks are justifiable, and for whom, in relation to potential gain.

2.3.4 A corollary of autonomy is that any research procedure must have, as far as possible, the free and informed consent of the experimental subject. Similarly, respect for the individual implies that safeguards should be provided to protect the experimental subject from physical and emotional harm including provisions for confidentiality.

2.4 *Assessment of risks and benefits*

Several questions should be asked in making an assessment of the risks and benefits of a research proposal:
2.4.1 *Is the proposal scientifically sound?*

Research projects which are not scientifically sound are, by definition, incapable of generating useful or new information. For this reason, research proposals which are not scientifically valid can never be ethically acceptable since experimental subjects may be exposed to risks unnecessarily. The evaluation of the scientific merits of a research proposal is therefore an integral part of ethics review.

2.4.2 *Should human studies be carried out at this time?*

The use of human beings in research should be essential for scientific reasons and should be based on earlier work on animal or other models as far as possible. Human research should not merely repeat work which has already been done elsewhere.

2.4.3 *What are the risks involved?*

All effort must be applied to determine, as far as possible, all the known and potential risks involved in the research protocol. Any foreseeable risk to society as a whole should also be considered.

2.4.4 *Are the research subjects appropriate?*

The risk-benefit analysis must be considered from the point of view of the experimental subjects. Ethically, the strongest justification for the research exists when the potential benefits can be applied directly to the experimental subjects. Conversely, potential subjects for whom the risks are particularly great may need to be excluded from the study.

2.5 *Consent*

One cardinal principle in research involving human subjects is that, as far as possible, a subject's involvement in research should be fully informed and fully voluntary. This ideal is rarely achievable. Nevertheless, procedures should be in place to ensure that experimental subjects are as well informed as possible and are as free as possible in deciding whether or not to participate in the research.

2.5.1 *Informing the experimental subject*

Prospective subjects should receive, in a language which they can understand, enough information about the proposed study to enable them to decide whether or not to participate. This could be in the form of an Information Sheet, which should be included in the research proposal if used.

The research proposal should provide details as to what information will be given to prospective subjects. The protocol should normally include, among others, the following items of information:
• the reasons for the research
• the anticipated benefits and consequences of the study
  (for the subject & society)
• the potential risks
• the rules for stopping the study or for withdrawing the
  subject from the study
• the right of the subject to withdraw from the study
  without penalty
• details regarding confidentiality
• details of compensation in the event of injury

If the experimental subject is a patient, additional information should be
provided, including:

• the patient’s prognosis without intervention
• alternative therapies available
• an estimate of the likelihood of success or failure of
  interventions offered
• the potential risks of interventions offered
• the distinction between research procedures and
  therapeutic measures to be applied

2.5.2 Free consent

Sufficient time must be given to the prospective subject for reflection.
Since patients may feel undue pressure if consent is requested by physicians
directly responsible for their care, it is desirable to delegate this task to
another health professional who has no direct link to the patient’s medical
management.

Subjects should be informed that their consent, duly signed and witnessed,
is not a contractually binding commitment and that they may withdraw from
the study any time without prejudice.

A consent form should be included as part of the research proposal.

2.5.3 Inducements

Inducements or rewards for entry into the study have to be carefully
examined. Remuneration limited to compensation for expenses or losses
incurred is ethically acceptable. Payments for time and inconvenience, if
nominal, are also acceptable. Excessive remuneration or other forms of
benefit, however, are improper if they are such as to persuade patients to
volunteer against their better judgement. Improved care should not be
offered as an inducement to participate. It is part of the ethics
committee’s responsibility to determine whether the remunerations or other
benefits are “reasonable”.

2.5.4 Non-consensual research

Consent is generally unnecessary for research using surplus blood, urine, tissue and similar samples obtained for diagnostic or treatment purposes if the patient is not identifiable and the research protocol does not influence the procedures used for obtaining the samples.

In cases such as epidemiological research where the data are identifiable, and prior consent is not to be sought, the investigators bear the responsibility of showing in the protocol that it is ethical for the consent requirement to be waived, and that adequate means exists to ensure the confidentiality of the data.

2.5.5 Research involving legally incompetent subjects

By definition, a legally incompetent subject cannot give a legally or ethically valid consent. These people, nevertheless, may have illnesses on which research is necessary. Research on such subjects may therefore raise conflicts on legal and ethical grounds.

2.5.5.1 Children

Research which could equally well be done on adults should not be done on children.

The ethical challenge is to determine the conditions and limits under which children may be involved in research. How far may parents or legal guardians go in committing their children to research? A relevant measure is that children should not be exposed to greater risks than those in their everyday lives. Parents and legal guardians control this level of risk now. Parents may consent to inspection of their children's medical records and may similarly approve the collection and analysis of excreted materials. They may also permit others to handle their children in ways that would otherwise be considered a minor legal assault (e.g. venepuncture), but not where pain or discomfort beyond carefully defined limits would be liable to occur.

A concept has developed that a child incapable of giving legal consent may give his or her "assent" and that a child should have power to decline invasive involvement with conclusive effect. Parental consent may be necessary but not sufficient condition: the child's negative preferences in such cases should be respected. The legal capacity of children to consent must be adjusted to relevant legislation: in Singapore, consent of parents or legal guardians is needed for those under the age of 21 years.

2.5.5.2 Mentally incompetent adults

The competence or otherwise of an individual must be determined
on the facts of the case. The principles outlined above for children may be applicable to adults who are established to be incompetent.

Particular care must be exercised when incompetent adults are under institutional care. Family members may not be sensitive to their preferences. Institutional heads should be consulted because they may have pragmatic objections to their patients’ taking part. Only courts have the authority to approve invasive forms of management, and to say what consent process will be adequate for invasive non-therapeutic procedures. Where research involves no more than minimal risk, a good guide might be that there should be agreement by the close relatives or guardians and that the patient does not appear to refuse or resist the research procedure.

Where non-invasive procedures, such as medical record review, are involved, appropriate discussions should be initiated with potential study subjects with a view to obtaining at least their assent. Further, proposals may be discussed with community groups concerned with the mentally disabled. Consultation with such groups may satisfy ethics committees that due consideration has been given to this question.

2.5.6 Research involving other special groups

2.5.6.1 Pregnant subjects

Research in pregnant subjects should be undertaken only if pregnancy is an essential part of the research. Research into pregnancy and childbirth requires special considerations since two individuals, mother and child, are involved and the rights and concerns of the father may need to be taken into consideration.

2.5.6.2 Prisoners

Because of their special status, questions can always be raised about their freedom to refuse consent. Research on prisoners should not be undertaken unless the fact of being imprisoned is itself an essential component of the research topic.

2.5.6.3 Elderly patients

In general, elderly patients should be assumed to be competent to give consent unless there is evidence to the contrary. It should not be thought that, because of their age, they need to know any less about the intended research than a younger subject.
2.5.6.4  *Severely ill patients*

Where the severity of a patient’s illness renders him incompetent to give informed consent, the principles which should apply resemble those applicable to those described above for legally incompetent subjects. Should the patient subsequently recover sufficiently to comprehend what was involved, he should be told of his participation in the research. In cases where consent is deemed possible, this should be obtained in the usual manner. In addition, a near relative should be informed of the nature of the research and should concur. No patient who refuses or, if incapable of refusing, resists, should be included or continued in the research.

2.5.6.5  *Subjects in dependent relationships with investigators*

Potential experimental subjects, who may be in dependent relationships with investigators (e.g. students, junior medical staff, nurses etc.) may not feel “free” to refuse. Calling for such “volunteers” is best done in group situations, or by notices, rather than by direct individual approach.

### 2.6  Confidentiality

2.6.1  The general rule is that confidentiality cannot be breached without the subject’s consent.

2.6.2  Identifiable data should be coded at the earliest possible time and involve a minimum number of research staff. Only those who need to link the data to a particular subject should be allowed to handle identifying data. Identifiable data should be held secure from theft, copying, interception and casual release.

Publication of research findings should preclude the possibility of subject identification unless prior consent has been obtained. If identifying information is to be maintained for the purpose of long-term follow-up, this intention should be made known to the subject at the beginning.

2.6.3  Access to relatives must in principle be controlled by the subjects themselves; subjects may be anxious to protect the confidentiality of their medical conditions from their families. Even when subjects consent, approaches to family members should be made through them, or their family physicians, rather than directly by the investigators.

2.6.4  There may be circumstances when obligations of confidentiality cannot be absolute. For example, there may be a legal duty for the investigator to warn family members of genetically-based risks of severe harm, or courts, for a variety of reasons, may order disclosure. Experimental subjects may be offered protection of confidentiality only within the limits of the law.
IMPLEMENTATION

3.1 Areas of responsibility

The responsibility for the proper conduct of human experimentation lies with all who are involved in the research, but most particularly with the investigator and the local ethics committee. The institution within which the researcher works has a major responsibility to ensure that the research meets the ethical standards of society. It is suggested that this responsibility be discharged through a Research Ethics Committee (REC). This is in accordance with the principle that investigators should not be the sole judges of the ethical acceptability of their proposed studies.

3.2 The Research Ethics Committee (REC)

3.2.1 Responsibility and objectives

The primary responsibility for decision-making on the ethics of human research should rest with the REC set up by each institution under the authority of the Principal of a university, or the Chief Executive Officer of a non-university institution.

The objectives of the REC are to maintain ethical standards in research, to protect research subjects from harm, to preserve the subjects' rights, and to reassure the public that this is being done.

3.2.2 Composition of the REC

The REC should have a defined membership which should turn over periodically so as to blend experience with fresh perceptions. Individual members should serve for at least 2 - 3 years. The composition of RECs may vary from institution to institution depending on local circumstances. The following suggested composition serves as an illustrative example.

(a) Community representatives. The REC should have members who can reflect community values. Lay (non-medical) membership is important if the community is to have confidence in the decisions of the REC. However, these members need to be people of goodwill, with a high regard for the human individual, for truthfulness, and for the continued advancement of medical science. Those who are totally opposed to human research should be left to attack the system from outside. On the other hand, individuals who are likely to give automatic approval are also not suitable members.

(b) Relevant specialists. The REC should contain at least one specialist in the relevant discipline of research. Scientists with a broad understanding of research design and of research in the areas usually considered by the REC should sit on the committee. Different specialists could be co-opted as necessary to consider specialised projects which the main committee may not have the expertise to deal
(c) Others. Bioethicists, theologians, philosophers, and psychologists may be able to contribute greatly to the work of an REC. The presence of a lawyer is desirable. A nurse should also be included, especially for RECs dealing with clinical research.

3.2.3 Operations of the REC

Regularly scheduled meetings are needed for the REC to discharge its duties and to enable its members to accumulate the necessary experience over time.

The workload of REC should be sufficient to ensure an experienced committee, but not so large that attention to necessary detail suffers.

The REC may allow its chairman (elected or appointed) to make interim decisions between meetings in certain areas, subject to ratification by the full committee.

The requirements for a quorum and the majority needed for approval of a project must be established with the agreement of the appointing authority.

It is important that minutes be kept. The proceedings of the REC (as distinct from its decisions) should be kept confidential because the issues considered are often complex and sensitive, and uninformed or unbalanced publicity could arouse emotions that are damaging.

Members of the REC should always declare any potential conflict of interest and the chairman will decide whether the conflict disqualifies the member from the discussions.

3.2.4 Assessing the ethical acceptability of research proposals

In reviewing the ethical acceptability or otherwise of a research proposal, the REC will need to consider the following points. When the form used for funding application does not request for all the information required by the REC, the REC should insist that supplementary information be provided. The REC should consider:

3.2.4.1 The scientific validity of the research proposal. Expert external input will be required if the REC does not have within it sufficient expertise to assess the scientific merits of research proposals. Since only scientifically meritorious studies should be done on human subjects, this factor must be considered by the REC. Assessment of the scientific validity of the research proposal includes an evaluation of the ability and qualifications of the investigator to do the proposed studies.

3.2.4.2 The appropriateness of performing the experiments on human
subjects. Relevant information derived from earlier experiments on animals or from other human studies should be provided and the need for the proposed experiments on human subjects in the current proposal should be justified.

3.2.4.3 The risks to the experimental subjects. Any known risks should be made clear and potential risks should be assessed as far as possible. Possible alternative protocols should be discussed to show that the protocol selected minimizes the risks. The precautions to be taken to ensure proper medical surveillance when subjects are placed at risk should be specified.

3.2.4.4 The selection of research subjects. The criteria and rationale for selecting experimental subjects should be discussed. This requirement is particularly important for groups like students, prisoners, employees, or others whose freedom to choose is often compromised.

3.2.4.5 The procedure for informed consent. The procedure for obtaining informed consent should be described, indicating the persons who will approach potential subjects for their consent. The description should include details of information to be given to the potential subjects. The consent form should be part of the research protocol. This form, or the Information Sheet referred to earlier, should contain statements of the aim of the project, the procedures the subject will undergo, and the risks inherent in those procedures, including side effects of drugs or treatments. It should describe areas of uncertainties in the research, including the statement that the procedures are experimental and that the subject may not benefit from the research. There should also be a statement that the subject may withdraw from the study at any time for whatever reason without prejudice. Where proxy consent is to be obtained, the procedure should be specified. Remunerations to subjects should be also specified. An example of a consent form is provided (Appendix I).

3.2.4.6 Protection of confidentiality. The investigator should describe measures which will be adopted to protect the confidentiality of the data generated in the research.

3.2.4.7 Safeguards. Where there is any possibility of serious adverse reactions, provisions should be in place to deal with these. The investigator should also consider whether it is advisable to stop the whole study when serious injuries occur unexpectedly.

3.2.5 Continuing review

The investigator is bound to act in exact accordance with the details submitted in the protocol once approved by the REC. If changes are desired
during the course of the study, the investigator must seek further approval of the REC. The investigator is obliged to report to the REC any adverse events and apparent risks beyond those predicted in the original submission. The investigator should also immediately inform the REC of any new information that may alter the ethical basis of the research programme. The REC should also be notified if the study is terminated prematurely. To ensure compliance, investigators should be required to provide, through their department heads, at least an annual update of their research to the REC, indicating any changes that may have occurred in scientific knowledge or experimental design, as well as the progress of the study. Where the REC is not satisfied with the conduct of an investigation, it may withdraw approval already given.

3.2.6 Accessibility to the REC

Access to the REC should be made available to all research subjects who may be unhappy about their continued participation in the research project. Investigators should inform research subjects of the opportunity to turn to the REC for advice if they are in any way unhappy with the research protocol.

3.3 Other issues

Several other issues may require consideration by the REC.

3.3.1 Remuneration for investigators

It is difficult to make generalisations here. Individual institutions may wish to establish their own regulations governing the extent to which their employees may be remunerated for research work.

Personal expenses incurred by physicians in the course of their research may be reimbursed by the sponsor of the research. Physicians, however, should not be paid a fee for carrying out research in the course of their daily work for which they are already being paid. Payments made to physicians or institutions on a per capita basis (i.e. according to the number of patients recruited for the study) are in general considered unethical, as these may lead to undue pressure to recruit patients. All financial arrangements and payments should be made known to the REC.

3.3.2 Compensation for experimental subjects for harm suffered

Although the chances of harm coming to patients in the course of carefully conducted research are very small, it is important that proper provisions be made to compensate patients in the event of such harm occurring. In the event of any significant injury, the subject must be entitled to receive compensation regardless of whether there may or may not have been legal negligence or legal liability on any other basis. Where no provision for compensation has been made, this fact ought to be disclosed to the research
subjects before the initiation of the study. Many institutions already have third party liability policies which could be extended to cover such compensation payable without proof of negligence. The extra premium should be acceptable since the number of such claims is likely to be small. Alternatively, companies sponsoring the research project should agree to accept responsibility.

3.3.3 **Publication of research results**

Ideally, results of research should be published free from any interference by the financial sponsors of the research. Whether this is in fact agreeable to all parties concerned will depend on negotiations before the initiation of the study. The terms of the negotiations should be made known to the REC which will assess their ethical acceptability. It is also recommended that copies of publications be included in the progress reports submitted to RECs.

3.3.4 **Indemnification of REC members**

RECs are advised to approach the authority appointing them to formally indemnify their members against the cost of any legal representation and any compensation ultimately awarded to research subjects. REC members should be given this indemnity in their letters of appointment.

3.3.5 **Special types of research**

Some types of research raise special concerns.

1. **Clinical trials**

The randomised controlled therapeutic trial, which has proved extremely useful, raises special ethical issues. Double-blind and placebo-controlled trials, for example, have sometimes caused anxiety for prospective participants because an element of deception seems to be involved, or because patients who are allocated to the control group may appear to be put at a disadvantage. Particular care must be taken to ensure that the subject's best interest is never sacrificed to that of the randomised controlled study. The use of placebos is ethical if patients give consent in advance. Since randomisation is necessary, patients must understand that their treatment allocation will be determined by chance. Randomisation without the patient's consent is unethical. If a patient expresses a strong preference for a particular treatment, he is probably ineligible as a participant.

In trials where the outcome has profound implications for the future health of the participants, the trial should be terminated as soon as it becomes apparent that one treatment is clearly superior to others. Arrangements need to be made from the outset to monitor results periodically. This allows termination of trial once a
A statistically valid result has been obtained. On the other hand, it should be noted that premature cessation may allow inadequately tested treatments to enter clinical practice.

2. **Drug and product testing**

Testing of drugs or products is often requested by manufacturers who are prepared to finance the study. Manufacturers will need to submit extensive data on their drug or product. Such data are often difficult to evaluate by RECs. Special assistance will be needed from external consultants, preferably appointed by the Ministry of Health, to assess the risks and benefits involved. The commercial nature of the research may also raise questions. For example, the extent to which universities and public hospitals permit their personnel and facilities to undertake private research, not intended for scholarly publications of results, has to be decided by the RECs of individual institutions. Furthermore, inducements to research personnel and experimental subjects, and the ultimate ends of research, have to be considered. The ethical implications of using human subjects for commercial rather than truly scientific purposes may raise additional questions which have to be addressed by the REC.

3. **Large-scale multicentre studies**

Ethical review of such studies present logistical problems. Consideration by all local RECs may not be practical. One possibility would be for the local RECs involved to accept the decision of the REC from the institution of origin of the Principal Investigator unless there are overriding concerns which require further discussion.

4. **Pilot studies**

Pilot studies are meant to test an idea, to determine whether the logistics of a proposed research protocol will work, or to train people in a new technique. Pilot studies are valuable guides to more extensive investigations but do not, in general, answer scientific questions. The REC, in considering a pilot study, should assess its potential benefits in a different perspective from that for a full study. The REC must ensure that the reasons for the pilot study are well defined, and that the design, including the number of subjects, will produce useful and reliable data. The REC should also satisfy itself that, if the pilot study succeeds, a full study will follow.

5. **Genetic engineering**

New capabilities in genetic manipulation introduce ethical issues in this area. Some fear that genetic engineering will bring about profound changes in the nature of human beings. Others see
enormous potential in the treatment of diseases which are currently untreated. Singapore currently does not have sufficient experience or expertise in this area to consider the full ethical implications of studies involving genetic engineering. It would, therefore, be prudent for us (i) to turn to more advanced countries for help when necessary, and (ii) to consider, at least for the foreseeable future, only those studies where there is no likelihood that the genetic alterations will be inherited.

6. Transplantation and implantation of devices

These issues raise concerns about health care costs, but they relate more to therapy than to research and need not be addressed in these Guidelines.
Reference Materials


Acknowledgements

In the preparation of this document, the Working Group on Human Research has drawn extensively from the guidelines published by other countries as well as from other relevant ethics literature. Acknowledgements are due especially to the Canadian Medical Research Council and the Royal College of Physicians of London for permission to use parts of their publications in the preparation of this document. In particular, material from “Guidelines on research involving human subjects” (Medical Research Council of Canada, 1987) and “Research involving patients” (Royal College of Physicians of London, 1990) have been quoted in part in this document. These and other works consulted during the preparation of this document are listed in the Reference Materials section.
### EXAMPLE OF CONSENT FORM FOR RESEARCH

<table>
<thead>
<tr>
<th>Title of Project</th>
</tr>
</thead>
<tbody>
<tr>
<td>(The subject should complete the whole of this sheet himself/herself) Please cross out as necessary</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Question</th>
<th>Yes/No</th>
</tr>
</thead>
<tbody>
<tr>
<td>Have you read the Information Sheet?</td>
<td></td>
</tr>
<tr>
<td>Have you had an opportunity to ask questions and discuss this study?</td>
<td></td>
</tr>
<tr>
<td>Have you received satisfactory answers to all of your questions?</td>
<td></td>
</tr>
<tr>
<td>Have you received enough information about the study?</td>
<td></td>
</tr>
<tr>
<td>Whom have you spoken to?</td>
<td></td>
</tr>
<tr>
<td>Dr/Mr/Ms ___________________________</td>
<td></td>
</tr>
</tbody>
</table>

Do you understand that you are free to withdraw from the study:

- at any time
- without having to give reason for withdrawing
- and without affecting your future medical care?  

<table>
<thead>
<tr>
<th>Question</th>
<th>Yes/No</th>
</tr>
</thead>
<tbody>
<tr>
<td>Do you agree to take part in this study?</td>
<td></td>
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</tbody>
</table>

<table>
<thead>
<tr>
<th>Signature</th>
<th>Date</th>
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<tr>
<td>________________________</td>
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Name in Block Letters

(Reproduced, with permission, from "Research involving patients", Royal College of Physicians of London, 1990)
ETHICAL GUIDELINES ON THE PRACTICE OF PSYCHIATRY

1. Professional Obligations
   a. The psychiatrist should safeguard patients confidences within the constraints of the law. He should not use the unique position of power arising from a psychotherapeutic situation to influence a patient in any manner not directly relevant to the treatment goals.
   b. A psychiatrist must conduct himself with propriety. The doctor-patient relationship in psychiatry is often intense. The psychiatrist should never let inappropriate personal desires, feelings, prejudices of beliefs interfere with treatment. Sexual activity with a patient is unethical.
   c. Psychiatrists are responsible for their own continuing education. They must provide the best care for their patients consistent with accepted scientific knowledge and ethical principles.
   d. When a psychiatrist becomes mentally unwell and is unable to provide competent psychiatrist care, it is ethical for another psychiatrist to intercede.

2. Confidentiality and Release of Information
   a. Confidentiality is essential to psychiatric treatment.
   b. Information given by a patient to his psychiatrist must be kept confidential unless
      i. the patient relieves the psychiatrist from this obligation and authorises release of information in writing
      ii. the psychiatrist makes disclosure to avert inevitable danger to others.
      iii. under legal compulsion.
   c. Psychiatrist records of the patient must be protected with extreme care.
   d. When a psychiatric case is presented for teaching or reported, the anonymity of the patient must be preserved.
   e. Psychiatrists are often asked to examine persons for suitability for various security purposes and to determine legal competence. In these situations, the psychiatrist must advise the person on the nature, purpose and lack of confidentiality of the examination.

3. Treatment
   a. A psychiatrist should try and establish a therapeutic relationship with a patient. When this is sometimes not possible, contact should be established with a relative or other person close to the patient. If such a relationship is established for non-
therapeutic purposes e.g. in forensic psychiatry, its nature and purpose must be explained to the patient.

b. Treatment (including electroconvulsive therapy) should not be given or a procedure performed without a patient’s informed consent except when the capacity to consent is lacking. For these patients, the guardian or other persons who have lawful charge of the patient can give the consent as allowed in Penal Code Section 89.

c. If the patient has no guardian or others in lawful charge of him, a psychiatrist can proceed with the treatment without the patient’s consent when the illness is regarded as life-threatening and treatment is necessary. A second opinion is needed in such cases (Penal Code Section 92).

d. The assessment of the patients’ ability to give consent for treatment and the nature and extent of information given in seeking consent is based on clinical judgment and guided by current professional practice and legal requirements.

4. Hospital Admission

a. Involuntary admission can only be to a hospital approved by law and there are statutes in the law which must be complied with.

b. The Mental Disorders and Treatment Act allows for a patient to be detained for treatment for as long as is deemed necessary. As soon as involuntary admission is no longer necessary, the psychiatrist should release the patient from the order.

5 Research

a. Patients’ participation in psychiatric research must be voluntary.

b. Information must be given on the objectives of the study, the methodology including risks and inconveniences, tests that are needed and observations that will be recorded.

c. Written consent from the patient is necessary. In the case of children and those who cannot give informed consent, consent should be obtained from a guardian or legal next-of-kin.

d. Every patient is free to withdraw for any reason and at any time from participation in research. (A patient’s withdrawal or refusal to participate in research must never influence the psychiatrist’s efforts to help the patient).

e. Approval for the research must be sought from the hospital’s Ethics Committee.

14 Nov 97
REFERENCES

1. Declaration of Helsinki
   (Adopted by the General Assembly of the World Medical Association Helsinki 1964; revised Tokyo 1975).

2. Declaration of Hawaii

3. Principles of Medical Ethics with Annotations Especially Applicable to Psychiatry of the American Psychiatric Association


8. Principles of Experimental Research on Human Beings
   (Adopted by the BMA 1963).

ANNEXES I, II & III
ANNEX IV

GUIDELINES
ANNEX V

PRESS CUTTINGS
Medical ethics committee formed to watch over practice, research

By Ng Wei Joo

The Health Ministry has formed a national ethics committee with members drawn from wide-ranging backgrounds to look into ethical issues in medical practice and research.

Led by Dr Chew Chin Hin, a former deputy director of medical services, and comprising doctors, lawyers and community leaders, its tasks include:

- Drawing up ethical codes of conduct for doctors,
- Advising the ministry on potential ethical issues based on trends in developed countries,
- Identifying prevailing ethical issues and forming sub-committees to deal with specific issues.

Announcing this yesterday, Health Minister George Yeo said that his ministry was also planning to empower the Singapore Medical Council to deal with doctors who misbehaved. He did not give other details.

Speaking to the medical Alumni Association, he said that the committee will also look into how medical ethics could be taught to medical students.

It would probably recommend that all private and public hospitals set up a formal ethics committee.

These would then give detailed guidelines on areas such as life support of terminally-ill patients and assisted reproduction.

Hospitals such as the National University Hospital, Tan Tock Seng Hospital, Mount Elizabeth Hospital and Toa Payoh Hospital already have such committees, made up of medical staff and others.

In his speech, Brig-Gen (NS) Yeo warned against reducing the practice of medicine to a trade, and the doctor-patient relationship to a mere commercial transaction.

He said: “The doctor-patient relationship and the teacher-pupil relationship are analogous. Both are fundamental to the well-being of society.”

Hence to preserve the relationship, he said, there was a need for sanctions and safeguards by the Health Ministry and a strong ethical code.

But he added that efforts should also come from within the profession.

Urging the Singapore Medical Association and the Alumni Association to take the lead, he said that no sanction was more effective than professional peer pressure.

Promoting a spirit of volunteering among doctors, he added, would also improve the ethical tone of the profession and increase public respect.

Although many already gave their services in medical and non-medical areas, fewer doctors were coming forward to serve in constituency grassroots groups.

“The doctor-to-patient relationship is transformed when doctors are also recognized by the community at large as leaders, mentors and benefactors.”

He concluded by challenging doctors to be prepared for the effect of technology on medicine and for “an age when ideologies and ideals matter little”.

Several doctors yesterday welcomed the move to have the national medical ethics committee.

A general practitioner in Ang Mo Kio said that clear guidelines would help doctors decide more confidently in a “50-50 situation”, such as whether to resort to costly equipment and procedures to try to repair a deformed or abnormal foetus.

Another GP, Dr Wong Wee Nam, who was at the lunch held at the Alumni Auditorium in College Road, said that the committee should perform more than a policing role and help doctors grapple with moral dilemmas.

Citing advanced technology that could prolong life but increase costs and even suffering, he said: “We, as doctors, are not trained to tell patients to die.”
Ethics committee proposes law to allow living wills

By Chua Mui Hoong

THE National Medical Ethics Committee has proposed that a law be drawn up to allow adult Singaporeans to make living wills if they wish to do so.

It has come up with guidelines and safeguards for such a law, but wants feedback from the public before going to the Government with recommendations in October.

Living wills allow people to state if they wish life-support to continue if they are terminally ill. They may be made anytime, but will come into effect only if a person is terminally ill.

The 13-member committee, which includes doctors, nurses and lawyers, suggested in a four-page report released yesterday that such a law should allow Singaporeans aged above 21 who are of sound mind to make living wills. But it should not be compulsory for anyone to do so.

As a safeguard, those who change their minds should be allowed to revoke the will in writing, orally, or through other forms of communication.

Anyone who compels another person to make such a will, or hides any document revoking such a will, should be punished by law.

To avoid ambiguity, the committee also said living wills should be made in a prescribed form made available to the public.

The committee, formed two months ago to advise the

Health Ministry on ethical issues, is chaired by Dr Chew Chin Hin, a consultant chest physician who is the former deputy director of medical services (hospitals) in the Health Ministry.

He said a law was needed to honour the wishes of patients who made living wills.

Such a law would also make it legal for doctors to stop or withdraw treatment if the patient willed it.

Such wills were in line with the state's recognition that a person had the right and responsibility to make decisions for his own health care, he added.

It was Deputy Prime Minister Lee Hsien Loong, who first broached the subject of living wills publicly in November. He had said that such wills were one solution to the ethical dilemma doctors and families faced in deciding on expensive treatment for terminally ill patients with no prospect of recovery.

Yesterday, Dr Chew stressed during a press conference that living wills would not legalize euthanasia or mercy-killing. Euthanasia was a deliberate act by a doctor to terminate the life of a patient, for example, by giving a lethal injection.

But a living will only allowed a patient to request that treatment be withheld if he was naturally when he is terminally ill, he said.

He added that medical advances have made it possible to prolong lives of terminally ill patients, but not necessarily for those of limited quality.

The committee also proposed that there should be two witnesses to such wills, one of whom should be a doctor. The wills should be kept in a confidential registry and made available only to those managing the patient directly.

Also, two doctors are needed to certify that a person is terminally ill: the attending doctor and a specialist in the patient's illness. If they do not agree, the case should go before an independent panel of doctors in the hospital.

On other ethical issues, Dr Chew said the committee will help hospitals' ethics groups to be more accessible to doctors and families. A sub-committee will also be formed to review the teaching of medical ethics to medical undergraduates. It plans to draw up an ethical code of conduct for doctors next year.

The committee had studied legislation on living wills in other countries, including 36 US states, and in Australia.

Over the next three weeks, it will canvass views from 17 religious organisations, and nine professional groups representing doctors, nurses and lawyers. Members of the public are invited to write in with their views to the committee at the Health Ministry, College of Medicine Building, College Road, Singapore 0313.

What the proposed law means

Terminate illness: here means a medical condition or injury from which there is no hope of recovery, and when death is imminent if no life-sustaining treatment is used. Life-sustaining treatment refers to artificial means used to prolong life by maintaining vital functions of the body, but which will have no effect on the underlying cause of the illness. Examples are the use of ventilators to take over a person's spontaneous breathing, or giving cardiopulmonary resuscitation when the patient's heart stops when he is terminally ill.

Living wills will not cover patients who are comatose but do not require life-sustaining treatment, such as accident victims in a coma who may recover. Those aged below 21, or of unsound mind, doctors will help families decide on whether to stop life-sustaining treatment, as happens now.
Living wills make headway

The campaign to gauge public readiness for living wills is going well, considering how easily feelings can overwhelm calm reflection on a matter of conscience. Since first mention in November last year by Deputy Prime Minister Lee Hsien Loong in a parliamentary debate on health care costs, public feedback has been largely supportive, though with qualification. That is opinion as articulated by professional interests such as lawyers and health professionals, aside from religious groups. Their support is crucial. What has been missing is the public's voice as heard in letters to newspapers and discussions at the grassroots level. Their support is just as crucial.

Citizens with even a passing interest in how policies affect their lives should now make themselves heard so that legislators can reach a balanced judgment when the matter comes before Parliament. Sending the Bill to select committee would be sensible too, as is the need for a public education campaign not unlike that which preceded the Goods and Services Tax. That the feedback gathering is reaching a peak is obvious from the exposure the issue has been getting on the evening television news and the media briefings given by the national medical ethics committee, which is taking opinion for the Health Ministry.

Dr Chew Chin Hin, who heads the committee, reports that of the 25 organisations asked to give their views, the 24 which have done so support the principle in large part. All accept that a person should be free to decide whether to refuse treatment when death from a terminal illness is inevitable, and aggressive medical intervention would only prolong pain and suffering to both patient and family. And think of the cost, although it shall never be the deciding factor. But not all accept that a law need be written. Here, the health professionals (all oppose legislation except the Academy of Medicine and the Singapore Medical Council) diverge from the lawyers who say, rightly, that there should be no ambiguity. Among religious groups, the Catholics and Protestants are squeamish about euthanasia. But the Muslims, Hindus, Buddhists and Muslims are not. As the latter groups form 73 per cent of the population, they deliver to the committee a notionally huge vote of acceptance.

The important distinction here is that disagreement over the need for legislation should not override the fact that there is near unanimity on the right to decide when nature should take its course in terminal cases. This is the object of the exercise. At this point, the committee has been correct in channelising its energies to addressing the misgivings of doctors and nursing groups. Making an audit mandatory of living wills which had been executed, as proposed by the doctors, is eminently sensible. It will do public confidence a power of good to know that due care had been taken and procedures observed by hospital evaluation panels when carrying out the wishes of terminal patients. Other safeguards — prominent ones being that revocations of living wills should be in writing, and that pain relief and other palliative treatments should not be denied even if a will had been made — are common-sensical.

When the law is in place, a confidence booster from leading citizens to nudge along the process will be in order. Because the subject remains an emotive mix of superstition and rational thought, fear and bravado, the probability is that not many people will make a will until social conventions change. For that to happen, prominent people in public life, the uniformed services, business and the professions must lead. In this regard, if calling living wills by a less forbidding name (advance directive is now the new term) would remove unhappy associations, then advance directive it shall be. Changes are that it will fall into disuse. The average Singaporean, not given to euphemism, is more inclined to call a spade a spade.
66 new doctors take the Physician’s Pledge

By Allison Lim

SIXTY-SIX newly-registered doctors yesterday pledged to uphold the ethical and professional standards of the medical profession.

They took the Physician’s Pledge before members of the Singapore Medical Council, representatives from the Academy of Medicine, College of Family Physicians and the Singapore Medical Association.

Of the 66, 42 were overseas graduates. The remaining 24 were trained here. In May last year, 142 Singapore graduates took the pledge in the first ceremony.

All promised to observe their duty to mankind and to their patients, and to uphold the honour and tradition of the profession.

The pledge is compulsory under the Medical Registration (Amendment) Regulations, 1995. Before, doctors did not have to take any oath.

The words of the pledge are adapted from the Declaration of Geneva and the Hippocratic Oath. Both are promises of ethical professional behaviour.

At the ceremony, SMC council member J.A. Tambyah said that apart from maintaining professional standards such as patient care and being aware of new findings, the medical practice has always had a strong ethical foundation, which doctors have to measure up to.

Dr Tambyah, an endocrinologist in private practice, said that in recent years, doctors had acquired the new responsibility of dealing with ethical dilemmas arising from working in a managed health care system. “The doctor in the managed health care system is faced with the bigger task of balancing the needs of the patient with the constraints of a budget imposed by a third party.”

Dr Loke Wei Ian, 25, a Leicester University graduate, led his colleagues in the pledge.

He said: “We haven’t made any big ethical decisions yet, but it is a reminder to us of all the ethical decisions that we will have to make in the next 20, 30 years of our career.”