

THE COLLEGE OF GENERAL PRACTITIONERS SINGAPORE



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MEDICO-LEGAL AND ETHICAL ISSUES

- Ethical Principles
- Legal Aspects
- Confidentiality
- Certification of Death

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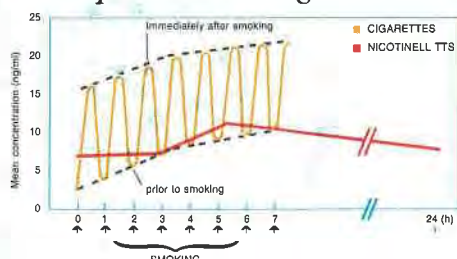
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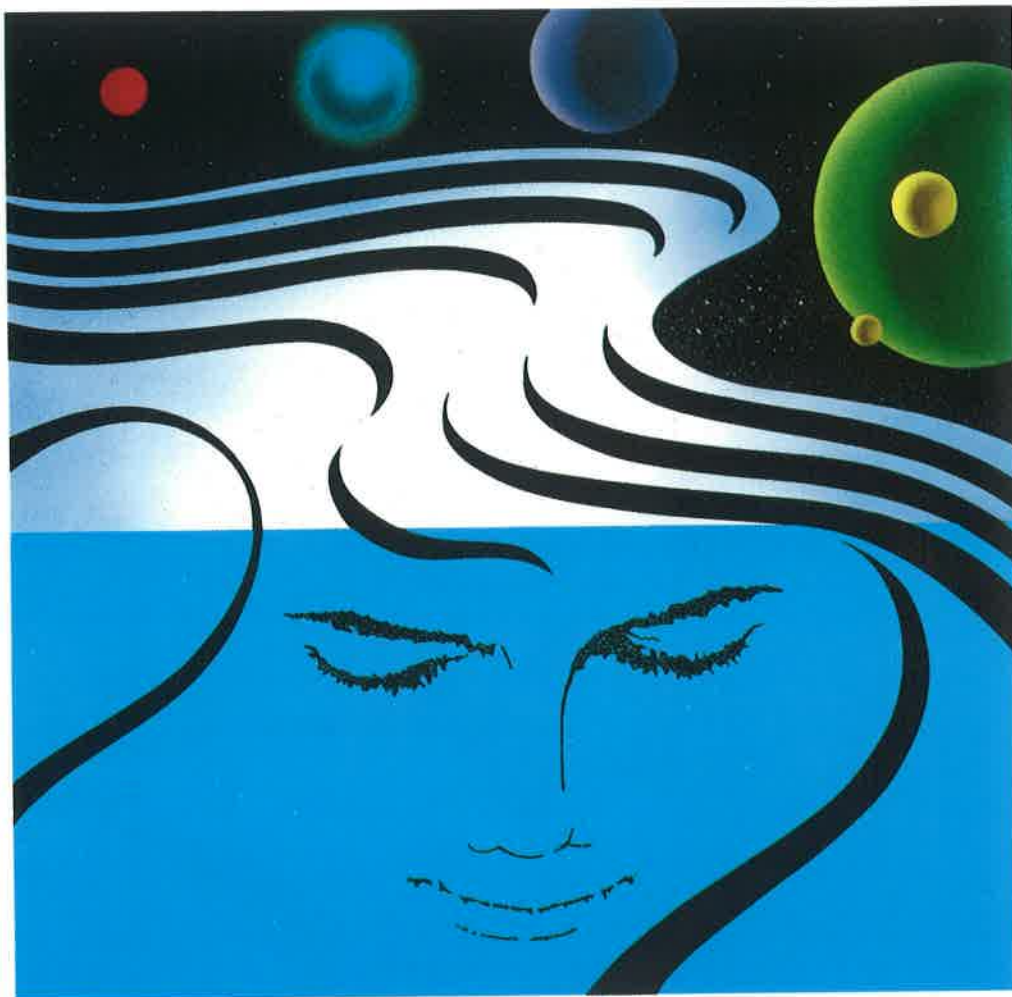
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THE DOCTOR-PATIENT RELATIONSHIP

L G Goh, MBBS (S), MMed (Int. Med), MRCP, FCGP(S)

Doctor-patient relationship is a large subject. In this editorial, three aspects will be covered, namely, empirical truths about the doctor-patient relationship, professional dimensions, and practice management considerations.

EMPIRICAL TRUTHS ABOUT THE DOCTOR-PATIENT RELATIONSHIP

The doctor is at various times a saint, scientist or shopkeeper in the eyes of the patient. This observation was made by Dr Rajakumar, a past president of the World Organisation of Family Doctors (WONCA) at a workshop in Manila in March this year. It is difficult to be a saint, but the family doctor has to try to act in the interests of his patients' welfare; in this lies the nobility of the medical profession. The family doctor is scientifically trained; he should reflect this in his professional work. His patients expect him to keep abreast with the scientific knowledge of the day. The family doctor has to charge his patients for services rendered. It is important that his charges are reasonable and customary. Where the charges may be high because of cost of medicines, laboratory tests or procedures, it helps the doctor-patient relationship to clarify matters.

A good doctor-patient relationship has great dividends. In business, it is abundantly clear that an organisation thrives because of repeat business and this depends on a good-client relationship. In the same way, each patient must leave with a positive frame of mind that he will come back

again because he enjoyed the good relationship with the doctor and the practice. A doctor with a good doctor-patient relationship is more likely to be forgiven for his shortcomings although one will hope that one does not have to depend on that.

Each visit is a moment of truth in doctor-patient relationship. There must be continuing attention and one should not take good relationships for granted. The good rapport built up over the years can be ruined by a few bad words, a bad mood or bad judgement. Each encounter must be a good moment of truth.

Grumbles against the doctor are more often on people handling slip-ups than on professional matters. The studies of Rudolf Klein, Professor of Social Policy in the University of Bath, provided important information about grumbles against doctors' showed that 19.9 percent were on manners and remarks of practitioners, 14.9 percent were on manners and remarks of receptionists, 7.6 percent because of dissatisfaction with the appointment system, 3.8 percent on inability to contact the practitioner by telephone; together they accounted for 46.2 percent of the complaints. In the same study, 14.7 percent of complaints were on failure to visit or delay in visiting, 10.9% were on inadequate examination or inadequate/incorrect treatment, 5.3 percent were on the failure to refer to hospital or specialist services, and 3.3 percent on failure to issue medical certificate; together these account for 34.2 percent of the grumbles. A better doctor-patient relationship will reduce many of the complaints.

PROFESSIONAL DIMENSIONS OF THE DOCTOR-PATIENT RELATIONSHIP

In practice, there are at least three different professional dimensions of the doctor-patient

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relationship: legal, ethical and negotiational. Each dimension can be complex and the doctor needs to be aware of the complexities and have a working model on how to achieve an optimum relationship for the patient and for himself.

Legal relationship: the notion of standard of care

The public expects a certain standard of care from his doctor. This has been defined by the General Medical Council in the United Kingdom in its booklet *Professional Conduct and Discipline: Fitness to Practice* (April 1987)². It says:

The public is entitled to expect that a registered medical practitioner will afford and maintain a good standard of medical care. This is shown below.

- * *conscientious assessment of the history, symptoms and signs of a patient's condition;*
- * *sufficiently thorough professional attention, examination and where necessary, diagnostic investigation;*
- * *competent and considerate professional management;*
- * *appropriate and prompt action upon evidence suggesting the evidence of a condition requiring urgent medical intervention;*
- * *readiness, where the circumstances so warrant, to consult appropriate professional colleagues.*

A comparable standard of practice is to be expected from medical practitioners whose contribution to a patient's care is indirect, for example, those in laboratory and radiological specialities.

The dependance on high technology at the expense of examination of the patient is likely to miss the obvious besides causing patient dissatisfaction.

Ethical (moral) relationship

There are moral standards laid down by society and the medical profession to regulate the doctor's behaviour towards his patient. The four basic moral principles in the doctor-patient relationship are:

- * beneficence (do good)
- * non-maleficence (do no harm)
- * autonomy (respect for person's decision; telling

the truth so that the person can make appropriate choices)

- * fidelity (maintaining the patient's confidentiality)

Other principles are:

- * respect for the sanctity of life
- * justice in resource allocation.

In practice there may be conflicts between one or more moral principles in a given situation and the doctor has to weigh which is more important in terms of the patient's interests. There may be different opinions from different doctors depending on the values and beliefs that the individual doctor attaches to each of these principles. It is not wrong to come to a different ethical action, simply because of the different weightage given to the ethical values. What is important is that the ethical decision must be a valid one, namely, it must be defensible on logic.

Negotiational relationship

The model of a negotiational relationship described by Richard Botelho (1992)³ helps a doctor to analyse and be aware of the usual difficulties that may arise in the doctor-patient relationship. Basically, in each doctor-patient relationship, there are two simultaneous relationships in action, namely, the medical relationship and the personal relationship. In the medical relationship, the doctor's tasks are to diagnose, care and palliate, relieve and confer sick role on the patient. In the personal relationship, the tasks are to understand illness in the context of the patient's life, share understanding (empathy), help the patient on information, explanation and education and strategies of coping.

The consultation has been described as a meeting of two experts (Tuckett et al, 1985): the disease expert (the doctor) and the illness expert (the patient). Each brings along a different perspective of the problem at hand depending on the perceptions, attributions, beliefs, values and meanings that are attached to this problem.

Within these two relationships, both the patient and doctor examine the content of the relationship which consists of disease, sick role, as well as

illness and context. Differing perception of one or more of these items leads to potential conflicts that have to be resolved. The greater the degree that the patient is allowed to participate (if the patient wants to) the greater will the reduction of the potential conflicts.

The doctor-patient relationship is in essence a balance of authority on the part of the doctor on one hand and autonomy on the part of the patient on the other hand. Each party exerts a varying degree of responsibility and control to the relationship. Both the doctor and the patient have to negotiate and agree what is the appropriate in the situation. Either can exhibit autonomism, egalitarianism, paternalism or autocracy.

If the patient takes control (autonomous), the doctor needs to understand why the patient wants control; the doctor needs to set limits for the patient's good and other considerations. Thus, if the patient requests a second opinion, the doctor may agree if it is reasonable but may resist if it is not for the patient's good or is not necessary.

Egalitarianism is the situation where the patient is encouraged to assume more responsibility in decision making. This is conceptually good for the patient, especially in chronic problems. However, the doctor needs to know that ill-health can diminish autonomy and make egalitarianism inappropriate. Also, the patient needs to be empowered to behave in an egalitarian way or else he may feel abandoned or neglected.

Paternalism is traditionally frowned upon, yet it may be appropriate if the patient is not in the situation to decide because he is unable to understand or is too young to decide.

Although autocracy is viewed by many to be unacceptable, yet it may be necessary in medical, surgical or psychiatric emergencies.

The "difficult patient". This is a well-known label in the doctor-patient relationship. Groves⁴ described four types of such patients in his paper "*Taking care of the hateful patient*" in the New England Journal of Medicine, some 20 years ago. He calls them the clinging patient, the oppositional patient, the hostile patient and the malingering

patient. A clinging patient is one who prolongs the consultation and is dependent on the doctor all the time. The oppositional patient is one who persistently fails to follow important medical plans. The hostile patient is one who is aggressive and critical of the doctor's actions. The malingering patient is one who is motivated by secondary gain to adopt a sick role.

A crucial aspect of treating the difficult patient is the cultivation of a clear awareness within the physician of what is happening to the doctor-patient relationship. He can then direct his efforts toward developing a structure for the relationship that will allow for efficient medical management and will be supportive of the patient's emotional needs. It must be recognised that the physician needs to examine himself carefully for negative feelings which are wholly or partially to blame for the problem in the relationship with the patient.

Some patients become difficult to treat because of frustration related to their disability to obtain proper diagnosis and treatment of a legitimate physical problem. The physician must not allow a patient's difficult behaviour to compromise an adequate medical evaluation.

Troublesome behaviour on the part of a patient may arise as a carryover from conflicts in other areas of the patient's life. Such patients often over-react to minor difficulties in their medical therapy. Pointing out that the patient seems unusually upset can, if done tactfully, often provide an opportunity for the patient to discuss such areas as marital or occupational conflicts.

The physician is not only responsible for his own behaviour with the patient but also for that of his employees. Employees who are inconsiderate of patients can cause many difficulties in the doctor-patient relationship. It is very important that the physician make certain that patients are treated in a pleasant and efficient atmosphere.

Physicians should not attempt to treat the difficult patient by ignoring the troublesome behaviour. The patient should be informed clearly that his behaviour is causing difficulty. This should be expressed to the patient in the sense that "we have a problem" rather than that he is causing a problem.

PRACTICE MANAGEMENT CONSIDERATIONS

With the principles already discussed, we need to see how they be made relevant in day-to-day practice. It must be impressed on all the staff in the practice that ensuring a good rapport with every person that visits the practice is everybody's job.

A framework that is useful is to view efforts in achieving a satisfactory relationship as belonging to one of the following categories: structural, process and outcome considerations.

Structural considerations

Waiting time, accessibility to the doctor on the telephone or on appointments, training and attitude of staff are structural elements that may improve or hinder the doctor-patient relationship.

Process considerations

Many of the principles discussed under the professional dimensions of doctor-patient relationship are relevant here.

Attention to the reason for encounter (RFE); efforts in discovering the ideas, concerns and expectations (ICE) of the patient are activities that will help greatly the tasks within the medical relationship and personal relationship.

The doctor has to determine the degree of participation that the patient wants in the consultation and the degree of patient-centred approach he will feel is appropriate for the situation.

Explanation to the patient and family members is important. This clarifies any misconception that may ruin a doctor-patient relationship. Patients who do not have enough information on what is happening are more likely to doctor-hop.

The body language and expressed language must be congruent: "say what you mean and mean what you say". Patients can pick up discrepancies easily.

Outcome considerations

It is good practice to evaluate periodically the clinical outcome of one's care as well as the patient's satisfaction. As the practice picks up, waiting time may become intolerably long, the service may become more impersonal. Suggestion boxes may yield good feedback. A review of your own work can be very educational and important to the practice.

CONCLUSION

The doctor-patient relationship should not be taken for granted. Enough time should be spent to reflect on it, to teach and impress on ourselves and on each staff its importance and relevance to the success of the practice.

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LEGAL AND ETHICAL ASPECTS OF FAMILY PRACTICE

"Doctors work under time and other constraints. They practise a science and an art and they deal with the most unpredictable, the most demanding, and a most variegated group of subject matter: human beings. Last but not least, they often deal with life and death under the most pressing and distressing circumstances, including even evolving the doctrine of the 'agony of the moment'". So succinctly put by Justice Lai Kew Chai in his 8th Sreenivasan Oration¹, such are the circumstances under which doctors practise their profession.

"There are very few professional men who will assert that they have never fallen below the high standards rightly expected of them. That they have never been negligent. If they do, it is unlikely that they should be believed" said a previous Master of the Rolls of the United Kingdom in his homily². In the climate of the circumstances outlined above, the numerous decisions and actions the individual practitioner takes daily with such autonomy during his work, must stand up to scrutiny and critical examination. Even if a physician relies upon "intuitive" moral values, conventional wisdom, armchair philosophy and his own religious upbringing and individual conscience, a decision or action of his may be construed to be wrong in the consensus opinion of his peers.

Hence the need for appropriate laws and ethical rules. Laws cannot guarantee that doctors will make proper decisions for their patients; they can only establish punishment for those that breach these, and attempt to redress, injury or grievance. Codes of ethics have been developed for issues where a physician's actions have social or moral implications. Yet, while obeying all the pertinent laws and abiding by all the relevant ethical codes, the physician can still experience the uncertainty and anguish of moral decisions. There are few, if any, ethical absolutes, but many ethical issues.

Questions will arise in the doctor's mind, especially in the area of confidentiality ---- when the bus driver admits he has epilepsy but does not want the authorities to know, when the spouse or employer of a terminally-ill patient wants information on the patient's condition, when the under-aged female patient requests contraceptives and when a patient asks for a referral to practitioners of alternative medicine (e.g. homoeopaths, chiropractors or native herbal physicians) not officially recognised by the medical society or association. Generally, the guiding principle must be that the welfare of the patient comes first, but this must be tempered by an awareness of the needs and rights of the community as a whole.

Malpractice action taken against any doctor, especially so the Family Physician, will be very vexing and cause great agony to the physician, even if he is finally exonerated. To prevent such malpractice suits ---- whether it is for criminal malpractice (government against doctor), civil malpractice (patient versus doctor) or ethical malpractice (doctor or Medical Council against doctor) ---- all Family Physicians would be well-advised to remember that they owe a duty to treat their patients with care, competence, skill and diligence. The importance of taking an adequate medical history, of conducting a careful and thorough (within constraints) medical examination, of exercising care in the management, of not treating beyond one's own level of competence, and of maintaining adequate medical records cannot be over-emphasized.

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Moti H. Vaswani



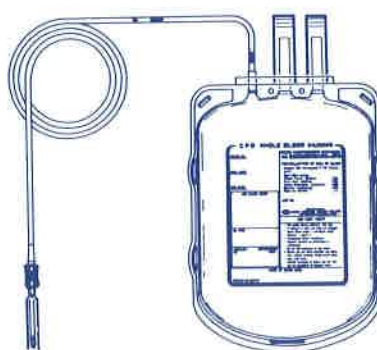
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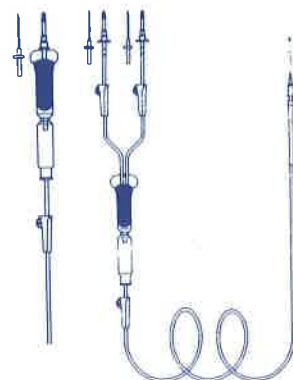
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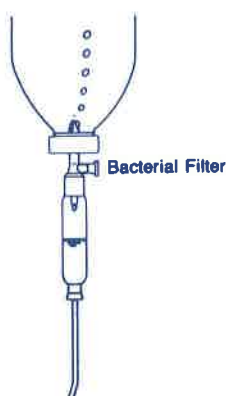
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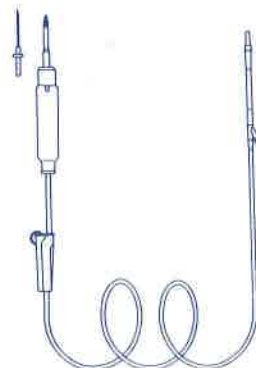
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ETHICAL PRINCIPLES IN THE DOCTOR-PATIENT RELATIONSHIP

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INTRODUCTION

Ethical concepts help us to resolve moral dilemmas faced in day-to-day practice in a rational way and in a way that we can give a valid opinion (an opinion that can be logically defended).

SOME DEFINITIONS

1. **Ethics:** is a discipline that includes study of ideal human conduct and an understanding of the moral life in which actions, persons and institutions are judged as right or wrong, praiseworthy or blameworthy. **Medical ethics:** is applied ethics concerning medical practice.
2. **Duties and rights:**
 - duties are moral obligations owed by an individual, group or institution to another individual, group or institution.
 - rights are claims by individual, group or institution on another individual, group or institution.
3. **Prima facie duty and actual duty** (Beauchamp & Childress, 1983 pg 46):
 - prima facie duties are duties that are on all occasions binding unless they are in conflict with equal or stronger duties. For example: The duty not to kill someone (non-maleficence) may come into conflict with

duty of justice, which includes protecting innocent persons from aggression.

- one's actual duty in the situation is determined by an examination of the weight of all competing prima facie duties. Duties such as beneficence (to benefit others) and fidelity (promise-keeping) are not absolute because they can be overridden under some conditions. Yet they are more than rules of thumb. Because they are always morally relevant, they constitute strong moral reasons for performing the acts in question, although they may not always prevail over all other prima facie duties. One might say that they count even when they do not win.

SOURCES OF MORALITY

These sources operate as the basis for rights (and duties) and for the development of principles.

1. *Divine command* - belief that God reveals (directly or through inspired scripture) norms by which humans shall live. Example: The Ten Commandments in the Bible.
2. *Natural law* - universal norms for human conduct. Example: one should not kill.
3. *Individual insight* - perception of what is right or wrong through intuition or common sense.
4. *Social contract* - specific rights may be drawn from implicit and explicit agreements by members of society. Morality is located in human custom. Example: parental rights.

MEDICAL ETHICAL PRINCIPLES

There are five general principles that are fundamental building blocks in dealing with an ethical dilemma. Each is a prima facie duty.

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1. **FIDELITY.** This is the duty to observe pledges made by the profession to society and thus to individual patients. The two key promises are:
 - 1.1 **Truthfulness** - the promise of telling patients the truth within bounds of fidelity.
 - a. The general assumption that physicians should have the sole authority to decide how much to tell their patients (directed paternalism) has been challenged by the courts and by physicians' organisations. Responsible truth telling - telling only when the patient is ready - is generally accepted.
 - b. A complete disregard for fidelity occurs when the physician adopts an attitude of careless truth-telling.
 - 1.2 **Confidentiality.** Access to a patient's records may be obtained legally by health professionals, hospital personnel and insurance or government representatives. General guidelines of confidentiality include limiting access to those who have a legitimate need, avoiding idle conversation about patients and using fake names and altering other data when presenting cases in conferences and teaching situations.
2. **AUTONOMY.** There is a basic understanding that in the relation between individuals in a moral situation there must be autonomy on the part of the moral decision-maker. Increasingly, medical ethics has stressed the autonomy of the patient or recipient of health care.
 - 2.1 **Truth-telling.** In a manner similar to fidelity, the recognition of autonomy requires that the patient have access to the truth about his or her condition.
 - 2.2 **Decision-making.** One mark of autonomy is the ability to make rational decisions, especially when considering one's own future. Truly moral decisions incorporate respect for the patient's own desires and needs.
 - 2.3 **Respect for individuals.** Patients, always unequal because of their limited knowledge and because they may be too frightened by their illness, are morally unequal to their caregivers and deserve encouragement and respect as individuals.
- 2.4 **Informed consent.** The law requires that diagnostic, medical and surgical procedures must be authorised by a voluntary, knowledgeable consent of the patient or the patient's legal representative. This important aspect of patient's rights originates from the principles regarding battery.
- 2.5 **Patient's rights.**
 - **Refusal of treatment.** A patient who is competent to give consent is also legally entitled to withhold it for whatever reasons he or she deems sufficient. This is true even if refusing treatment may result in serious harm or death to the patient.
 - **Treatment of terminally ill patients.** Under the US legislation, terminally ill patients whose death is imminent have a constitutionally protected right of privacy, which allows them to refuse life-support care that serves to prolong the process of dying.
3. **BENEFICENCE.** The medical profession has a responsibility to do good for patients and the general public. This responsibility may be exercised through the care of individual patients or through efforts directed to preventing or ameliorating health problems in a community. Beneficence includes all efforts to increase the health of a community.
4. **NONMALEFICENCE.** The duty to "do no harm" is one of the oldest guiding principles of the medical profession.
 - 4.1 **Deliberate acts to harm.** This is unacceptable in medical practice.
 - 4.2 **Calculated risk**
 - a. When possible harm may occur, then there must be a compensating and compelling possibility of benefits in order to justify the action.
 - b. For health care professionals, standards of "due care" include knowledge, craft (skill), and perseverance.

5. **JUSTICE.** Equitable distribution of benefits and burdens constitute the subject matter of the principle of justice.

5.1 **Procedural justice.** One means of just distribution is the establishment of rules. To be fair, exceptions to rules should be clearly built into the procedures. The distribution of services on the basis of "first come, first served" is an example of a procedural rule.

5.2 **Distributive justice.** Equal sharing may not always be the most just way to distribute benefits or burdens; additional claims may be involved. Claims requiring decisions based on distributive justice arise when resources are limited; thus, reductions on spending for health care generate the questions of who shall have health care and who shall not.

5.3 **Compensatory justice.** Punishment as retribution is one form of compensatory justice. The more positive aspect is the attempt to reward victims for losses not the consequences of their own action - for example, quotas to combat discrimination.

5.4 **Individual and society.** Often issues of justice rest upon claims of the rights of individuals against claims of the society in which the individual lives. Decisions made for the "good of society" are particularly painful when they discriminate against an individual patient. The physician is often caught between primary duty to the patient and obligations to society.

THE "MORAL CENTRE" OF MEDICINE

1. This concept helps us to define our scope of responsibility when there is a conflict of loyalties. Jonsen and Jameton, 1977 described the content of this "moral centre" as follows:
 - a. diagnosis and treatment
 - b. of an illness or injury
 - c. for an individual
 - d. who presents with a complaint
 - e. within the context of an established therapeutic relationship.
2. Some conflicts of loyalties include:

- clinical research
- obligations of company doctors to the employer
- obligations of the military doctor to the military institution
- obligations to the family members
- obligations to the health care institution e.g., non-payment of bills.

3. How can conflicts of loyalties arising in these and other situations be avoided and/or resolved? Several proposed policy decisions may be helpful.

- Give high priority to the patient's welfare.
- Apply the golden rule on the situation: "Do unto others as you would have them do unto you". One should be careful this is not imposing one's value choices on other people.
- Informed consent. Informing patients of possible conflicts of interest can put the individual on guard so that later choices can be monitored from that perspective.
- Regard the family as the unit of care, since the roots of an individual's problem and/or the means to alleviate it may lie in family dynamics and home environment.

PROFESSIONAL ETHICAL CODES

The doctor-patient relationship is governed by several ethical codes. Examples are The Hippocratic Oath, the International Code of Ethics and the Rights of the Patient. These are reproduced below:

I. THE HIPPOCRATIC OATH

The Hippocratic Oath was probably written in the 5th century BC and was intended to be affirmed by each doctor on entry to the profession. In translation it reads as follows:

I swear by Apollo the physician, and Aesculapius and Health, All-heal, and all the gods and goddesses, that, according to my ability and judgement, I will keep this Oath and this stipulation - to reckon him who taught me this Art equally dear to me as my parents,

to share my substance with him, and relieve his necessities if required; to look upon his offspring in the same footing as my own brothers, and to teach them this Art, if they shall wish to learn it, without fee or stipulation; and that by precept, lecture and every other mode of instruction, I will impart a knowledge of the Art to my own sons, and of my teachers, and to disciples bound by a stipulation and oath according to the law of medicine, but to none other. I will follow that system of regimen which, according to my ability and judgement, I consider for the benefit of my patients and abstain from whatever is deleterious and mischievous. I will give no deadly medicine to anyone if asked, nor suggest any such counsel; and in like manner I will not give to a woman a pessary to produce abortion. With purity and with holiness I will pass my time and practise my Art. I will not cut persons labouring under the stone, but will leave this to be done by men who are practitioners of this work. Into whatever houses I enter, I will go into them for the benefit of the sick, and will abstain from every voluntary act of mischief and corruption; and, further from the seduction of females, or males, of freemen or slaves. Whatever, in connection with my professional practice, or not in connection with it, I see or hear, in the life of men, which ought not to be spoken abroad, I will not divulge, as reckoning that all such should be kept secret. While I continue to keep this Oath unviolated, may it be granted to me to enjoy life and the practice of the Art, respected by all men, in all times. But should I trespass and violate this Oath, may the reverse be my lot.

II THE DECLARATION OF GENEVA AND THE INTERNATIONAL CODE OF MEDICAL ETHICS

The Declaration of Geneva, which is the modern restatement of the Hippocratic Oath was produced by the World Medical Association in 1947 and subsequently revised. Based upon the Declaration of Geneva, an international Code of Ethics which applies in times of both peace and war was also drawn up. The Declaration was amended by the 22nd World Medical Assembly, Sydney, Australia, in August 1968 and the 35th World Medical

Assembly, Venice, Italy, in October 1983. It reads:

At the time of being admitted as a member of the Medical Profession:

I solemnly pledge myself to consecrate my life to the service of humanity;

I will give to my teachers the respect and gratitude which is their due:

I will practise my profession with conscience and dignity;

The health of my patient will be my first consideration;

I will respect the secrets which are confided in me, even after the patient has died;

I will maintain by all the means in my power, the honour and the noble traditions of the medical profession;

My colleagues will be my brothers;

I will not permit consideration of religion, nationality, race, party, politics or social standing to intervene between my duty and my patient;

I will maintain the utmost respect for human life from its beginning even under threat and I will not use my medical knowledge contrary to the laws of humanity;

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

The English text of the **International Code of Medical Ethics** is as follows:

Duties of physicians in general

A PHYSICIAN SHALL always maintain the highest standards of professional conduct.

A PHYSICIAN SHALL not permit motives of profit to influence the free and independent exercise of professional judgement on behalf of patients.

A PHYSICIAN SHALL, in all types of medical practice, be dedicated providing competent medical service in full technical and moral independence, with compassion and respect for human dignity.

A PHYSICIAN SHALL deal honestly with patients and colleagues, and strive to expose those physicians deficient in character or competence, or who engage in fraud or deception.

The following practices are deemed to be unethical conduct:

- (a) Self advertising by physicians, unless permitted by the laws of the country and the Code of Ethics of the National Medical Association.
- (b) Paying or receiving any fee or any other consideration solely to procure the referral of a patient or for prescribing or referring patient to any source.

A PHYSICIAN SHALL respect the rights of patients, of colleagues, and other health professionals, and shall safeguard patient confidences.

A PHYSICIAN SHALL act only in the patient's interest when providing medical care which might have the effect of weakening the physical and mental condition of the patient.

A PHYSICIAN SHALL use great caution in divulging discoveries or new techniques or treatment through non-professional channels.

A PHYSICIAN SHALL certify only that which he has personally verified.

Duties of physicians to the sick

A PHYSICIAN SHALL always bear in mind the obligation of preserving human life.

A PHYSICIAN SHALL owe his patients complete loyalty and all the resources of his science. Whenever an examination or treatment is beyond the physician's capacity he should

summon another physician who has the necessary ability.

A PHYSICIAN SHALL preserve absolute confidentiality on all he knows about his patient even after the patient has died.

A PHYSICIAN SHALL give emergency care as a humanitarian duty unless he is assured that others are willing and able to give such care.

Duties of physicians to each other

A PHYSICIAN SHALL behave towards his colleagues as he would others behave towards him.

A PHYSICIAN SHALL NOT entice patients from his colleagues.

A PHYSICIAN SHALL observe the principles of 'The Declaration of Geneva' approved by the World Medical Association.

III RIGHTS OF THE PATIENT (DECLARATION OF LISBON)

This was considered by the World Medical Association. In 1981, it adopted a Statement on the rights of the patient. Known as the Declaration of Lisbon, it reads:

Recognising that there may be practical, ethical or legal difficulties, a physician should always act according to his/her conscience and always in the best interest of the patient. The following Declaration represents some of the principal rights which the medical profession seeks to provide to patients.

Whenever legislation or government action denies these rights of the patient, physicians should seek by appropriate means to assure or to restore them.

- (a) The patient has the right to choose his physician freely.
- (b) The patient has the right to be cared for by a physician who is free to make clinical and ethical judgements without any outside interference.
- (c) The patient has the right to accept or to refuse treatment after receiving adequate information.
- (d) The patient has the right to expect that his physician will right to expect that his physician will respect the confidential nature of all his medical and personal details.
- (e) The patient has the right to die in dignity.
- (f) The patient has the right to receive or to decline spiritual and moral comfort including the help of a minister of an appropriate religion.

FURTHER READING

On principles of medical ethics: Beauchamp and Childress. Principles of Bioethics, 2nd edition. Oxford: UOP, 1983. Chapters 3-7.

On physician-patient relationships: Graber GC, Beasley AD & Eaddy JA. Ethical Analysis of Clinical Medicine. Baltimore: Urban & Schwarzenberg, 1985. Chapter 1.

On the "Moral Centre" of Medicine: Graber GC, Beasley AD & Eaddy JA, Ethical Analysis of Clinical Medicine. Baltimore: Urban & Schwarzenberg, 1985. Chapter 3.

ETHICS IN FAMILY PRACTICE

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Ethical issues pervade family medicine, although the ethical questions that have attracted the most attention are the controversial "headline" issues such as euthanasia, abortion, human experimentation and genetic engineering, including the use of foetal tissue for treating certain diseases. Thus, the more mundane but more pervasive problems that arise in the daily practices of family physicians have been left aside.

Further, economic, social, legal and political factors have combined to effect major changes in medical practice and government health care policies. Also, concern for patient rights and patient autonomy, as well as the demands of third party payers, like insurance companies, have transformed the practice of medicine.

A family physician has been educated, trained and equipped with attitudes and skills to provide continuing, comprehensive health maintenance and medical care to the entire family regardless of age, sex or type of problem, be it biological, behavioral or social. Further, the practice of primary care/family medicine is rooted in a relationship between the patient as a person and the physician as a professional.

Thus, ethics in family medicine is the consideration of the ethical aspects of this physician-patient

relationship, bearing in mind that the family is the unit of care, a key conceptional component of family medicine.

The ethical issues that will be considered in this paper are:

1. Confidentiality
2. Informed consent
3. The noncompliant patient
4. Referrals
5. Financial gatekeeping
6. The physician as a human being

CONFIDENTIALITY

Although few medical graduates take the Hippocratic oath, the principle of confidentiality remains a cornerstone of medical ethics. The principle of confidentiality is one of the most widely accepted and historically influential principles governing the patient-physician relationship. The Hippocratic oath mandates that the physician not divulge "whatsoever I shall see or hear in the course of my profession as well as outside my profession in my intercourse with men, if it be what should not be published abroad". However, certain national medical bodies have qualified this by mandating that physicians "shall safeguard patient's confidentiality within the constraints of the law".

Confidentiality is important as a way

- (1) of encouraging patients to be frank in their communication with physicians
- (2) of physicians keeping an implicit promise to patients that their confidence will be respected
- (3) of emphasizing the patient's rights to privacy.

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This preserving of confidentiality strengthens the relationship between an autonomous patient and a professional physician.

As the delivery of health care has changed from the model of a single physician caring for individual patients to the model of a team of health care workers in an institutional setting providing care to a wide variety of patients, this mandate of confidentiality has changed. Physicians can now divulge information about their patients to those members of the health care team and those institutional employees who have a need for the released information, either to provide appropriate care or to meet appropriate institutional needs. Note the underlying theme remains that information should not be provided to anyone else without the patient's consent.

The principle of confidentiality extends to not providing information to family members of competent adult patients unless the patients want the information to be shared. In cases of doubt, the patient should be consulted, especially if the information is of a sensitive nature or if there is evidence of family discord. Particular care must be taken especially in pregnancy, venereal disease, AIDS, and family dispute over property inheritance when prognosis is poor.

Certain cases are particularly troublesome. Among the most troublesome are those involving teenage patients seeking abortions, contraceptive advice, or treatment for venereal disease, drug abuse, or psychiatric problems. Unless confidentiality can be guaranteed, such patients may not seek out the care they need. If confidentiality is protected, such patients may not get the parental counselling and support from which they could also benefit.

Equally troubling are cases involving elderly patients who are less than fully competent but far from totally demented. Families of such patients often ask physicians to provide them with information about the patient's condition, information that they may not want to share with the patient. Such a request may be perfectly appropriate for the clearly incompetent demented patient, whereas it is obviously inappropriate for normal geriatric patients.

Exceptions to the general rule of confidentiality:

The exceptions to the rule of confidentiality are:-

- (1) Consent of the patient
- (2) Medical colleagues
- (3) Statutory duty
- (4) Information to relatives
- (5) Research projects
- (6) The public interest
- (7) Disclosure in court
- (8) Court order for disclosure of documents

1. Consent of the patient

A doctor may divulge information about a patient if asked to do so, either by the patient or by his legal adviser. After the death of the patient, consent to the disclosure of confidential details can be given by the executor of the estate.

2. Medical colleagues

Information concerning a patient may be shared with medical colleagues who are also responsible for the clinical management of the patient, also as mentioned previously, with other members of the health care team like social workers, health visitors, physiotherapists etc - people who are properly concerned with the care of the patient and who appreciate the rule of professional secrecy.

3. Statutory duty

Where the doctor is required by law to notify an authority of a particular disease, eg the notification of infectious diseases, or of drug addicts, the doctor may do so without prior reference to the patient.

4. Information to relatives

Doctors are frequently asked questions by anxious relatives, and, in most cases, it is appropriate to make limited comments to the nearest relative. The information may be given provided:-

- there is no reason to believe that the patient would object, and

- particularly where it is inappropriate on medical grounds to seek the patient's consent for disclosures.

Particular care must be taken in any matters involving pregnancy, venereal disease and other sensitive issues.

5. Research projects

It is ethical to disclose information for bona fide research projects which have the approval of a recognised ethics committee.

6. The public interest

Doctors sometimes face a conflict between their duty to individual patients and their duty to the general public. Common examples include uncontrolled epileptics and alcoholics, who continue to drive.

7. Disclosure in court

A doctor, like a priest, but unlike a lawyer, has no privilege in court, and if ordered to divulge medical information when acting as a witness must do so even under protest. A judge, magistrate or coroner may demand such disclosure on pain of a fine or even imprisonment in the event of refusal.

8. Court order for disclosure of documents

Under certain circumstances, an application may be made to the courts for an order for the production and disclosure of relevant medical records to the applicant and/or medical adviser or any other professional adviser of the applicant. Once this court order has been made, the doctor concerned is not entitled to withhold the documents in question.

It is interesting to note that in its publication "Professional Conduct and Discipline: Fitness to Practice", the General Medical Council of the United Kingdom emphasizes the duty of professional secrecy even after the death of the patient.

INFORMED CONSENT

The principle of informed consent is a much more recently articulated principle than the principle of confidentiality, and has come to be accepted as

one of the fundamental principles governing the relation between patients and physicians.

The principle basic mandate is that the physician must obtain the free and informed consent of his patient if the patient is competent to give that consent, or of the patient's surrogate if the patient is not competent, before any medical treatment is provided or carried out.

Two exceptions are normally recognized:

- (1) The emergency exception
- (2) The therapeutic privilege

The first (the emergency exception) is invoked when emergency treatment is necessary to protect the patient's life or health and consent cannot be obtained in a timely fashion.

The second (the therapeutic privilege) is invoked when there is strong reason to believe that the very attempt to obtain consent will be harmful to the patient because of the psychological impact of the information conveyed. In other words, this therapeutic privilege allows physicians to withhold information when they think a patient may be unable to cope with the information or may be harmed by it.

Informed consent also addresses the physician/surgeon to focus on the narrow question of which risks associated with a medical procedure should be disclosed to the patient.

The cornerstone of informed consent and doing no harm to your patient is the patient's welfare. What a physician tells a patient and when and how it is told must be determined with the patient's welfare in mind. However, it should be emphasized that the moral and legal presumption is in favour of disclosure and that the onus of justifying an exception to this presumption is on the physician.

Giving information to a patient may be harmful

1. Information could cause patient to reject the treatment plan
2. Complete disclosure might jeopardise the therapeutic effect of the physician-patient relationship
3. Information might generate a self-fulfilling prophecy, e.g. nausea

4. Amount of time required for complete disclosure
5. Withholding information can also maintain physician control

Therapeutic benefits attached to complete disclosure

1. More compliance with treatment plans
2. Less anxiety
3. Recovery from surgery more quickly
4. Ability to protect their own health, eg detecting errors in dosage or type of medication and recognizing side effects of drugs.

In the area of informed consent, difficulties will arise when treating teenage patients. Informed consent is obtained from parents before we treat children, but from patients once they become adults. How should physicians treat teenage patients? There are special laws passed in certain countries allowing physicians to treat them after obtaining only their consent when

- (1) the treatment is for venereal disease, pregnancy, contraception or drug-related problems;
- (2) they are living away from their parents and are responsible for their own affairs; or
- (3) they are married.

THE NONCOMPLIANT PATIENT

Implicit in the principle of informed consent, the principle that medical treatment can only be provided after the patient has freely and knowingly consented to it, is the concept that a patient may choose not to comply with the physician's recommendations and that the choice not to comply must be respected.

Several studies of noncompliance have indicated that the majority of cases of noncompliance involve failures of communication, lack of trust due to previous bad experiences with the physician concerned, and psychologic and psychopathologic factors.

Physicians confronting noncompliant patients need to assess:

- (1) the noncompliance,
- (2) evaluate its cause, and
- (3) react appropriately.

A form of noncompliance that deserves special attention is the patient who does not go and buy the medicine prescribed, or attend follow-up consultations. This is sometimes due to the patient's financial condition.

A similar problem often arises when one considers the question of side effects of various drugs. Different patients with different values and different tolerances may find certain side effects unacceptable. The physician should certainly not assume that a pattern of side effects that is acceptable to the physician will be acceptable to the patient.

SPECIAL PROBLEMS IN TERTIARY CARE MANAGEMENT

When the focus shifts from primary care provided by the family physician to care provided by subspecialists in tertiary care settings, new ethical problems arise and old ethical problems become even more complicated.

Referrals

Referrals to subspecialists practising in tertiary care institutions can provide anxiety on the part of patients.

The referring family physician risks losing a patient and is subject to embarrassment if a mistake is discovered.

Knowing when to use consultants requires courage and humility.

Courage is the ability to act competently and wisely without being swayed by irrational fears.

Humility is the willingness to recognise one's actual limitations and to act accordingly.

An important point to note is that even if the primary care physician does decide to refer the patient, he or she remains the patient's primary physician.

When initiating a referral, the primary care physician's responsibilities are

1. to educate the patient as to the reasons for referral
2. to recommend a subspecialist or treatment centre best suited to the patient's medical and personal needs
3. to prepare the patient for what lies ahead, and
4. to provide the specialist with data relevant to the patient's illness.

Even after the referral the primary care physician remains responsible for the quality of the patient's care.

Finally, in referrals, primary care physicians must

1. *know* the patient and the patient's family well enough to recommend the appropriate specialist
2. *educate* the patient and the family on the strengths and weaknesses of the available options
3. *find* a subspecialist who will be appropriate to their patient's medical needs and personal preferences.

Financial Gatekeeping

With soaring costs of health care leading to corporations and government agencies to develop prospective payment systems and capitation plans, the role of primary care physicians serving as gatekeepers of the health care network is more important than ever. It is hoped that will save money and streamline the referral process. On the other hand, this might allow money to compete with quality in determining the standard of care, and inhibit the physician's freedom to practise holistic family medicine.

In this system, when particular patients require care in excess of the normal level of reimbursement by an organization, the primary care physician confronts a major ethical dilemma.

In caring for individual patients, physicians should distinguish between providing what the patient wants and what the patient needs. When patients request unnecessary or marginally beneficial procedures and services, physicians must refuse.

THE PHYSICIAN AS A HUMAN BEING

It is ironical that in this era where truly impressive gains have been acclaimed in the battle against sickness, suffering and death, physicians themselves seem remarkably inept at maintaining their own health and well-being for they suffer high rates of alcoholism, drug abuse, divorce, burnout and suicide.

To deal with these problems, it is recommended that physicians learn to distinguish between competence and perfectionism, dedication and "workaholicism", and compassion and sentimentalism. Young doctors very often have put their careers ahead of self and family, coupled with an unrealistic perception of their capabilities and those of their profession. They have also allowed their egos to become too closely identified with their successes and failures, and become obsessed with insecurity (they are not good enough) and guilt (they do not work hard enough).

Mistakes are inevitable, and physicians must learn to acknowledge their capacity to err and must learn to discuss errors in a constructive manner. Physicians who do not admit their mistakes are doomed to repeat them. Physicians who discuss their mistakes can learn from them and experience healing in the process, and become more effective clinicians. The physician who takes the time to care for personal and family needs is a more effective clinician. The primary care/family physician, by maintaining a healthy lifestyle, will become a role model for personal health and fitness.

Emotions have an important role in reminding physicians of their humanity and the humanity of their patients. Clinicians must help patients recognize, express and interpret their emotions. Clinicians must similarly become aware of their own emotions, recognize their clinical values and learn how to express and interpret them. Thus, the physician who ignores the emotions deharmonizes the physician-patient relationship.

Suffering patients need a physician who will suffer alongside them and who will help them to express and interpret their feelings. The physician who suffers alongside a suffering patient or family allows the opportunity for healing of self as well as of the patient or family. To maintain personal well-being, therefore, the physician must find appropriate outlets for expression and interpretation.

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LEGAL ASPECTS OF MEDICINE

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INTRODUCTION

The doctor is a citizen like everyone else and therefore he is subject to the laws of the land. In addition, in the course of his professional work, there are certain areas of the law that have special relevance to him. He needs to have a working knowledge of these areas. It is important to note here that a plea of ignorance of the law is no excuse for any contravention of the law.

STATUTORY LAWS

The following are statutory laws regulating medical practice in Singapore. The main provisions of some of these (marked + below) are described in the Appendix.

Registration to practice	- Medical Registration Act+
Clinic licensing	- Private Hospitals & Medical Clinics Act+
Medicinal products and medical advertisements	- Medicines Act 1975+
Drugs	- Poisons Act+ - Misuse of Drugs Act, 1973+

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Radioactive materials	- Radiation Protection Act 1973
Treatment related	- Mental Disorders and Treatment Act - Termination of Pregnancy Act - Voluntary Sterilisation Act - Medical (Therapy, Education & Research) Act - Human Organ Transplant Act
Public health related	- Registration of Births and Deaths Act - Infectious Diseases Act 1976 - Destruction of Disease-Bearing Insects Act - The Environmental Public Health Act
Work related	- Factories Act - Workmen's Compensation Act 1975 - Employment Act
Others	- Companies Act

TORT

In the area of tortious liability, the doctor may be exposed to charges of medical negligence by his own actions or omissions. His duty of care and standard of care may be questioned. As an employer he is also vicariously liable for his employee's negligence. When he writes a medical report on a patient he may be liable to a defamation suit if his patient has been defamed.

Medical negligence

In order to succeed in a civil action in medical negligence, the plaintiff must prove four things:

- that he was owed a duty of care by the defendant.
- that the defendant was in breach of that duty of care.
- that the plaintiff suffered injury.
- that the injury was caused by the breach of the duty of care.

The plaintiff must establish that all of these conditions have been fulfilled before negligence is proven.

In law, medical negligence does not mean carelessness, though carelessness is included in it. It means lack of professional skill causing injury. It has been suggested that it would be better to call it "liability for medical mishap" (Ref: Ormrod R. An aetiological approach to the law. J Royal Soc Med 1987;80:731-7). Doctors when facing a charge of negligence must remember this concept in order to answer the charge rationally and without emotion.

Lawyers have broadly analysed the work of a doctor in medical practice as falling into three categories: diagnosis, advice and treatment. As far as diagnosis and treatment are concerned, whether or not negligence has occurred has been decided in accordance with what is now described as the "Bolam principle".

In the case *Bolam v Friern Hospital Management Committee* (1957), Mr Justice McNair directed the jury that a doctor is not guilty of negligence if he acts "in accordance with a practice accepted as proper by a responsible body of medical men skilled in that particular art".

Duty of care

The duty of care begins when the doctor sees the patients. In the case of the Accident and Emergency Department of a public hospital, duty of care appears to begin as soon as the patient enters its doors.

In Barnett v Chelsea and Kensington Hospital Management Committee (1969) 1 QB 428, a man

visited the defendant hospital's casualty department complaining of vomiting after drinking tea. The nurse on duty reported the duty to the duty medical casualty officer who refused to see him and directed he be sent home. The man died five hours later from arsenical poisoning. It was held that both the hospital and the casualty officer owed the man a duty of care.

Standard of care

The law requires a standard of care to be observed by a man professing some particular skill or competence, which is different to and of higher order than, that required to be exercised by the ordinary man in the street. The standard of care that is to be expected will be that of his peers, in accordance with the Bolam principle. Some examples of unacceptable standard of care are described below.

(1) Failure to attend or examine

Where a person comes to harm because the doctor has not responded to his request to attend or examine, that doctor will be liable for negligence.

What about the situation of the general practitioner when asked to do a house visit? The doctor will be permitted to exercise his discretion when determining whether or not a patient's condition warrants a house visit. His decision will be weighed against what a reasonably competent general practitioner will do in coming to a decision whether or not a doctor in the particular circumstances has exercised this discretion negligently or not.

On balance, unless one is very certain about the patient's condition and that there is a means for monitoring the progress, it is safer to go than to just give advice over the telephone. Certainly, abdominal pain should not be dealt with over the telephone.

(2) Failure to diagnose or incorrect diagnosis.

Failure to diagnose a condition correctly, in circumstances where a reasonably competent member of the same class of practitioners would not have so failed, will render a doctor liable in negligence.

In McCormack v Redpath Brown and Co Ltd, the Times, 24 March 1961, a hospital casualty doctor was found to be negligent in failing to find a hole in the plaintiff's head of $1\frac{1}{4}$ - $1\frac{1}{2}$ inch diameter, after he had been hit on the head with a spanner. It should not have been overlooked on a proper physical examination.

In Dale v Munthali (1124), the defendant was found liable, not for failing to diagnose meningitis, but for wrongly diagnosing flu. He should have referred the patient to hospital for further testing.

(3) Error in judgement, or giving of treatment.

It is comforting to note that not every error will be considered negligent. The following case illustrates this point.

In Whitehouse v Jordan (1981) 1 All ER 267, during what had been a very difficult labour, the defendant, a senior hospital registrar, attempted a trial by forceps delivery. He pulled six times and when there was no progress or movement on the fifth or sixth occasion and twenty-five minutes after starting, he went on to Caesarian section, which was quickly and skilfully performed. However, the plaintiff's child was found to have suffered severe brain damage from asphyxia. It was alleged that the defendant had pulled too hard and too long. The House of Lords unanimously held that he had not been guilty of negligence. The expert and other evidence did not justify the allegation.

There may have been an error of clinical judgement - in one sense there obviously was - but it was not negligent.

(4) Failure to communicate.

From time-to-time during the management of a patient, information critical to the well-being of the patient will need to be transmitted either to the patient or to another medical professional involved in the treatment. A failure to communicate sufficient information, or accurate information, may amount to negligence.

(5) Failure to explain or warn.

Where a medical practitioner fails to explain fully to the patient, the treatment or procedure which he proposes to undertake, or fails to give an adequate warning of possible complications or side effects that might occur, the doctor may be guilty of negligence.

(6) Duty to inform where something goes wrong.

It is important to inform the patient when something goes wrong. However, one need not admit liability. This is better left till after consultation has been made with the medical defence union or society.

In Gerber v Pines (1934) 79 Sol Jo 13, where a needle broke in the course of the giving of an injection, it was held that there was negligence in not informing the patient of what had happened, although not in the giving of the injection itself.

Defamation

Defamation may be defined as a false statement about a person to his discredit or which exposes him to hatred, ridicule or contempt. It is called libel when the statement is permanent e.g., writing or printing and called slander when the words are conveyed in some form that is not permanent e.g., spoken.

Defamation by a doctor. Testimonials, medical reports and various certificates may be defamatory if they are not thoughtfully composed. Publication may arise if any of these fall into wrong hands - a defamation suit may ensue.

Defamation of a doctor. Doctors like everyone else may sue when they are defamed. He does not need to show proof of actual loss when he is slandered in respect of his professional competence or professional conduct.

CRIMINAL LAW

In the area of criminal law, the aspects relevant to the doctor are being a witness and obtaining informed consent. Of course the doctor may be named a defendant if he has contravened the Penal Code.

Being a witness

The doctor may be asked to examine persons who have been assaulted or raped. Subsequently, this doctor will render evidence in court as a witness.

Occasionally, he may be summoned as an expert witness, if he has special skills which can help the Court.

Informed consent

Treatment or investigations carried out without the consent of the person concerned (or in the case of a child, a parent) can amount to an assault and may result in an action for damages. Consent once given can be withdrawn by a competent patient at any time prior to the completion of a procedure.

The types of consent can be implied, oral and written.

Implied consent. For most physical contacts between doctor and patient, consent is implied. It can be assumed that a patient has consented to abdominal palpation for instance, when he or she voluntarily undresses and lies on a couch; likewise, when a patient offers an arm for venepuncture.

Oral consent. Oral consent is not usually appropriate for major procedures. If only oral consent is obtained, the doctor is advised to make an entry (which may be abbreviated) in the clinical notes which confirms that consent has been given.

Written consent. Written consent is not absolutely necessary to defend an action for assault but it will afford documentary evidence that consent has been obtained. Written consent is recommended:

- for all procedures requiring a general anesthetic;
- for operations other than minor ones performed under local or regional anaesthesia;
- for major invasive procedures like endoscopies, biopsies etc; and
- for potentially hazardous investigative techniques such as angiography or the use of radio-active isotopes.

Obtaining a consent. Consent should be obtained

preferably a short time before the proposed operation (but before pre-medication is given.) Time should be spent explaining to the patient. Consent should be limited to what is necessary for the patient's condition. If the patient is not competent to understand, then his or her consent will not be valid; the next-of-kin needs to be sought to give consent.

Inability to obtain consent. If a patient is unconscious or if there is a genuine emergency a doctor may safely undertake whatever treatment is necessary to ensure the patient's life or health without waiting to obtain formal consent.

MAIN LEGAL TRIBUNALS

The main legal tribunals related to medical practice are: the coroner's court, the criminal court and the civil court.

Coroner's Court. This is the court convened to conduct inquiries as to the cause of any death, and is held by Coroner under the provisions of the Criminal Procedure Code. The Court is assisted by a state pathologist and an investigating officer who is usually a police officer.

Criminal court. Criminal proceedings following a finding of negligence may be instituted under the provisions in the Penal Code.

Civil court. The civil courts which include the Supreme Court and the Subordinate Courts are the forums which hear civil cases, which in the case of doctors usually cover negligence, trespass and contract.

APPENDIX - Notes on Relevant Statutes

THE MEDICAL REGISTRATION ACT

1. This Act provides for the registration and provisional registration of duly qualified medical practitioners.
2. The Act also provides for the establishment of the Medical Council.
The Medical Council consists of 13 members.

The Director of Medical Service by virtue of his position is the Registrar of the Medical Council. Six other members are appointed whilst six members are elected from amongst all medical practitioners.

3. It appears that all persons with recognised qualifications are registered unless
 - a. he has been convicted of any heinous offence or
 - b. he is deemed by the Medical Council to have been guilty of infamous conduct in any professional respect.
4. Privileges of persons registered under the Act are
 - a. to practice medicine, surgery and midwifery and
 - b. to recover in due course of law reasonable changes for professional and advise, services etc
 - c. sign any certificate or document required by written law to be signed by a duly qualified medical practitioner.
5. The Medical Council is the disciplinary body of the medical profession. It is empowered to censure, suspend or strike off any registered medical practitioners from the medical Register.
6. An aggrieved person may appeal to the High Court against any decision of the Medical Council.
7. The Penalty against practising medicine without being duly registered is a fine up to \$500 and \$50 for each day of continuance of the offence.
8. Exemption from the Act
 - a. Serving Medical Officer of Armed Forces.
 - b. Ship's surgeon in discharge of their duties.
9. Nothing in this Act shall be construed to prohibit or prevent the practice of systems of therapeutics according to Malay, Chinese or Indian method.

10. The Medical Registration Regulations, 1972 provide for procedures for Medical Council meetings, registration, disciplinary proceedings.

PRIVATE HOSPITALS & MEDICAL CLINICS ACT

1. An Act to provide for the control, licensing and inspection of private hospitals, medical clinics and clinical laboratories, to prohibit trading in human blood, and for purposes connected therewith, and to repeal the Nursing Homes and Maternity Homes Registration Act.
2. This Act shall come into operation on 1 January 1993 for private hospitals and 1 January 1994 for Medical and Dental Clinics.
3. In the Act "Medical Clinic" means any premises used or intended to be used by a medical practitioner, a dentist or any other person:-
 - (a) for the diagnosis or treatment of persons suffering from, or believed to be suffering from, any disease, injury or disability of mind or body; or
 - (b) for curing or alleviating any abnormal condition of the human body by the application of any apparatus, equipment, instrument or device requiring the use of electricity, heat or light.

Hence, besides doctor's clinics, premises of dental surgeons, dentists, physiotherapists and others will need to be licensed.

4. Any person who manages or controls any unlicensed hospitals, clinics or laboratories is liable to a fine of \$5000 and/or imprisonment of up to two years.
5. There is provision for registration of different types of hospitals, e.g. maternity hospital, children's hospital, psychiatric hospital.
6. Licences are subject to terms and conditions as the Director of Medical Services may impose. Licences may be modified or revoked.

7. The Act provides for appeal against the Director's decision to the Minister whose decision is final. In the case of an appeal by a doctor relating to his medical clinic, his appeal shall be referred to an advisory committee consisting of the members of Medical Council.

The Minister shall have regard to any report made to him by the Advisory Committee.

8. The Minister may exempt any private hospital, medical clinic or clinical laboratory from all or any of the Provisions of this Act.

THE PRIVATE HOSPITALS AND MEDICAL CLINICS REGULATIONS - 1991

1. These regulations provide for procedures of licencing private hospitals, clinics and laboratories.
2. Licence fees for medical clinics of 1 to 5 doctors are \$600.
3. Qualifications for various hospitals, homes, clinics, laboratories are laid down.
4. Every manager of private hospital shall ensure that every patient be informed of the estimated total charges which are likely to be incurred in respect of his hospitalisation and treatment.
5. Every hospital, clinic, laboratory shall maintain proper medical records.
6. A private hospital shall maintain an intensive care unit and where obstetric services are provided, neonatal intensive care services are to be provided.
7. Regulations provide for every private hospital to provide anaesthetic, blood, diatetic, emergency, laboratory, medical nursing pharmaceutical and radiological services.
8. Every private hospital shall have a quality assurance programme to monitor and evaluate the quality and appropriateness of patient care, pursue opportunities to improve patient care and identify and resolve problems.

9. Every medical clinic shall provide adequate privacy to every patient under examination or treatment.

10. Patients should not be lodged at a clinic for more than 12 hours.

11. Approval from Director required for provision of special care services, namely

- (1.) Blood and blood product collection, processing, storage, distribution and transfusion services (including Autologous blood transfusion).
- (2.) Ambulatory surgery.
- (3.) Endoscopy.
- (4.) In-vitro fertilisation.
- (5.) Lithotripsy.
- (6.) Renal dialysis.
- (7.) Specialised cardiac investigation.
- (8.) Specialised diagnostic radiology.

12. Where ambulatory surgery is done, provisions for recovery and anaesthesia are required.

13. Every medical clinic shall have resuscitation facilities for emergencies.

14. Adequate equipment and provision for sterilisation are laid down.

15. All clinical procedures must be carried out by adequately trained doctor and delegation to any staff duties which can only be performed by a doctor.

16. Provisions for licensing of different types of laboratories, their facilities, quality control, personnel and records.

17. Unlicensed premises shall not be called "hospital", "medical clinic", "dental clinic".

Any occupier of any premises which is not licensed under these Regulations shall not use the name "hospital", "medical clinic", "dental clinic", "medical centre", "dental centre",

"medical surgery", "dental surgery", "clinical laboratory", "medical laboratory" or any other term or name to imply similarity to the practices and premises of a private hospital, medical clinic or clinical laboratory.

MEDICINES ACT 1975

This is an Act to make provisions with respect to medicinal products and medical advertisements and matters connected therewith.

S5 "Except in accordance with a licence granted for the purposes of this section, no person shall in circumstances to which this section applies:-

- a. sell, supply or export any medicinal products,
- b. procure the sale, supply or exportation of any medicinal product; or
- c. procure the manufacture or assembly of any medicinal product for sale, supply or exportation.

S6 (2) No person shall manufacture or assemble any medicinal product except in accordance with a licence granted for the purposes of this subsection.

S7 (4) The restriction imposed by S5 and S6 shall not apply to the preparation, dispensing and assembly of any medicinal product by or under the supervision of a practitioner for the purpose of administration to a patient under his care.

S8 Exemption in respect of herbal remedies.

S31 No adulteration of medicinal products to affect injuriously the composition of the product.

S44 The labelling of medicinal products. All dispensed medicine must have

- a. Patient's name
- b. Name and address of the clinic
- c. Date of supply of medicine
- d. Direction for use
- e. Name of medicine
- f. Strength of medicine

S49-53 These sections deal with medical advertisements and promotion of sales of medicinal products.

S76 The Medicines (Advertisement and Sale) Act and the Sale of Drugs Act were repealed by this Act and Poisons Act amended.

POISONS ACT

An Act to regulate the importation, possession, manufacture, compounding, storage, transport and sale of poison

S3 The substances in the Poisons List must shall be deemed to be poisons within the meaning of this Act.

S5 No person shall without a licence from a licensing officer import, possess for sale, sell or offer for sale any poison.

S7 (1) Nothing in S6 shall apply in

- a) to a medicine which is supplied by a medical practitioner for the purposes of medical treatment of his patients.

(2) Labelling of poisons

(3) Maintenance of Poisons Book

S15 (1) Powers of licensing office to search and take possession of any substance found therein and reasonably believed to be or to contain a poison.

(2) Licensing office may take extracts from any book or record relating or reasonably believed to be related to any dealing in or with poisons.

S17 (1) Penalty

a) A fine not exceeding \$1000 or in default of payment imprisonment not exceeding 6 months.

b) Where on the opinion of the court there is culpable negligence, a fine not exceeding \$5000 and/or imprisonment not exceeding 12 months.

(4) Where an agent or servant, in the course of his employment is guilty of an offence and where it is proved that the offence was committed with the consent or connivance of, or is attributable to any neglect on the part of his principal or employer, such principal or employer shall be deemed to be guilty of that offence.

THE MISUSE OF DRUGS ACT, 1973

1. An Act to provide for the control of dangerous or otherwise harmful drugs and for purposes connected therewith.
2. This Act makes it an offence to traffic, offer to traffic, manufacture, possess, smoke, administer, consume a controlled drug.

- (a) Name
- (b) Identity Card No
- (c) Sex
- (d) Age
- (e) Address
- (f) the drug to which the person is believed to be addicted

MISUSE OF DRUGS REGULATIONS 1973

Regulation 6 (2) A medical practitioner or dentist may administer to a patient any drug specified in the Second or Third Schedule.

Regulation 14, 15 Keeping of register for scheduled drugs (see Fifth Schedule)

Regulation 17 All registers shall be preserved for a period of 3 years.

Regulation 19 A medical practitioner who attends a person who he considers, or has reasonable grounds to suspect, is a drug addict shall within seven days of the attendance furnish to both the Director of Medical Services and the Director, Central Narcotics Bureau the following particulars of that person:-

Regulation 20

(1) All stocks of controlled drugs shall be kept under lock and key in the dispensary or in any other suitable part of the premises under the control of a pharmacist or of the person authorised to supply controlled drugs by or under these Regulations.

Regulation 21

Appointment of inspectors
(2) An inspector may at all reasonable times enter upon any premises in which he reasonably believes controlled drugs are kept or stored and may with such assistance as he considers necessary inspect stocks of controlled drugs held in such premises, take abstracts of and take possession of records and documents relating to purchase, sales and supply of controlled drugs from the premises.

Fifth Schedule				
ENTRIES TO BE MADE IN CASE OF OBTAINING				
Date on which supply received	NAME	ADDRESS	Amount Obtained	Form in which obtained
	Of person or firm from whom obtained			
ENTRIES TO BE MADE IN CASE OF SUPPLY				
Date on which the transaction was effected	NAME	ADDRESS	Particulars as to licence or authority of person or firm supplied to be in possession	
	Of person or firm supplied			

CONFIDENTIALITY AND THE RIGHTS OF THE FAMILY

C M Y Chang, MBBS(S), MCGP(S), FCGP(S), P.B.M

Four clinical situations are described that illustrate the ethical conflicts in the rights of the patient and his/her family. Suggested solutions are given at the end of the questions.

CLINICAL SITUATIONS

Case 1

An eight year old girl comes to consult you with symptoms of fever and a rash. You diagnose her as suffering from chicken pox. You inform the parents of the diagnosis, prescribe treatment, gives two weeks of medical leave (diagnosis stated in medical certificate) and inform the Ministry of Environment?

What are the ethical issues involved?

What are the conflicts of medical ethics?

Case 2

A forty year old businessman presents to you with a purulent urethral discharge. History of exposure and a positive smear confirms diagnosis of gonorrhoea. He has had sex with his wife after his sexual exposure, but she has no symptoms yet. You tell him that both he and his wife have to be treated. With considerable emotion, he begs you not to tell his wife the truth, and also not to inform the Ministry of Health, as he is a socially well known personality.

What are the ethical issues involved here?

How would you manage the situation?

Family Physician

Chang Clinic

1 Jalan Anak Bukit #B1-09/10 Singapore 2158

Case 3

A sixteen year old school girl requests contraceptive pills. She and her family are your patients of many years standing. Her parents have trusted you in many matters, both medical and non-medical. She requests that her parents not be told.

What are the ethical issues and dilemma involved here?

How would you solve the problems?

Case 4

The reason for Mr A's chronic diarrhoea is now clear. He has an advanced carcinoma of the colon, diagnosed by a barium enema X-ray. His wife and their children request that you do not tell him the diagnosis, as they think he will get depressed and give up all interest in life if he knows what he is suffering from.

What are the ethical issues involved here?

How would you solve the problems?

SUGGESTED ANSWERS TO THE CASES

Case 1

Ethical issues are

1. diagnosis revealed to parents
2. diagnosis written in the medical certificate
3. informing Ministry of Environment.

No conflicts because

1. she is a minor
2. to prevent spread to other students. Confidentiality is not kept because it is a disease most people do not mind revealing and that you have given her a long leave of 14 days
3. statutory requirement warrants it.

Case 2.

Ethics with regards to wife:

1. **Beneficence** - to treat wife as she is most likely to be infected.
2. **Fidelity** - truth telling to wife, as your patient.
3. **Nonmaleficence** - telling the truth may hurt her and the marriage.

Ethics with regards to Ministry of Health:

1. **Fidelity** - to the patient by not reporting.
2. **Law** requires notification.

Management

Encourage the patient to tell the wife himself. If difficult, you will help. Alternatively you can, with his consent, tell her in his presence. If you sense that truth telling may hurt her too much and may ruin the marriage, then encourage her to be treated first (beneficence) and arrange a conference at a more appropriate time and setting where the three of you will participate. Truth or something close to truth can be revealed and discussed. Other related problems can then be thrashed and sorted out.

Never tell the wife behind his back.

Ministry of Environment notification is not a problem, as no name or NRIC need be filled in.

Case 3

Ethical Issues:

1. **Fidelity and beneficence** to the family as a unit.
Truth, honesty and trust are important.
Secrets are destructive:
 - a Erosion of family unit if parents are not informed.
 - b Truth will hurt the parents otherwise.
2. **Autonomy** - Entering into collusion with the youth will give the autonomy, but parental or corporate family autonomy will be eroded.

3. **Moral centre concept** If you do not know the parents, then her confidentiality outweighs any duty you have to her parents.

Management of the situation

Discuss with the youth, explain that her parents always mean her good no matter how they may react initially. Convince her that parents best know about her sexual activity. You can help cushion the impact by having a joint conference with her and her parents either in the consultation room, or even at their home.

Case 4

Ethical issues are:

1. **Fidelity** to patient by telling the truth.
2. **Nonmaleficence** to patient by preventing him being adversely affected by the bad news.
3. **Autonomy** to the patient because truth telling enables him to make decisions for himself regarding treatment, writing his will, or even making peace with God.
4. **Regard to family as a unit.** Most probably the assessment of the family members about the readiness for the patient to accept the truth is better than the doctor's.

Solution

To assess the patient's mental attitude, to see if he is a person who wants the truth or can tolerate the truth or not.

To comply with the family's wishes on proviso that if the patient wants the answer and is able to accept it, you will tell him. In this way, you can take into consideration **nonmaleficence** to the patient and **regard of family as a unit** and at the same time, **autonomy** for the patient is not compromised.

CERTIFICATION OF DEATH

Prof Chao Tzee Cheng PPA, FAMS FRCPATH FCLM

INTRODUCTION

In Singapore, all deaths must be certified in prescribed form, the Certificate of Cause of Death (CCOD), which is a legal document. The persons qualified to sign these certificates are registered medical practitioners, pathologists or inspectors of death. The laws in Singapore require all unnatural, violent, unexpected deaths, deaths from unknown causes and deaths under suspicious circumstances to be reported to the Coroner through the Police, so that the police can carry out the appropriate investigations. These cases are subjected to post-mortem examination by forensic pathologists to establish a cause of death. The CCOD is then signed by the forensic pathologist. Other registered medical practitioners and the inspectors of death are allowed to sign up NATURAL causes only. These CCODs are then brought by the relatives to register death and exchange for a Death Certificate and Burial/Cremation Permit at the Neighbourhood Police Post, or Registry of Deaths and its branches. All the CCODs are then returned to the Registry of Deaths where the Registrar will scrutinise all the certificates. If the certificates are not properly filled in he will inform the Coroner who will ask for an opinion from the forensic pathologist and if need be, instruct the police to investigate the impropriety. Based on the investigations and the advice from the forensic pathologists, the Coroner may decide to hold an inquiry.

To avoid embarrassment and adverse publicity, Family Physicians are well advised to issue certificates of natural causes of death only. Do not be coerced, intimidated or pressurised by relatives to sign up unnatural causes, or as in the words of one family physician "on compassionate grounds". All unnatural causes of death must be referred to the Coroner.

Director

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FILLING UP THE CERTIFICATE OF CAUSE OF DEATH

It is important to know the wording of the CCOD and to fill up properly. The top part is about the deceased's particulars and there is no difficulty.

The Cause of Death section consists of two parts. Part I is for reporting the sequence of events leading to death, proceeding backwards from the final disease or condition resulting in death. Please note the small print on the side with instructions to fill in "Disease or condition directly leading to death (This does not mean the mode of dying, e.g. heart failure, asthenia etc. It means the disease, injury or complication which caused death). This is often ignored by doctors who fill in with exactly the words told not to be used: "heart failure" and others like "cardiac arrest", "cardiorespiratory failure", "bedsores", "senility", "senile dementia", "malnutrition". These causes are unacceptable as causes of death and will be rejected by the Registrar of Deaths.

Family physicians are not allowed to write unnatural causes of death in Part I (a). CCODs with causes of death like "Drug overdose", "Asphyxia", "Drowning", "Unknown" have been rejected by the Coroner and the Registrar of Death. Another bad example is, the cause of death in one CCOD was written as "Road Traffic Accident". When queried by the Coroner, the doctor answered "I did it on compassionate grounds". That was not accepted as an explanation.

Part I (b) and (c) are "Antecedent Causes Morbid Conditions if any, giving rise to the above cause (Ia) stating the underlying condition last". The sequence must be correct, and the approximate interval between onset and death must be filled in correctly also. There was a case of death where the medical practitioner certified the cause of death as "hanging in the bathroom". This was wrong as the case must be referred to the Coroner. To further complicate the issue he wrote the time

interval between hanging and death as two years. Another incomprehensible cause of death was "Cardiorespiratory failure 3 months due to bleeding per vaginum 20 days due to bronchial asthma 10 years". Sometimes the sequence is reversed like "Multiple right cerebral clots from head injury due to hypostatic pneumonia". Conditions in I (b) and (c) must be related to I (a). No entry is necessary in (b) and (c) if the disease or condition leading to death in (a) adequately described the train of events that led to death.

Part II is for "Other significant conditions contributing to the death but not related to the disease or condition causing it". Do not use words like fractures, injuries, asphyxia (except asphyxia neonatorum) on this part II as these denote unnatural causes and have to be referred to the Coroner. In the case of fracture femur, if it is not the direct cause of death, do not put it in the CCOD.

INADVISABLE TO CERTIFY

In certifying the cause of death, the certifier must have:

1. attended to the deceased during his last illness
2. conducted a post-mortem examination on the deceased
3. inspected the body of the deceased

Thus it is not advisable for doctors who have not attended to the deceased during his life, did not know the medical history, and did not inspect the body to sign the CCOD. You may be inadvertently made into an accessory to a crime or fraud. There was a case of a doctor who signed the CCOD of an old lady without inspecting the body as Myocardial Infarction. Later the embalmer found a rope mark round the neck and reported to the police. Post-mortem examination revealed that the old lady died of hanging. CCODs from doctors who have not attended to the deceased will not be accepted.

The Inspectors of Death at the Institute of Science and Forensic Medicine can be contacted to inspect the body and to sign the CCOD if there is a clear medical history of the patient died from a natural

disease. They can be contacted during office hours from 8.00 am to 5.00 pm from Mondays to Fridays, and from 8.00 am to 1.00 pm on Saturdays, Sundays and Public Holidays at Telephone No 2221712 or 3214935/6. After office hours the Inspector on call can be contacted at pager 3093053.

The guideline is very simple. Unnatural, violent, unknown causes of death can only be certified by the Forensic Pathologist after a post-mortem examination. All other doctors can only certify NATURAL causes of death. Sometimes a traumatic case may survive for weeks or months. If the cause of death is linked to the traumatic condition it must be reported to the Coroner.

CASES TO BE REPORTED TO THE CORONER

A list of the cases that have to be reported to the Coroner is appended. This is not an exhaustive list. Do not sign the CCOD if the cause is unnatural, doubtful or unclear.

- Alcoholic intoxication
- Allergic reaction
- Amniotic Fluid Embolism
- Anaphylaxis
- Asphyxia eg due to choking
- Barotrauma
- Blood transfusion
- Burns, scalds
- Dehydration
- Drowning
- Extradural haemorrhage
- Fractures (except for pathological fractures)
- Heat Stroke
- Neglect
- Old age
- Overdosage
- Poisoning
- Senile Dementia/Senility
- Septicaemia (related to injuries)
- Steven Johnson's syndrome
- Subdural Haemorrhage (acute or chronic)
- Toxic Epidermal Necrolysis
- Deaths related to operations/procedures
- Deaths related to injuries

THE TREATMENT OF THE PATIENT WITH HYPERCHOLESTEROLAEMIA: WHAT ARE WE TRYING TO ACHIEVE? A Experience with a HMG-CoA Reductase Inhibitor: Pravastatin

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** *F L K N Sin, MBBS(S), FRCP (Ireland)*

INTRODUCTION

Probably all patients with hypercholesterolaemia will develop atherosclerosis of the coronary blood vessels and may eventually suffer a fatal myocardial infarction. In fact clinical manifestation of coronary atherosclerosis is a fatal myocardial infarction in up to 30% of patients. Even patients with "normal" cholesterol levels (<5.2 mmol/L or <200 mg/dl) may suffer myocardial infarction through the presence of associated risk factors (e.g. cigarette smoking, hypertension, diabetes mellitus), which enhance the development of early atherosclerosis of the coronary arteries. For serum cholesterol, there is no natural threshold value to separate a range that would confer high risk from a range that does not confer risk. Associated risk factor/factors compound the development of atherosclerosis even at low serum cholesterol levels.

The MRFIT and the Shanghai study have shown us this association of the risk of myocardial infarction and the level of serum cholesterol; the increase in risk with increasing levels of cholesterol is steepest in the higher parts of the serum cholesterol range. We know from these two, and other studies, that serum cholesterol >4.1 mmol/L (>160 mg/dl) and LDL-Cholesterol >2.6 mmol/L (>100 mg/dl) are primary risk factors.

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Although in our consideration of atherosclerosis, we assess the disease in toto with respect to all the associated global risks, it is the level of serum cholesterol that is the primary risk. All the other risk factors e.g. smoking, obesity, hypertension, diabetes mellitus, are aggravating factors that only seem to achieve importance in the presence of the elevated serum cholesterol levels to promote atherosclerosis.

In 1984, the published results of the Coronary Primary Prevention Trial (LRC-CPPT) where the cholesterol lowering agent used was cholestyramine showed that, following a mean period of 7.4 years, there was a reduction in total and LDL-Cholesterol of 8.5% and 12.6% in the intervention groups. This was associated with a significant 19% reduction in definite cardiac death or non-fatal myocardial infarction. There was also a reduction in the number of positive exercise tests, new angina pectoris and need for bypass surgery of 25%, 20% and 21% respectively in the intervention groups. Subsequent primary lipid lowering trials, like the Helsinki Heart Study, which used gemfibrozil as the cholesterol lowering agent also showed the effective reduction of total and LDL-Cholesterol by 9% and 11% respectively, reduction of triglyceride by 35% and increase of HDL by 9%. The net effect was a 34% reduction in all CHD end points, although, without a significant reduction in total mortality.

These two studies, plus other secondary intervention trials, e.g. Coronary Drug Project,

and the Stockholm trial, illustrate that the reduction in the incidence of CHD end points is proportional to the degree of risk factor intervention. In three of the studies (LRC-CPPT, Coronary Drug Project, Helsinki Heart Study) a reduction in cardiovascular risk began to appear 24-28 months after the initiation of treatment. The relatively uniform results of these large scale trials indicate that it is possibly the cholesterol reduction *per se* and not the use of any particular therapy that explains the lower cardiovascular morbidity and mortality.

Finally, when the cholesterol lowering trials are studied in aggregate, they provide strong evidence that cholesterol reduction decreases the risk of ischaemic heart disease in proportion to the amount of serum cholesterol reduction. For men aged 30-70 with cholesterol levels in the range of 6.5-7.8 mmol/L (260 mg/dl - 310 mg/dl) the results indicate that for each 1% reduction in the serum cholesterol level, there is an approximate 2% reduction in risk for coronary heart disease.

With this awareness of hypercholesterolaemia as a risk factor for premature cardiovascular disease, newer and more effective cholesterol lowering agents that may prevent or even reverse coronary vascular disease have been developed. A new class of drugs, the Statins, (Lovastatin, Simvastatin, and Pravastatin) or HMG-CoA reductase inhibitors, act primarily in the liver and reduce plasma concentrations of LDL-Cholesterol and remnant VLDL, through the inhibition of the rate-limiting step in cholesterol synthesis. The liver is the most important organ contributing to cholesterol biosynthesis. The majority of cholesterol transported in plasma proteins is derived from synthesis within the body rather than from dietary source. The Statins, by inhibiting HMG-CoA reductase, reduce the production of cholesterol in the liver cell. As the liver cell is deprived of cholesterol, LDL-receptors are expressed on the surface for the hepatocytes, thereby removing LDL particles from the blood.

The liver is one of the most important organs contributing to total cholesterol biosynthesis. It is also responsible for the excretion of cholesterol into bile, the biosynthesis of very low density lipoprotein (VLDL) and low density lipoprotein. Hence, inhibitors of HMG-CoA reductase, such

as this group of statin drugs, represent a very attractive therapeutic approach to lowering plasma concentrations of atherogenic lipoproteins, e.g. LDL-Cholesterol and Intermediate density lipoprotein (IDL).

PATIENTS AND METHODS

We studied 13 patients with hypercholesterolaemia to obtain experience with the use of Pravastatin in South East Asia patients. All our patients were ambulatory. The patients we selected had to have a total serum cholesterol of >6.2 mmol/L after at least 3 months of dietary control, and were not already on other hypolipaeic agents. Excluded from the study were patients with a myocardial infarction within the last 6 months, or with severe or unstable angina, congestive cardiac failure, poorly controlled diabetes mellitus, alcoholism, hypothyroidism, chronic pancreatitis, severe renal impairment, nephrotic syndrome, impaired liver function, collagen vascular disorders or gastrointestinal disease. Patients with excessive obesity (>40% ideal body weight) and concomitant use of drugs which may affect lipid levels or lipid metabolism were similarly excluded. Patients were seen every 4 weeks until the 12th week, and in addition to a physical examination, assessment of compliance was made by tablet count. Interim events and adverse drug effects were inquired and studied. Blood investigations including a full lipid profile, fasting blood sugar, insulin, liver function tests and muscle enzymes were performed.

RESULTS

There were 7 male and 6 female subjects. The mean total cholesterol level prior to treatment with Pravastatin was 7.74 mmol/L, and the mean LDL-Cholesterol was 5.67 mmol/L. All of our patients completed the study. None of our subjects reported any adverse effects requiring withdrawal from the study. There was no demonstrable deterioration of liver function tests and muscle enzymes. There was no noticeable effect on the fasting blood sugar, insulin or glycosylated haemoglobin values.

Figure 1 demonstrates that a dose of 10 mg Pravastatin was able to produce a fall of 19% in total serum cholesterol by 12 weeks. The fall in

Effect of Pravastatin 10 mg
on Total Cholesterol level

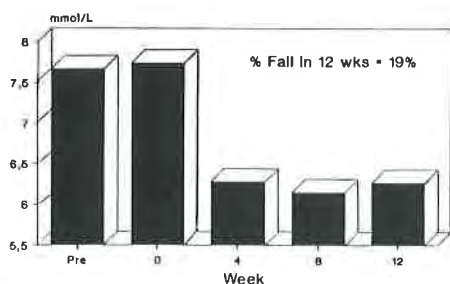


Fig 1

Effect of Pravastatin 10 mg
on LDL-Cholesterol

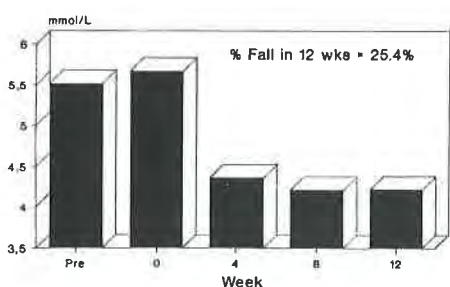


Fig 2

LDL-Cholesterol of 25.4% was even more impressive at 12 weeks as shown in Figure 2. It is also obvious that most of the benefits of Pravastatin was seen within the first 4 weeks.

It has been well established that the Cholesterol/HDL-C ratio has better prognostic significance than Total Cholesterol level. In addition, the Helsinki Heart Study has also demonstrated that the LDL-C/HDL-C ratio was the best single predictor of cardiac events. We tried to determine the effect of Pravastatin 10 mg on these 2 important parameters. Figures 3 and 4 show that by 12 weeks, there was a fall of 21.3% in the Cholesterol/HDL-C ratio, and 18.2% in the LDL-C/HDL-C ratio.

Our study also demonstrated that 10 mg of Pravastatin did not cause any change to the levels of HDL-Cholesterol or the Triglyceride levels (Figures 5 and 6).

Our study has demonstrated that Pravastatin at a dose of 10 mg daily is effective in lowering both the total Cholesterol as well as the LDL-Cholesterol, which it is able to lower up to 25.4%. It is also able to improve on the prognostic parameters of Total Cholesterol/HDL-Cholesterol

Effect of Pravastatin 10 mg
LDL/HDL ratio

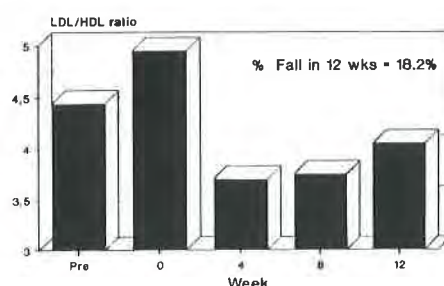


Fig 3

Effect of Pravastatin 10 mg
Cholesterol/HDL ratio

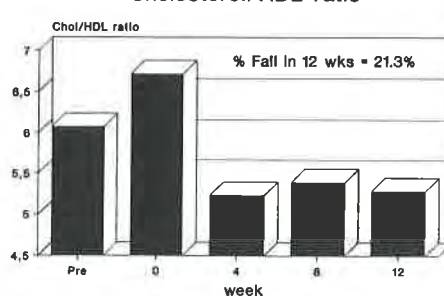


Fig 4

and LDL-C/HDL-C ratios, which are important in predicting the risk of a cardiac event.

Effect of Pravastatin 10 mg
on HDL-Cholesterol

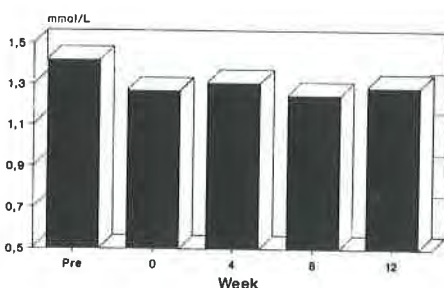


Fig 5

Effect of Pravastatin 10 mg
On Triglycerides

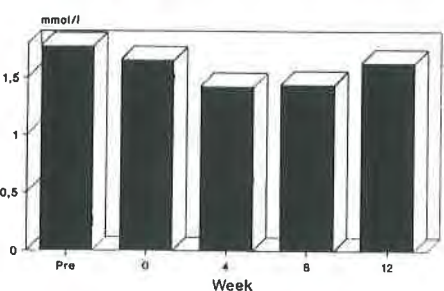


Fig 6

DISCUSSION

10 mg of Pravastatin, in our study, competitively inhibits HMG-CoA reductase, the rate-limiting enzyme in the cholesterol biosynthesis pathway, leading to substantial reduction in blood level of total cholesterol by 19.0% and LDL-Cholesterol by 25.4%. There is no change or fall in triglyceride levels and no increase in HDL-Cholesterol. Our conclusion from this small and limited study is that a 10 mg dose of pravastatin is highly effective in lowering total and LDL-Cholesterol in Asian patients. A comparative study of the hypolipidaemic effect of 10 mg of HMG-CoA reductase inhibitors is shown in Table 1. A 10mg dose of pravastatin is as effective as Simvastatin in its capacity to lower LDL-Cholesterol. It to be remembered in this comparison study that our South-East Asian patients may be smaller in size than the Caucasian patients in whom Simvastatin was used. Nevertheless, for the Asian patient with hypercholesterolaemia a 10 mg dose of Pravastatin is highly effective with substantial reduction in both total and LDL-Cholesterol.

Table 1:

Comparative hypolipidaemic effects 10 mg of HMG-CoA reductase inhibitors in patients with heterozygous familial hypercholesterolaemia. (Number in parenthesis indicate the patients studied).

	% decrease in LDL- Cholesterol
Lovastatin (Illingworth & Sexton)	- 20 (13)
(Havel et al)	- 17 (20)
Simvastatin (Mol et al)	- 28 (8)
Pravastatin (Illingworth)	- 19
(Chew & Sin Fai Lam)	- 25.4 (13)

All three currently available HMG-CoA reductase inhibitors have very similar chemical structure. All these drugs are taken up primarily by the liver and exert their hypolipidaemic effects primarily by influencing hepatic HMG-CoA reductase. Lovastatin and Simvastatin are administered orally as the lactone and are hydrolysed to the effective open form in the liver, i.e. they are pro drugs. In contrast, pravastatin is administered as the open acid active metabolite.

To date, many thousands of persons world wide are on medication with pravastatin or continue to participate in pravastatin clinical trials. Two large primary (Glasgow) and secondary trials (Oxford) with pravastatin are in progress to determine its effectiveness in the prevention of myocardial infarction and the reduction of cardiac morbidity and mortality. An overview of some of the key safety results derived from six previously concluded long-term, multicentre controlled clinical trials in the United States have shown that pravastatin is a safe and well-tolerated lipid lowering agent. The overall frequencies of adverse drug reactions between pravastatin and placebo are not different. Rash, which was generally mild and transient, was the only clinical adverse event whose incidence was statistically greater among pravastatin-treated patients than in those treated with placebo.

We studied the effects of pravastatin on liver function, glucose and insulin and found no abnormalities over the 12 weeks' trial. Our patients had no complaints associated with clinical illness of skeletal muscle or sleep. Unlike other HMG-CoA reductase inhibitors, pravastatin is both hydrophilic and selective. One potential clinical benefit of a hydrophilic drug might be its relative inability to cross the blood brain barrier and hence, its subsequent lack of effect on sleep patterns. In contrast to pravastatin, lovastatin is hydrophobic, and its use has been associated with significant increase in wake time after sleep onset.

Drug-induced myopathy is a potentially serious event that has been associated with lovastatin therapy. As was reported by JA Tobert (1988), drug-induced myopathy occurred in approximately 0.5% of lovastatin-treated patients, including two patients with rhabdomyolysis and renal failure. Among these patients, risk was greater in patients concurrently treated with cyclosporin, gemfibrozil or niacin. The incidence of drug-induced myopathy in those patients, without concomitant agents, was 0.2%. No definitive cases of pravastatin-caused myopathy have been reported in approximately 5,500 patients who have been treated worldwide. In one patient in a series of

1,142 patient, however, a questionable pravastatin-induced myopathy was suspected. This patient had arthritis and her CK was mildly elevated even prior to treatment. She suffered no rhabdomyolysis.

Pravastatin is highly effective as a lipid lowering drug. The benefits of treatment with pravastatin, appear to outweigh the minimal risks associated with its administration. Recent works have suggested that regression of coronary atheroma is possible as a result of hypolipidaemia therapy. In trials which utilized agents primarily directed against LDL-Cholesterol, the therapy was associated with less progression of coronary artery disease, and arrest of lesions in many cases. Favourable angiographic changes were also associated with a significant decline in cardiovascular events (MARS, STARS study). These clinical trials indicated that aggressive reduction of the plasma LDL-Cholesterol has a substantial role to play in the primary and secondary prevention of coronary atherosclerosis. The degree of LDL reduction required for regression to occur, may, however, be only achievable by co-administration of an HMG-CoA reductase inhibitor and a bile acid sequestrant (cholestyramine). This combination of drugs, results in profound lowering of LDL-Cholesterol by as much as 50-70%. The result of studies on atherosclerosis regression are only now being completed and reported, e.g. STARS study which used cholestyramine and Niacin and the MARS study which used lovastatin as LDL-Cholesterol reducing agents.

Even though we now have the means to effectively lower total and LDL-Cholesterol and achieve atherosclerosis regression, we may not always succeed through therapy to cause all lesions to regress. In some individuals atherosclerotic lesions still progress, indicating to us that other factors in the atherosclerotic process have yet to be identified and therapeutically addressed. Some of these factors may include elevated Lp (a), very low HDL-Cholesterol levels, oxidized LDL accumulation in the arterial plaques, insulin resistance and hyperinsulinaemia. In these cases, the total cholesterol level or the LDL-Cholesterol level may not provide a clue that lipid metabolism is deranged. Unfortunately for many (30%), the first clinical manifestation of coronary atherosclerosis is a fatal myocardial infarction. We have no way to identify these patients currently. We need to better identify individuals especially those prone to developing premature atherosclerosis. The best approach then is to target all patients --- for counselling, life-style change, or therapy--- who have two or more risk factors for heart disease in addition to a high LDL-Cholesterol level. (>160 mg/dl or 4.0 mmol/L).

1. *References* are available from the authors.
2. *Further reading:* Lipoprotein metabolism and lipid lowering therapy: The state of the art. Edited by: Betteridge, Macgregor, Sever. J. of Drug Development 1990 Vol 3, Suppl 1.

PRIMARY LAPAROSCOPY FOR SUBFERTILE WOMEN

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ABSTRACT

Primary laparoscopy was performed on 200 consecutive subfertile women in a tertiary referral centre in Kandang Kerbau Hospital, Singapore from January to October 1989. Significant pelvic abnormalities were found in 76.5% of subfertile women. Pelvic endometriosis was present in 41% and 32% of women with primary and secondary subfertility respectively. Pelvic adhesions were found in 28.8% and 32.3% of women with primary and secondary subfertility respectively. A third of all pelvic adhesions were associated with tubal blockage. Tubal blockage was found in 25.8% and 8.8% of women with secondary and primary subfertility respectively, unilateral tubal blockage being more common than bilateral tubal blockage. Hydrosalpinges were more common in women with secondary subfertility. Ovarian pathology was more common in women with primary subfertility. Uterine fibroids were present in 28% and 20% of women with primary and secondary subfertility respectively.

Laparoscopy is recommended as primary procedure to investigate every subfertile woman in a referral centre for early diagnosis. Facilities for simultaneous therapy during primary laparoscopy may potentially facilitate early treatment.

Key words: Primary, laparoscopy, subfertility.

INTRODUCTION

A couple who fails to conceive after a year of trying can be considered to be subfertile. This is because 90% of fertile couples will conceive within this period of time¹. Approximately, 10-15% of couples are subfertile and will seek medical treatment.

The pattern of subfertility can vary widely in different countries. Tubal diseases and other pelvic pathology may occur in 25-50% of subfertile couples^{2,3}. Laparoscopy and hysterosalpingography are both used to investigate the pelvis of subfertile women.

There is agreement that laparoscopy and hysterosalpingography should complement each other^{4,5}. However, controversy exists over the choice of laparoscopy or hysterosalpingography as the primary investigation for subfertile women^{6,7,8}. Laparoscopy may reveal pelvic abnormalities undetectable by hysterosalpingography². Laparoscopy is performed following an abnormal hysterosalpingogram⁹, prior to tubal reconstructive

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surgery¹⁰, unexplained subfertility^{10,11} or failure to conceive after a reasonable period of treatment. Portuondo et al¹² have used laparoscopy as the primary investigation for subfertile women with chronic pelvic pain, prolonged subfertility, abnormal pelvic examination, previous pelvic and abdominal surgery, previous pelvic infection and previous users of intra-uterine contraceptive device and have found a high incidence of pelvic abnormalities in these women. Laparoscopy when performed in the early stage of investigation may provide an early diagnosis and thus shorten the interval between investigation and treatment for all subfertile women, especially those with prolonged subfertility.

It is envisaged that pelvic abnormalities may be more common in subfertile women treated in a tertiary referral centre. Early detection of pelvic abnormalities by primary laparoscopy may enable the simultaneous use of endoscopic surgery and the benefits that may derived can be substantial¹³. There are many infertility-related pelvic abnormalities which are amenable to laparoscopic surgery^{14,15,16,17}. In addition, the availability of laparoscopic surgery services in these centres may encourage the greater use of primary laparoscopy in the investigation and treatment of subfertile women.

This paper examines the use of laparoscopy as a primary procedure in the investigation of subfertile women in a referral centre, determine the relative incidence of subfertility-related pelvic abnormalities and as a pilot study examine the potential for simultaneous laparoscopic surgery during the primary laparoscopy. The results of this study will be used to plan the services for diagnostic laparoscopy and therapeutic laparoscopy for the subfertile women in this centre.

MATERIALS AND METHODS

The Department of Reproductive Medicine, Kandang Kerbau Hospital, Singapore is a referral centre for subfertility treatment. Two hundred consecutive subfertile women requesting subfertility investigations in this department from 1st January to 31st October 1989 were subjected to primary laparoscopy.

Laparoscopy and dye hydrotubation were performed within a month after the first visit at the subfertility clinic during the luteal phase of the menstrual cycle. The procedure was performed under general anaesthesia with endotracheal intubation and controlled ventilation. A Verres' needle was inserted into the peritoneal cavity through the skin crease at the umbilical edge. A pneumoperitoneum was created with two to three litres of carbon dioxide. A trocar and cannula were inserted into the peritoneal cavity. A diagnostic laparoscope (Storz 7mm, 30') was passed after the trocar was removed. A second puncture with a probe was made over the suprapubic area to allow manipulation of the pelvic organs for a detailed examination. One per cent Methylene blue dye (diluted with forty millilitres of normal saline) was injected through a cervical cannula to test for tubal patency. The pelvic findings were recorded in an annotated diagram. Hysterosalpingogram was performed at a later date for those patients whose fallopian tubes did not demonstrate any spill of dye during the laparoscopy.

There were 135 (67.5%) women with primary subfertility and 65 (32.5%) women with secondary subfertility. Of the women with primary subfertility, 80% of them were between 26-35 years old and the remainder were between 20-25 years old. On the other hand, of those women with secondary subfertility, 60% were between 31-40 years old, 25% were between 25-30 years old and 15% were above 40 years. Sixty-six percent of these subfertile women were referred from general practitioners, 28% from gynaecologists and 6% were self-referred.

RESULTS

Significant pelvic abnormalities were found in 153 (76.5%) of 200 subfertile women during laparoscopy. The percentage of women with primary subfertility and secondary subfertility with significant pelvic pathology was 74.1% and 81.5% respectively (Table I).

Table I: Laparoscopic findings in 200 subfertile women.
Figures are in number (%) of patients.

Laparoscopic findings	Primary Infertility n = 135 (100%)	Secondary Infertility n = 65 (100%)	Total n = 200 (100%)
Abnormal	100 (74.1%)	53 (81.5%)	153 (76.5%)
Normal	35 (25.9%)	12 (18.5%)	47 (23.5%)

The incidence of endometriosis is shown in Table II. Pelvic endometriosis was present in 56 (41%) of 135 women with primary subfertility and 21 (32%) of 65 women with secondary subfertility. The majority of subfertile women with endometriosis were found to have mild endometriosis. Almost equal proportions of mild, moderate and severe endometriosis were found amongst the women with primary and secondary subfertility. Mild, moderate and severe endometriosis were found in 41 (20.5%), 9 (4.5%) and 18 (9.0%) of subfertile women.

Table II: Incidence of endometriosis.
Figures are in number (%) of patients.

Endometriosis	Primary Infertility n = 135 (100%)	Secondary Infertility n = 65 (100%)	Total n = 200 (100%)
Mild	26 (26.6%)	15 (21.5%)	41 (20.5%)
Moderate	7 (5.2%)	2 (3.1%)	9 (4.5%)
Severe	13 (9.6%)	5 (7.7%)	18 (9.0%)
TOTAL	56 (41.0%)	21 (32.0%)	77 (38.5%)

The distribution of endometriosis in the pelvis is shown in Table III. Pelvic endometriosis was found mainly in the uterosacral ligaments (48.1%) and in the ovaries as endometriotic cyst (19.4%).

Table III: Distribution of Endometriosis.
Figures are in number (%) of patients.

SITE OF INVOLVEMENT	TOTAL n=77 (100%)
Uterosacral ligaments	37 (48.1%)
Ovarian endometriotic cyst	15 (19.4%)
Isolated ovarian deposits	2 (2.6%)
Pouch of Douglas	5 (6.5%)
Broad ligaments	2 (2.6%)
Uterus	2 (2.6%)
Uterovesical fold	1 (1.3%)
Combination of sites	13 (16.9%)

Table IV shows the incidence of pelvic adhesions and tubal blockage. Pelvic adhesions were found in 28.8% (39 patients) and 32.3% (21 patients) of women with primary subfertility and secondary subfertility respectively. The incidence of tubal blockage in secondary subfertile women was two and a half times greater than that in primary subfertile women, the incidence being 25.8% (16 patients) and 8.8% (12 patients) respectively. Unilateral tubal blockage (17 patients) was found to be more common than bilateral tubal blockage (11 patients) in subfertile women.

Table IV: Incidence of pelvic adhesions and tubal blockage.
Figures are in number (%) of patients.

Pelvic adhesions and Tubal blockage	Primary Subfertility n = 135 (100%)	Secondary Subfertility n = 65 (100%)
Total number with pelvic adhesions	39 (28.8%)	21 (32.3%)
Bilateral tubal blockage	4 (2.9%)	7 (11.3%)
Unilateral tubal blockage	8 (5.9%)	9 (14.5%)
Total number with tubal blockage	12 (8.8%)	16 (25.8%)

The relation of tubal blockage and type of pelvic adhesions is shown in Table V. Pelvic adhesions to the adnexae are divided into peritubo-ovarian adhesions which are filmy or dense fibrous adhesions and gut or omental adhesions which are parts of these structures adhering to the fallopian tubes and ovaries. Tubal blockage was found in 11 (33.3%) of 33 subfertile women with peritubo-ovarian adhesions and 10 (37.0%) of 27 subfertile women with gut or omental adhesions to the fallopian tubes and ovaries. Hence, approximately a third of the subfertile women with either peritubo-ovarian adhesions or gut and omental adhesions to the adnexae were associated with tubal blockage. The type of pelvic adhesions did not bear any relationship to the frequency of tubal blockage in these subfertile women.

Table VI shows the type of pelvic adhesions in relation to a history of previous abortion, pelvic surgery, appendicectomy and endometriosis found during laparoscopy in subfertile women. Pelvic adhesions were found in 8(33%) of 24 subfertile

women with previous abortion, 18 *58%) of 31 subfertile women with previous pelvic surgery and 7 (70%) of 10 subfertile women with previous appendicectomy and 27 (35%) of 77 subfertile women with endometriosis. When pelvic adhesions to the adnexae were present, subfertile women with previous abortion (6 of 8 women) and previous appendicectomy (6 of 7 women) were found more likely to have peritubo-ovarian adhesions whereas those with previous pelvic surgery (12 of 19 women) were found more likely to have gut or omental adhesions to the adnexae. There were 10 subfertile women with endometriosis who had gut and omental adhesions to the adnexae and all of them were also found to have either moderate or severe endometriosis. Hence, it was found that when pelvic adhesions to the adnexae were present in subfertile women with moderate and severe endometriosis, gut and omental adhesions to the adnexae were more likely than peritubo-ovarian adhesions. However, pelvic adhesions were seldom seen in subfertile women with mild endometriosis.

Table V: Relation of tubal blockage with type of pelvic adhesions.
Figures are in number (%) of patients.

	PERITUBAL- OVARIAN ADHESIONS n = 33 (100%)	GUT AND OMENTAL ADHESIONS n = 27 (100%)	NO ADHESIONS n = 140 (100%)	TOTAL n = 200 (100%)
Tubal blockage	11 (33.3%)	10 (37.0%)	7 (5.0%)	28 (14.0%)
Tubal patency	22 (66.7%)	17 (63.0%)	133 (95.0%)	172 (86.0%)

Table VI: Pelvic adhesions in relation to previous abortion, pelvic surgery, appendicectomy and endometriosis
Figures are in number (%) of patients.

PELVIC ADHESION	ABORTION n = 24 (100%)	*PELVIC SURGERY n = 31 (100%)	APPENDICECTOMY n = 10 (100%)	ENDOMETRIOSIS n = 77 (100%)
Peritubo-ovarian adhesion	6 (25%)	6 (19%)	6 (60%)	17 (22%)
Gut or omental adhesion	2 (8%)	12 (39%)	1 (10%)	10 (13%)
TOTAL	8 (33%)	18 (58%)	7 (70%)	27 (35%)

*Caesarean section, ovarian cystectomy, ovarian wedge biopsy and abdominal ventrosuspension.

The frequency of other pelvic abnormalities is shown in Table VII. Uterine fibroids were present in 38 (28.1%) and 13 (20.0%) subfertile women with primary and secondary subfertility respectively. There was one case each of a bicornuate uterus, arcuate uterus and double uterus. Hydrosalpinges were found to be four times more common in women with secondary subfertility than primary subfertility, the incidence being 6 (9.2%) of 65 women with secondary subfertility and 3 (2.2%) of 135 subfertile women with primary subfertility. Ovarian pathology was found to be more common in women with primary subfertility than secondary subfertility.

Table VII: Frequency of other significant pelvic abnormalities.
Figures are in number (%) of patients.

Abnormalities	Primary Subfertility n = 135 (100%)	Secondary Subfertility n = 65 (100%)
Uterine anomaly	3 (2.2%)	0 (0%)
Uterine fibroid	38 (28.1%)	13 (20.0%)
Hydrosalpinx	3 (2.2%)	6 (9.2%)
Fimbrial cyst	6 (4.4%)	4 (6.2%)
Polycystic ovary	5 (3.7%)	1 (1.5%)
Ovarian cyst	3 (2.2%)	0 (0%)
Streak ovaries	0 (0%)	1 (1.5%)
Remnant ovary (cystectomy)	2 (1.5%)	0 (0%)

Table VIII shows the complications of the laparoscopic procedures in this series. The complications encountered in this study were minor. Complications were found in 20 (10.0%) of 200 subfertile women. However, half of these complications were contributed by vomiting from early oral feeding following general anaesthesia. There were no major complications.

Table VIII: Complications of the Laparoscopic Procedure

COMPLICATIONS	NUMBER OF PATIENTS
Vomiting	10
Skin bleeding	4
Post-operative pyrexia	1
Abdominal distension	1
Abdominal pain	3
Superficial injury to uterus	1
TOTAL	20

DISCUSSION

This study revealed that 76.5% of subfertile women were found to have significant pelvic abnormalities by laparoscopy when performed as a primary investigative tool. This result was comparable to a previous study done in the same hospital which reported abnormalities in the pelvis related to subfertility in 66.5% of the subfertile women¹⁹. However, in other studies, laparoscopy revealed significant pelvic abnormalities to be present in 39-60% of subfertile women^{6,7,8,12,20,21,22}. This difference may be due to a large number of subfertile women being referred to this department for tertiary care. About 28% of the subfertile women in this study had prior treatment by a gynaecologist before being referred to this department. The implication of this study is important because of the potential benefits of laparoscopic surgery as a therapeutic tool in conjunction with primary laparoscopy during the diagnostic work-up on subfertile women. The high number of subfertile women who have infertility-related pelvic abnormalities in this study may suggest that primary laparoscopy in conjunction with therapeutic laparoscopy during the same setting be an attractive approach in investigating and treating subfertile women in a tertiary referral centre. The reason why laparoscopic surgery was not performed in this study was because this service was not available at the time of the study.

Endometriosis in the pelvis can only be diagnosed with certainty by laparoscopy or laparotomy. Laparoscopy is the method of choice for diagnosis,

staging and assessment of outcome of treatment for pelvic endometriosis. Pelvic endometriosis has been found to be common among the subfertile women in Singapore who are predominantly of Chinese origin. In this study, we had found an almost similar incidence of endometriosis in both the subfertile women with primary subfertility (41.4%) and secondary subfertility (32.3%). This result was comparable to two other series performed in the same hospital^{19,23}. A review of studies done among subfertile women of Caucasian origin reported a lower rate of pelvic endometriosis ranging from 5-30%^{6,8,24,25} and among the subfertile Black Africans, a rate of 1.4% was reported²⁶.

However, the diagnosis of pelvic endometriosis by laparoscopic visualisation is known to have its limitations. Microscopic endometriosis deposits had been found in abnormal looking peritoneum, in "subtle" lesions which were pink, red, clear white and puckered bluish colour in the peritoneum and even in seemingly normal peritoneum^{27,28,29,30,31}. Hence, the diagnosis of pelvic endometriosis may be missed on laparoscopic examination unless the appropriate areas in the peritoneum are biopsied.

The majority of the pelvic endometriosis in this study were mild (AFS, 1985¹⁸). This was also found by Chan et al¹⁹ in the same hospital. Mild endometriosis was usually not associated with any tubal blockage and pelvic adhesions. However, it is known that mild endometriosis can affect subfertility in a variety of ways³². Pregnancy rates for mild endometriosis are no different when expectant treatment is compared with medical or surgical treatment³². However, relief of pain can be achieved by medical or surgical ablation of mild endometriosis when dysmenorrhoea and dyspareunia are associated. Laparoscopic ablation of endometriotic spots in the pelvis by electrocautery or laser during primary laparoscopy for subfertile women will be ideal. In addition, laparoscopic surgery for moderate and severe endometriosis is an alternative to laparotomy³³⁻³⁶.

In this study, a high incidence of pelvic adhesions in subfertile women who had previous abortion, appendicectomy, pelvic surgery and moderate and severe endometriosis was found. There was a suggestion in this study that when pelvic adhesions

to the adnexae were present, peritubo-ovarian adhesions were more common in subfertile women with previous abortion and appendicectomy and in contrast, gut and omental adhesions to the adnexae were more common in those with previous pelvic surgery and moderate and severe endometriosis. This may indicate that mild post-abortion infection and spreading infection from acute appendicitis may result in the formation of filmy peritubo-ovarian adhesions and severe inflammatory reaction from pelvic surgery and endometriosis may result in the formation of gut or omental adhesions to the adnexae. The cause of the peritubo-ovarian adhesions in subfertile women with a previous abortion is probably secondary to mild subclinical pelvic infection and those with appendicectomy a consequence of direct spread of infection to the fallopian tubes and the parametrium. The cause of pelvic adhesions in those subfertile women with previous pelvic surgery is probably a result of poor surgical technique leading to tissue dehydration, trauma from tissue handling and extensive raw areas remaining uncovered after the surgery. Pelvic surgery using conventional technique may pose a higher risk to developing dense pelvic adhesions. Nordenskjöld and Ahlgren²⁵ reported that 71% of their patients who had undergone pelvic surgery by the conventional technique developed pelvic adhesions. Pelvic surgery should be performed meticulously with good technique in order to minimise pelvic adhesions. Endometriosis is known to cause pelvic adhesions from inflammation and tissue repair. There is a suggestion that treatment of pelvic endometriosis at an early stage may prevent the formation of pelvic adhesions. If this is confirmed, the early diagnosis of pelvic endometriosis by laparoscopy in subfertile women may have an increasing important role.

The incidence of tubal blockage in this study is comparable to other studies which reported an incidence of 12-33%^{1,37,38}, though higher incidence of tubal blockage has been reported among the African Blacks, and incidence of 35% as reported by Otolurin et al²⁶ where a higher incidence of post-abortion and puerperal pelvic infection and sexually transmitted disease is also found³⁹. In this study, tubal blockage was found mainly in patients who also had pelvic adhesions. The cause of the

tubal blockage was probably due to distortion and kinking of the fallopian tubes by adhesions. Winston and Darling⁴⁰ had reported that 63% of their patients with tubal subfertility was the result of adhesions formed following a previous pelvic laparotomy. Not all pelvic adhesions will cause blockage of the fallopian tubes. However, pelvic adhesions that do not cause tubal blockage may still prevent conception by interfering with tubal ovum pick up. Even in those patients with both tubes patent, one must also consider the state of the tubal mucosae, fimbriae and motility as important prerequisites for conception. Laparoscopic salpingolysis and ovariolysis^{41,42} has the potential to maintain patency of the fallopian tubes and to facilitate ovum pick up by releasing the adhesions.

In this study, tubal blockage was two and a half times more common in women with secondary subfertility than those with primary subfertility. Those women with secondary subfertility were generally older and were sexually active for a longer period of time and hence might be exposed to a greater risk of pelvic infection. The tubal blockage in these women with secondary subfertility could be due to subclinical salpingitis which only damages the mucosae of the fallopian tube as most of them had no co-existing pelvic adhesions.

In selected patients, laparoscopic salpingostomy, neosalpingostomy and fimbrioplasty can be performed after the prognosis of the affected fallopian tubes is assessed^{43,44,45}. Factors that affect the outcome of the surgery will include the condition of the endosalpinx, extent of the ampullary dilatation, thickness and rigidity of the tubal wall and the extent of the periadnexal adhesions⁴⁶. Laparoscopic ovarian cystectomy^{47,48} in particular for endometrioma, electrocautery or laser for polycystic ovaries^{49,50,51} and myomectomy⁵² have been reported with good results.

Ovulation can be diagnosed during laparoscopy by visualising the presence of a corpus luteum in the ovary although this cannot be relied upon. Sykes and Girsburg⁵³ had used laparoscopy to biopsy the ovary to assess gonadal function by studying the follicular tissue. However, we feel

that the ovulatory status of subfertile women is best assessed biochemically because biopsy of the ovary can cause the formation of adhesions around the fallopian tubes and ovaries. However, a more important assessment of the ovary of subfertile women will be the detection of any ovarian abnormality.

Laparoscopy is an invasive procedure not without its danger. In this study, we found a low incidence of minor complications and there were no major complications. Other studies have also reported favourably on diagnostic laparoscopy with very few major complications^{25,26,54}. However, the risks for therapeutic laparoscopy are marginally higher⁵⁴.

Subfertile women with a normal history and clinical examination may be considered to be at low risk of having pelvic abnormalities. However, in this study, we had found a proportion of subfertile women with a normal history and clinical examination with significant pelvic abnormalities. This finding may emphasise the importance of an early laparoscopic examination in the low risk subfertile woman. The early detection of pelvic abnormalities will also enable treatment for the "apparently" normal subfertile women to be instituted earlier.

CONCLUSION

In our subfertility clinic and in other clinics in areas where subfertile patients are found to have a high incidence of pelvic abnormalities, in particular, endometriosis, pelvic adhesions and tubal blockage, we recommend that laparoscopy be performed as the primary investigative tool for subfertility for all subfertile women. Laparoscopy will also help to define the pattern of subfertility-related disorders in the pelvis. This study shows that primary laparoscopy in conjunction with therapeutic laparoscopy in the same setting for subfertile women in a tertiary referral centre will benefit from early diagnosis and treatment. This service will need to be planned because laparoscopic surgery involves utilization of special instruments, operating theatre time, and the availability of trained personnel to perform the surgeries. The benefits of laparoscopic surgery are numerous: brief hospitalisation, reduced discomfort, avoidance of a laparotomy scar, rapid

recuperation, cost savings and results-yield are satisfactory^{55,56}

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by A. El Bindari-Hammad and D. L. Smith

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of the role of feeding in the management of diarrhoea. Recommended lines of action draw their authority from published research and extensive WHO experience in programmes for the treatment and prevention of diarrhoea.

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RECENT ADVANCES IN MEDICALLY ASSISTED ---- CONCEPTION

Report of a WHO Scientific Group
Technical Report Series, No. 820
ISBN 92 4 120820

This report provides a state-of-the-art summary of procedures used in medically assisted conception, emphasizing what is known about the medical indications for specific procedures, their safety, and the factors influencing their success. Procedures covered include *in vitro* fertilization, gamete intrafallopian transfer, and similar procedures, as well as established techniques for artificial insemination by the husband or a donor. Addressed to the managers of programmes for the treatment of infertility, the book makes a special effort to distinguish procedures of demonstrated efficacy from those whose potential advantages remain to be confirmed.

The opening sections outlines the most common causes of infertility and summarizes the historical development of current techniques for investigation and treatment. Subsequent sections address the need to reduce the psychological stress linked to infertility and its treatment, and describe

fundamental ethical principles that should govern programmes for medically assisted conception.

Advances in *in vitro* fertilization are covered in five sections. Information includes an outline of the medical indications for treatment, followed by discussions of the procedures and preferred protocols for the induction of multiple follicular development, for oocyte fertilization and subsequent embryo culture, and for intrauterine and intrafallopian transfer.

Artificial insemination is covered in three sections, which offer advice on the collection, storage and preparation of donor semen, outline indications and techniques, and provide guidance on the assessment of results. The remaining sections identify requirements for personnel, equipment, and quality assurance, as well as for future research in such areas as sperm abnormalities, oocyte quality, embryo culture, and cryopreservation.

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1. INTERNATIONAL COMMITTEE OF MEDICAL JOURNAL EDITORS. Uniform requirements for manuscripts submitted to biomedical journals. *Ann Intern Med* 1988; 108:258-265.
2. Bailar III J C and Mosteller F. Guidelines for Statistical Reporting in Articles for Medical Journal(s). *Ann Intern Med* 1988;108:266-273.

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