

**Symposium
Proceedings**

Patients' Rights Reproductive Technology Transplantation

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**The Bioethics Consultative Committee
Malta 2000**



**PATIENTS' RIGHTS
REPRODUCTIVE TECHNOLOGY
TRANSPLANTATION**

PROCEEDINGS OF A SYMPOSIUM

Editor: M.N. CAUCHI

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**THE BIOETHICS CONSULTATIVE COMMITTEE
MALTA 2000**

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1 FOREWORD

THE HON. DR LOUIS DEGUARA
The Minister for Health

I thank the organisers for asking me to address this three-day seminar organised by the Bioethics Consultative Committee in collaboration with the Malta College of Family Doctors. The three days are dedicated to Patient Rights, Reproductive Technology and Transplantation. The need for a wide and open debate with the medical community and the public on these areas cannot be fulfilled admittedly by a one-day session on each of the issues, but definitely this is a step in the right direction and hopefully will be followed by more fora and/or seminars in the near future.

This seminar comes at an important time, coinciding with the need to formulate a Charter for Patient Rights, and also in view of the two documents currently prepared and forwarded to me by the Bioethics Consultative Committee on Reproductive Technology and Transplantation. These two documents raise important issues and touch upon delicate areas which need to be addressed in public debate. The Reproductive Technology document touches upon third party sperm donation and the storage of gametes. It is not an agenda which any government can adopt without going through the channels of public fora and the important institutions representing the main religious beliefs and cultures of the Maltese people.

Conversely the Transplantation document raises the important issue of organ donation and the means of procuring such organs. There needs to be proper protocols which allow or disallow, say, donation by young people who have not as yet reached the age of majority. Should one outlaw the donation of a kidney by a young person or should this person be treated as having an autonomy

of his or her own and be allowed, after going through the proper ethical committees and guidelines, to donate a kidney thereby saving the life of a brother or sister?

Such questions need thorough scrutiny by the Bioethics Committee. but they need also to be put forward for debate by the general public.

The Charter of Patient Rights is on the agenda for my government. A document on Informed Consent has already been issued by the Bioethics Committee¹. We now need to look more closely at our system and see that issues such as truth-telling and informed consent are closely followed. We need to provide medical personnel with adequate training in these areas and give them detailed instruction not only on general issues but also on how to deal ethically with patients unable to give consent, such as those who are in too much pain or agony to give any valid consent and patients who are becoming or have become demented. What about the prisoner-patient who often cannot provide free consent without some form of pressure? And what about young people not yet of majority age who are autonomous in their own right?

We need to see that careful procedures for protecting information and guaranteeing confidentiality are implemented, especially with the introduction of computers. Research is also becoming more frequent in our hospitals. We must ensure that all research, including that carried out by students under supervision by superiors, goes through the proper channels of ethical scrutiny and approval. Each research project must clearly say how it intends to respect the principles of informed consent, confidentiality etc.

My government is also committed to improving primary health care and to promote collaboration and co-operation between the private and the government health sectors. Together we will strive to find a way to give the basic right in health care to all patients - that of providing the doctor of one's choice. Naturally this is no easy task

but with discussions with the main medical bodies we hope to arrive at a suitable system that ensures patient registration. In the meantime we are looking into innovative ways of co-operating with the private general practitioners. The provision of free blood tests through the private doctor was a step in this direction and hopefully other investigations to aid the private GP will be introduced in the very near future.

But when we speak of patient rights we cannot put all patients in one basket. Thus it is customary to have separate specialities, services and wards (indeed in other countries even separate hospitals) for children and adults. With the same reasoning, adults should be separated from elderly people. In order to provide equal opportunity and rights for the older patient, my government has always been in favour of the policy of having specialised institutions and hospitals for the elderly. Not that the general medical and surgical services do not provide good care for this category under one roof, but because geriatrics is a speciality in its own right and people in this age group have a need for specialised treatment in specialised hospitals. We hope to arrive at a point where all elderly people needing hospitalisation are assessed and examined, on admission to the acute wards, by geriatricians before proceeding, if deemed necessary, to specialised units. I am convinced that the geriatrician should form part of any hospital admitting team. Ideally we should also start thinking of the possibility of introducing separate lists for surgical and other procedures specifically for the elderly. If children do not wait with adults but have separate lists of their own, why should not the elderly be treated likewise. Would such steps not ensure a better quality of life to our elderly?

The environment is also an area which concerns Bioethics. Indeed the person who coined the word 'Bioethics' was an oncologist, Dr. Van Rensselaer Potters, at the University of Wisconsin². Studying the causes of cancer he noticed the important role the environment plays as a causal factor of cancer. When thinking about ethics in medicine he included environmental ethics. Now, thirty years later,

he is being proved right as Bioethics Committees around the world are becoming increasingly conscious of the issue of the importance of the environment on their agenda. My government is conscious, as pointed out in the electoral programme, that physical and mental health also depend on the environment. We need to focus on educating the public about the multi-sectoral environmental issues and understand that the Planning Authority also has an important role to play in preventive medicine. Naturally this will not always go down well with everybody, but Malta is small and any environmental impact will effect all the population very easily. We cannot afford to be wise after the damage has been caused.

Patient Rights are a direct result of Human Rights. We are on the verge of the third millennium though regrettably there are still many countries where human rights are not respected. They can only dream of 'patient rights'. We should be glad that our country is in a position of developing further Patient Rights and is in the process of issuing a Charter. Rights are not about opinions, they are about international consensus. We are confident that locally we will reach consensus on a political level, as in the case of the elderly. In Malta we follow closely what happens in the western world. We must adopt this within our system of justice.

The Malta College of Family Doctors has issued a Document for Patient Rights in General Practice. This is a step in the right direction and I encourage all medical bodies to develop such charters and also to elaborate them as guidelines for doctors to use in special situations as well. I would furthermore encourage them to have separate Bioethics Committees of their own with qualified people to give them informed advice and to work collaboratively with the Bioethics Consultative Committee which works wholeheartedly to deal with Patient Rights and the moral issues of the new technologies being developed in medicine today.

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2 INTRODUCTION: PATIENT RIGHTS

M.N. CAUCHI

Last year we had a symposium on Informed Consent, which is now published. Most of you should have received a copy of this document.

This was an attempt on our part to emphasize some of the patient's rights within a medical setting. It is a subject which is too often taken for granted, and too often ignored by the medical and paramedical team.

Apart from crass abuses of human relations, that hopefully occur only occasionally, one is constantly reminded of the very frequent, relatively minor, yet none the less annoying aspects of patient-doctor relationship, where the patient is less than happy with the encounter. Such dissatisfaction arises not so much from incompetence on the part of the medical/paramedical team, as from lack of information, or from an inability to meet the patient's expectations. These in turn may be realistic or otherwise depending on the sort of practice that we indulge in. When there is a queue of 50 persons at out-patients for instance, it is unrealistic to expect more than the most perfunctory of exchanges of information. I also believe that an unprepared patient requires far more time to digest biological and medical facts than one who has a reasonable background of education and biological information. We in Malta still have a long way to go in this direction.

A Charter for patient's rights appears to be a minimum benchmark for us to have in front of us. I believe also that we require a change in attitude, an attempt to deal with patients as equals and not merely as dependent inferiors. It is amazing how less frequent are complaints relating to patients' rights in the private sector where

the question of status and equality is perhaps less obvious.

The list of patient rights is large and even conflicting. There are rights to treatment and to not having treatment, rights to live and to die, rights that affect the individual adult and the unborn, rights of minors and of the aged; rights to know and not to know one's genetic constitution, rights to know reasonable risks associated with any procedure, and so on.

Today's panel will no doubt touch on many of these topics from the medical, legal, philosophical as well as the layperson's point of view. I believe this is a topic which should make us concentrate on what sort of practice we have, and whether we can improve on this service. Particularly relevant in my opinion is to highlight those factors which prevent us from identifying major issues and circumstances where we perceive a less than ideal practice of patient rights.

3 PATIENT RIGHTS IN PRIMARY CARE

PIERRE MALLIA

As everyone knows there are two tiers of provision of health care: state and private. Whilst government provides a good service at hospital and health centres, which is by right free for all, only private doctors provide Family Practices. WHO criteria for a family service advocate that, ideally, doctors should be life-time partners with the family, and that doctors should know their patients by name, and each patient able to mention by name his or her primary care physician¹. For many private GPs this is still the case.

Health centres have however competed directly with the family doctor. This raises the issue of the family doctor not knowing the full medical history of his or her patients and having to share medical care with other, often unknown doctors, who may not make it their prerogative to communicate with the family doctor since the latter has been temporarily waived. As a result the right to one doctor directly responsible for the health of an individual is unknowingly lost.

In health centres patients are generally not seen by the same doctor. Although files are frequently kept, they miss out on an important aspect of patients' medical history and care - that provided by the private family doctor, which many patients will have. Conversely the family doctor not only does not have access to tests done at the polyclinic but finds himself having to repeat many of them.

Theoretically, a GP can send patients for investigations to a health centre but with the exception of a limited amount of basic blood tests, these have to be done through, and at the discretion of another health centre doctor. This, in my opinion is unethical and

going against the right to the doctor of one's choice. If this facility is to be offered, it cannot go against patient rights and professional ethics.

Another recent area of concern was the administration of vaccines through Local Councils. The Malta College of Family Doctors has expressed its concern to the Department of Health that doctors are not present during the administration of vaccines, and 'that the family doctor should be involved in any health-related decisions regarding his or her patients'.

Ironically, in case of death, health centre doctors ask patients whether they have a GP, and it is not the first time I am called to certify a cause of death after the health centre doctor has already been called in by the family. So if this procedure is convenient at the time of death, then why not for the health management of living patients. Patients have a right to be seen or to be followed-up by their GP for all conditions of health-related problems. This right should be made known to them through the system.

It is obvious that not only patients are unclear about their rights, but maybe also health care personnel are not clear of the right ethical procedures. Let me take diabetes as an example. Diabetes is a condition which can be adequately treated and followed up by General Practitioners many of whom hold diabetic clinics themselves². Patients discharged from hospital needing monitoring of their blood glucose are as a general rule referred to health centres, even if they were admitted to hospital by a private GP. Since patients are not given a choice, they are not reassured that they will continue receiving free medicinals if their private GP continues to see them.

Moreover many patients may then be lured into the private practice of a so-called diabetologist, who of course never communicates with the General Practitioner. In the case of an emergency, it is the GP who is often called, and who then has to make heads or

tails, under emergency conditions, of a situation which he or she has not been following. All this because patients are subtly coerced into believing that their Family Doctor is not capable of taking care of their diabetes.

Although patients should be allowed to change their GPs whenever they feel best, it does not follow that one may shop around. Like most modern countries, we should, in my opinion, be thinking about patients registering with one or a group of doctors under a comprehensive scheme.

If the government cannot at this stage introduce a National Health Service similar to that in the UK or Canada, at least co-operation with private general practitioners on all levels of health management of patients is something attainable and in order.

The Right to know and Informed Consent

Although there are legal implications of improper handling of informed consent, *informed consent is not only about law, it is about what is morally right; it is not solely about consent, it is about adequate information.*³

Although practices are changing, as a general practitioner I am still concerned to see patients, especially elderly ones, who are not told the truth about their condition. Terms like "laħam hażin" are still frequently used to describe cancer. Although one has to respect culture and also the patient-specialist relationship, this occurrence is too frequent to be ignored. Everyone knows that the trend is towards more truth telling rather than paternalistic secrecy - if only because the patient needs to make an informed choice. This is especially the case when a patient refuses treatment, as one never knows whether that refusal would have occurred had the patient known the truth about his or her condition. Also, maybe more attention need be given to the truth when there is family pressure not to tell the patient of his or her condition, or

when the patient demands that the family are not told. Family members may also need to know if they are going to be the future carers responsible for the patient on returning home. Unless exerting their right not to know, patients need to know as much information as is reasonably considered enough in order to participate in the choices of their treatment.

The role for teaching about Rights.

The right to adequate health care begs the right that patients know the limits of both private and state sectors. One is not in competition with the other. Patients must know that their family doctors need to participate in most if not all of their medical management if they are to receive optimum health care. Moreover, in my opinion doctors in health care centres should know whether people have a GP they wish to inform about test results, investigations and other matters discussed during their visit.

Questions of ownership

According to the British Medical Association, the ownership of patient information is not the doctor's or the State's but the patient's.⁴ Patients therefore have a right to ask for any test results to share with whomsoever they wish - whether state or private. Patients thus own all that is put on their files and computers, and copies should be readily made available for the patients' perusal. It is ironic that hospital files still have a sign "not to be handled by the patient" on them.

Patient rights and Professional Ethics

Is it time we start considering a national scheme for primary care with patients registered with GPs who dedicate their time solely to primary care and not part-time as is frequently the case. In Malta a doctor may be training for a specialised post in hospital in

the morning and do some primary care in the evening. They may feel this is their right - but is it in the interests of patients and *their* rights?

Conversely, what is sauce for the goose is sauce for the gander. There are GPs who are audacious, for example, in surgical procedures. Recently a new patient of mine had a D&C done under the impression that it was going to be done by a specialist, and then finding to her surprise that it was her GP who performed the procedure. Appendectomies and haemorrhoidectomies are known to have been done by GPs. Although they may be quite capable of performing surgical procedures, all the normal ethical channels of informed consent and clear information of available choices have to be respected. And in my opinion, not all minor surgery can be done at Primary Care level.

Are we tolerating therefore more than we should? Why is it that some doctors, because they own a large clinic can advertise and others cannot? Why is it that some doctors practise in family-owned pharmacies when there is a law prohibiting this because of conflict of interests thereby violating patient rights? Why is it that insurance will pay for blood tests carried out in a private laboratory and not always for those carried out in the General Practitioner's own clinic?

A few years ago someone blew the whistle on a primary care physician who advertised laser treatment by another specialist in his clinic. Following a fine of Lm200 imposed by the Medical Council the advertising goes on.

Only last week the New England Journal of Medicine published an article in its Sounding Board column which showed concern about medical professionalism. I quote:

“Today, at the dawn of a new century, genuine medical professionalism is in peril. Increasingly, physicians encounter perverse financial incentives, fierce market competition, and

the erosion of patients' trust, yet most physicians are ill-equipped to deal with these threats".

Although our problems are different to the American doctor, the same can be said of our society to some extent. The article calls on physicians to "speak out about their values" and concludes that:

"there is an essential role for professionalism in society that market-driven and government-controlled health care alone cannot provide" proposing amongst others a negotiation within society.⁵

Conclusion

It is a WHO criterion that all medicine should start from primary care. The Malta College of Family Doctors has prepared a Patients' Charter. It is a neat document which explains to patients what should be expected from their doctor. I feel we need to work on such charters and create a more coherent health care system which works in co-ordination and co-operation.

Health care is about the 'care' or 'concern' that Heidegger's phenomenology⁶ speaks about, whereby each Being comes into contact with other beings. It is about being-with and being-in-the-world. Heidegger warned against the levelling down of relationships when many beings come into contact with each other in masses. There is not a being-with which projects itself into the full potential of human relationships. Rather it is a reduced form of contact which 'they' - the masses - bring about. With health care for the masses this levelling down is easily slipped into, depriving patients of the intimate doctor-patient relationship which they deserve. Patients have to be allowed to find their potentiality-for-being within a doctor-patient relationship; conversely the true becoming of a doctor is not merely in acquiring qualifications, but in coming into relationships; in being-with patients.⁷

This potentiality-for-being is the purpose of health care education and as such, therefore, cannot deprive the doctor of a full

knowledge the ontology of patient, the physician and the doctor-patient relationship. The potential-for-being-in-a-relationship is the only road to avoid the levelling down of relationships found in mass-handling health centres.

The patient has a right to this full potential of the doctor-patient relationship which is fundamental to medicine. To protect this relationship one has to protect the Family doctor who enters into direct relationships with individual members of families, and knows them, understands them and lives through their experiences. A right to health care is not merely a right to a service; it is a right to this phenomenology of medicine - the patient-physician relation which is not levelled down to routine examinations, tests and diagnoses. It is a right to a true long-standing relationship.

Governments should not compete with family doctors who know you from birth through to the age when you have your own children; doctors who know you by name and are almost part of the household. There are other ways which have been implemented successfully abroad for providing free primary health care through private doctors. The right to the doctor of one's choice provides for better long term relationships which in turn promotes better communication⁹ - the basis of informed consent, fidelity, truth telling and all that patient rights are about.

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4 THE RIGHTS OF THE ELDERLY PATIENTS

DR SANDRA BUTTIGIEG

Older Persons should have specific rights that society in general, health care providers as well as the elderly themselves should be aware of.

Two fundamental questions need to be considered:

1. Why do we need rights for the elderly patient?
2. What are these rights?

1. Two main reasons why we need rights

- a. Demographic reviews of developed countries do show us the reality that we are sitting on a demographic time bomb. The ageing population is increasing. In Malta, by the year 2010, it is projected that 22% will be over 60 years of age whereas 8% will be over 75¹ years. By the end of the century, 20 years will have been added to the average life span. In the course of a few generations, the proportion of older persons (age 60 and above) to the overall population will increase from approximately 1 in 14 to 1 in 4. Therefore society in general is bound to focus more on all areas pertaining to the elderly, not least on their rights.
- b. The older person is not always a patient receiving short-stay care but frequently has to follow long-stay care management programmes. They often suffer from multiple often chronic pathology,² non-specific presentation of disease, rapid deterioration if untreated, and high incidence of complications of disease and treatment. They often need rehabilitative care and some like those in institutional care do become eternal patients. A case in point is St Vincent De Paule previously a

hospital now being referred to as St Vincent De Paule Residence for the Elderly, notwithstanding the hospital setting. The elderly at SVPR are referred to as residents.

2. What are these rights?

The United Nations³ spells out these rights as principles. Appreciating the contribution that older persons make to their societies, And recognising ageing as one of the major achievements and, at the same time, challenges of the twentieth century, the United Nations convened the World Assembly on Ageing in 1982. In 1991, it adopted the United Nations Principles for Older Persons. In 1992, the Assembly adopted a strategy for decade 1992-2001, including the International Year of Older Persons 1999. The mission statement is "To add life to the years that have been added to life".

The UN Principles address five major areas, which are: *care, independence, participation, self-fulfilment and dignity of older persons.*

A. Care of the older person:

- 1. Older persons should benefit from family and community care and protection in accordance with each society's system of cultural values.**
- 2. Older persons should have access to health care to help them to maintain or regain the optimum level of physical, mental and emotional well being and to prevent or delay the onset of illness.**
- 3. Older persons should have access to social and legal services to enhance their autonomy, protection and care.**
- 4. Older persons should be able to utilise appropriate levels of**

institutional care providing protection, rehabilitation and social and mental stimulation in a humane and secure environment.

5. Older persons should be able to enjoy human rights and fundamental freedoms when residing in any shelter, care or treatment facility, including full respect for their dignity, beliefs, needs and privacy and for the right to make decisions about their care and the quality of their lives.

Two scientific studies published in medical journals this year clearly show that the relationship between the health care provider and the elderly patients may have to be revised. A study published in the February 10 1999, issue of JAMA⁴, which included enrollees into a Medicare managed care organisation, has shown that many elderly patients are lacking the basic skills necessary to participate in their care and may not comprehend simple health instructions. Another study published in the January 19 1999⁵, issue of the Annals of Internal Medicine, showed that American doctors are often unaware of their elderly patients' desire to receive aggressive life-sustaining care, and as such are likely to withhold proper care. Researchers found that a great percentage of the elderly wanted life-extending care even if it meant additional pain and discomfort.

B. Independence:

The most relevant principle in this context is that older persons should be able to reside at home for as long as possible. In practice, relatives and sometimes society often put enormous pressure on the elderly to be admitted into institutional care without first tackling problems such as housing, social problems, access for home help and for that matter lack of information on what they are entitled. Consent should be always sought and forced admission never accepted. Society should avoid being overprotective at the risk of abusing the right of independence. This is relevant particularly in long-stay care where the older person may be discouraged from performing the activities of daily living as these may require more patience and therefore more time than if the elderly is allowed to perform these activities especially under supervision.

C. As regards participation, older persons should remain integrated in society, participate actively in the formulation and implementation of policies that directly affect their well being and share their knowledge and skills with younger generations.

D. Self-fulfilment

Older persons should be able to pursue opportunities for the full development of their potential and should have access to all the resources of society.

E. Dignity

Older persons should be able to live in dignity, security and be free of exploitation and physical or mental abuse. Older persons should be treated fairly regardless of age, gender, racial or ethnic background, disability or other status, and be valued independently of their economic contribution.

The overall objective for International Year of Older Persons 1999 is to promote the 18 United Nations Principles for Older Persons and to translate them into policies, practical programs and actions. A comprehensive Aged Care Act, which if passed through Parliament, becomes law, would be the best method of expression of these principles. The main profiles in this act would be the older persons themselves, the health care workers and the carers. The common denominator is the care and welfare of every individual older person.

In Malta, the standing of the older person in society has improved over the past two decades. Community services have expanded with the provision of home help, meals-on-wheels, telecare and social assistance. Several Government Residential Homes and Day centres, in various villages have been opened to keep the older person at the centre of society and in the community. But unfortunately, St Vincent de Paule Residence may probably be the largest institution for the elderly in the world. And as explained earlier the older person should today be in the community and

definitely not in an institution. I believe that care in general has improved but we still have to understand the full meaning of the principles highlighted earlier as lack of knowledge would surely result into unintentional abuse of the older person.

Providing care to elderly individuals is far more than meeting the requirements stated in a health care worker's job description. Health care providers need to understand the physical, emotional and social losses associated with the ageing process and to minimise these losses whenever possible. Inspirational and dedicated care providers should maximise the safety and quality of life, the strengths and independence of elderly individuals as well as incorporate respect, love and friendship into their daily care.

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5 PATIENT RIGHTS DOCUMENT OF THE MALTA COLLEGE OF FAMILY DOCTORS

DR DENIS SOLER

Bioethics arose in a delicate social and political moment in the history of mankind.¹ It appeared in the second half of the 20th century in the middle of a spectacular advance in biological knowledge and technology, as opposed to medical ethics, which was formulated in the 5th century BC in relation to medical care. The two most important factors that enabled Bioethics to develop so rapidly at this time were the widening of human biologic horizons with the evolution of genetic engineering and the changes in medical enterprise and health care ethics.²

The scope of Bioethics is wider and different from that of medical ethics and is the result of diverse attitudes that the culture of Western man has assumed towards the concepts of truth and morality.³ A concrete definition of Bioethics raises more questions than answers, though it definitely serves as a bridge between science and philosophy.

Perhaps the most important practical realisation of Bioethics has been the creation of Ethical Committees. The modern health care system is being transformed as a consequence of scarce resources and better informed consumers, and these committees help establish a climate in which physicians can share relevant health information, learn about patient and family concerns, promote health education and informed consent, and facilitate effective decision making about complex health care practice issues.⁴

There are few days in the life of a medical practitioner when he is not faced by decisions that have ethical implications, occasionally

of a nature with which he is not fully conversant. In the last decades, medical technology and research have greatly altered the boundaries of care and a changing society is less sure where it should draw the line. The medical profession was probably the first to enunciate, and impose on its members, 2500 years ago, a Code of Ethics in the form of the Hippocratic oath. This was done in view of the very special and exceptional position that the physician played in society. Traditionally the health care professions have relied on this "oath" and other rules that have changed very little over the centuries. With the frontiers of medical science changing continuously, society rightly expects a continuous update of ethical guidelines that form the basis of acceptable medical practices.

The term "Bioethics" is seductive and has an attractive ring, however the name may be a bit of a misnomer, and in some ways misleading. Strictly speaking, there is no such thing as ethics in Biology to justify the term Bioethics. The universe of life, Biology, reveals a panorama of growth, mutation and interaction obeying intrinsic laws and the whims of chance, which are not regulated by any supreme ethical law. One can hardly hope to find ethical principles in this tangled matrix.

Also, if what we mean by Bioethics is the ethical implications and conundra of medical practice, the term itself would also include ethical or unethical practice in veterinary medicine such as vivisection. However the term has now been widely adopted and redefined as exclusively relating to the human domain.

Ethics normally means a code of behaviour. It refers to acts, or what one ought or ought not to do. In short it is a normative discipline. Although ethics is not a philosophy of man, it must be based on one. Patients and physicians can inhabit distinctive social worlds where they are guided by diverse understandings of moral practice.

Malta is blessed with a situation characterised by the contemporary presence of a common moral tradition, religious communities and ethnic backgrounds. On the other hand pluralistic moral traditions of moral reasoning are bound to pose a considerable challenge for Bioethicists because these can lead to difficulties regarding a consensus on moral reasoning. This becomes evident when considering topics such as truth telling, informed consent, euthanasia, brain death and organ transplantation, where different understandings of moral “common sense” may exist.⁵

Does this mean that the foundation of ethics is or should be denominational, especially if there is overwhelming religious uniformity in a particular society, such as ours? The obvious advantage of having a denominational basis is that one would find social consensus about an already established and elaborate system of morality and view of life on which to base ethical guidelines. The disadvantage would be that it would not be universally applicable, especially in countries with marked difference in social milieu. Non-believers would opt for founding ethics on non-religious, preferably rational grounds.

Bioethics implies a belief in good and evil as otherwise it would be impossible to designate what is allowable and what is not. Ethics is not a science in the contemporary sense; its foundations are not based on observation, experimentation and mathematics. It is based on values. Unless ethics is to be starkly relativistic, and therefore of limited application, ethics should be founded on some fundamental values.

In either case one should depart from axiomatics, a body of assumptions taken to hold without proof. These are not provable. After all, the international community has adopted other documents involving essential values like the Universal declaration of Human rights, in spite of widely differing political and religious convictions.

Bioethics should embody these basic principles:

- 1. Life, as embodied in the person, has supreme value. The sanctity of the person should be held inviolable**
- 2. Person should not be qualified by age, sex, race, colour, intelligence or disease.**
- 3. Person should not be artificially qualified by the stage of development. Nobody and no organisation should have the criminal arrogance to decide at what stage a zygote or an embryo or baby is a person.**
- 4. The aim of an ethical code should be to protect and guarantee the good of the person.**

Bioethics in its widest sense, and Medical morality are part of general morality and the process of formulating new professional codes, calls for the joint expertise of thinkers from diverse backgrounds, from outside as well as inside medicine. No field of thought should be excluded which may contribute to the debate and help create new guidelines governing a continuously changing medical scene. Furthermore, any change in such formulation should be a constructive response to the spirit of the times.

In his book "Manipulation", Bernard Haring states, "Man has reached a new crossroad. We have come to a point in Biological history where we are now responsible for our own evolution. We have become self evolvers."

Having assumed this rather presumptive role, man must concurrently evaluate his methods and draft rules that should be, ideally universally applicable and binding. Bioethics for the future must rest on an all-embracing concept of totality; the dignity and well being of man as a person in all his relations to GOD, to his fellow man and the world around him.

Bioethics is not only about cloning and genetic engineering. It is about the respect and dignity that medical practitioners exercise in their daily mundane contact with their patients. Physicians should go back to the Hippocratic oath as the fundamental guide for their professional activity.

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6 PATIENTS' RIGHTS: THE LAY PERSPECTIVE

CECILIA XUEREB

The doctor-patient relationship was historically based on trust rather than on monetary considerations. The family doctor, or the village doctor was a friend, a counsellor, a person of authority, a person to be honoured. The Welfare State brought about with it the socialisation of medical attention, and the right to proper medical care is nowadays recognised as part and parcel of the most fundamental human rights. The State which has the widest resources at its disposal and which is funded by the people's taxes has the obligation of providing the best kind of medical and health services, both therapeutic and preventive, that it possibly can. As a result, a consumerist mentality entered the medical field. The doctor became only one of the many and various social workers serving in dependence on, or in collaboration with insurance groups and social agencies and the patient became a consumer expecting high quality service. Health care is only one factor of the market economy. In many countries, this has resulted in the depersonalisation and in the dehumanisation of medical services.

In Malta, State provision of medical and health care exists alongside a reasonably strong private sector. The Government provides a free health service for all, which is covered from general taxation. Every citizen resident in Malta has a right to free health care, immaterial of income. Free medication is also guaranteed to those in the lower socio-economic strata. Generally speaking, patients can choose their general practitioner or their specialist or the hospital if they go privately. A patient can go directly to a specialist, privately, and then that specialist, who very often is also a public officer, takes the patient on in the public system. The idea of voluntarily joining private insurance schemes is gradually but steadily gaining ground. In this way one of the basic rights of

the citizen is adequately fulfilled: all medical services are available to all people independently of whether they can pay for them or not.

However the rights of the citizens go beyond the right to medical care to their rights in medical care, whether this is publicly or privately funded.

Most people in Malta regard their relationship with their doctor as sacred. While the family doctor is no longer the consultant on a wide variety of subjects, he is still looked upon with respect by most people. No matter how critical a medical situation can be, the mere presence of the doctor is for most people a great source of comfort. This has led to abuses by the public at large. They call in the doctor for house calls when they could very well have gone to the clinic themselves, or call out a doctor for a visit during the night or on a holiday when they could have done so at some other time. On the other hand, the patient needs to feel that the doctor considers him/her and his/her ailments important, and that he/she is prepared to give him/her all the time needed. This is certainly the case with most of our doctors and consultants whose bedside manners are impeccable. However it starts falling short further down the medical hierarchy: with nurses and paramedics and other hospital staff. While there are those among these people who are friendly and courteous and make the patient feel at ease and confident that he/she is in good hands, there are still several - I do not want to say many - others whose manners with patients seem to cater for the lowest levels: while they should make the beggar feel like a king, they in fact make the king feel like a beggar. Does it take much, for example, for a doctor who is seeing a patient for the first time to introduce himself instead of remaining a nameless face? The name gives the person an identity and it is amazing what difference this makes to the morale of the patient. The system whereby patients choose their own doctors who will follow them throughout their lives unless they want to change them, has remained a dead letter. Patients may find themselves being treated

by different practitioners every time they attend polyclinics.

Similarly the College of midwives had instituted a system whereby an expectant mother is followed throughout her pregnancy by the same midwife who would also deliver the baby. This system was discontinued: administrative criteria overcame personal and even, in this case, medical criteria.

Whatever the system it must remain primarily human.

Much has been said about informed consent and the right of the patient to refuse treatment, or to choose one form of treatment rather than another. Yet several doctors and people in the medical profession treat patients as some kind of morons who are unable to understand what is happening to them. They refuse to disclose to patients the real nature of their condition. I can personally recall the time when my own father was operated for the removal of the gallbladder: as a result of the operation he got the condition "ileus", or paralysis of the intestines. We only found out the real nature of his condition when the hospital authorities accidentally left his file where we could find it and we looked inside it. Not only should doctors inform patients, or their next of kin as the case may be, about the real nature of their patients' condition but these should be able to have access to their files and to all the data, medical or otherwise, which has been recorded about them.

The recent patients' charter issued by the College of Family Doctors adopts a very paternalistic attitude: patients' wishes in relation to any treatment or care proposed, including "any risks and any alternatives", are only "taken into account as far as possible". How far, one may ask, is as far as possible? Shouldn't the patient's wishes be taken into account and regarded as supreme at all times, even if these do not quite coincide with the wishes of the doctor? What is required here is that the person be given all the information needed for him to be able to take autonomous decisions.

Respect for the patient also implies keeping appointments. While the same Charter mentions that when a patient keeps appointments made for him/her he/she is helping the doctor, it only provides that “patients should be satisfied with the waiting time in surgery”. What criteria constitute satisfaction? It is one thing if there is no appointment procedure, but what about those doctors/specialists who do not time their appointments properly and allow patients to wait for over an hour before they attend to them. Obviously accurate calculations cannot be made since not all patients would require the same amount of time. The patients or clients of one particular gynaecologist, mostly pregnant women, have been known to wait for as long as two and a half hours, and this in the most uncomfortable of conditions, since the crowd in the waiting room necessitated that the women in question wait outside, seated on the steps of the clinic. Seeing to a simple fracture in the emergency department at St Luke’s just ten days ago took from 1.30 in the afternoon till 5.15, while an appointment with the consultant a week later which was scheduled at 9.00a.m. only materialised at 10.45. Is this reasonable, I ask?

Another big source of irritation for patients is long-term appointments. Prompt attention to requests for nursing or medical assistance is, or should be, one of the rights of patients. We have by now got used to being given appointments for six or more months ahead. This does not matter in the case of routine visits, but what happens in the case of an emergency? A patient who has already been treated by a particular person feels safer if he/she is attended by the same person who knows his/her history. Doctors should make allowances for such emergencies. Very often they make themselves inaccessible and although they themselves would never refuse to see such a patient, it is often the receptionists at clinics that have the task of putting people off. In Malta we do not have the system of group practices: but the least that could happen on such occasions is for the doctor or his clinic to refer the patient to another doctor whom the doctor him/herself trusts. Such trust might then be passed on to the patient.

All this can in fact be summarised in the fact that the patient expects to be treated with respect as an intelligent person. Closely linked with respect of the patient as an intelligent being is respect for the patient's dignity, privacy and confidentiality of his condition. Not all patients like to be turned into 'a case' and made the object of study. This happens because our major hospital is a teaching hospital - but I feel very strongly that the patients' permission should be required before they become an object of demonstration to medical or paramedical students. Also, how dignified is it to find an old person tied up to his/her bed or chair simply because there is not enough staff on the ward to see to the safety of the persons concerned?

Good gentle manners and a gentle soft voice should be the rule rather than the exception. I have known members of the nursing staff mock their patients, especially the elderly, in front of outsiders. Although the patients themselves might not realise what they are being subjected to (and sometimes they only pretend not to notice), their next of kin will certainly do - and closely related to the rights of patients are the rights of patients' families. Although I would not like to generalise and say that this is common practice, I have witnessed it myself on more than one occasion. Although some patients may be irritating, I hardly call such behaviour keeping a sense of humour.

I cannot end my paper without a word about the rights of patients with mental problems and their families. Traditionally these patients have been regarded as objects of charity. There still exists widespread prejudice in this regard, especially if the patient needs to be institutionalised. Organisations like the Richmond Foundation have done much to minimise the prejudice and the resulting social stigma but unfortunately these still exist. Patients with mental illness are just like any other patients and have the same rights as any other patients. They have a right to be treated with dignity and respect, to be given information in words they can understand about their medication; and about their diagnosis; to have some

choice of treatment; assurance of confidentiality; and to have a say in how the services they use are planned. They have a right to decent living conditions: for basic things like being allowed to wear their own clothes, use their own personal possessions and toilet articles, have some secure storage space, privacy when they want it, and to be able to complain about any abuse they feel they have received without fear of recrimination.

After having said all this, however, and in spite of all our moaning, I must say that the general opinion about our medical services, both public and private, is very high. Unfortunately it is usually the unpleasant exceptions rather than the efficient day-to-day service that makes the rounds among the public. We are proud of our personalised service which we must be very careful not to lose: rather it should be made even more personalised. We must not allow routine to justify shoddy treatment. We appreciate the fact that both our doctors and our nursing staff are over-worked with extremely long hours when they are on duty. It is easy to say that, like us, they are human: but each patient expects to get the best possible treatment as is his/her due. And I am afraid that in this case it is up to the medical profession to live up to the patient's expectations rather than the other way round. A patient's state of health will make him even more irritable and more demanding. What is so sad is the fact that it is usually those patients who cannot stand up for themselves, the patients with no connections, the less fortunate, who become the victims of an inefficient medical service.

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7 LEGAL ASPECTS OF CHILD AND PARENTAL RIGHTS

DR RUTH FARRUGIA

The principles which govern the relationship between the legal capacities of children, the responsibilities of parents and the limits of State intervention are best exemplified in the field of medical decision-making. This is primarily because the health of children is evidently the most basic and essential element in protecting their welfare. It is therefore somewhat perplexing to discover that issues relating to child and parental rights in the context of consent continue to generate debate as a matter of conflict rather than consensus in the best interests of the child.

Conflict of rights and responsibilities

In determining the interplay of rights and responsibilities, three essential factors should be taken into account :

- the limit of parents' powers and duties;
- the extent of children's rights (whether to be protected or to exercise autonomy); and
- the limits of State paternalism exercised through the Courts.

Central issues

Although there are many queries, which have been posed in the field of medical issues affecting children, they can be reduced to two central questions :

1. Who decides what medical procedures or treatment are appropriate for a child?
2. On what criteria ought such decisions to be based?'

1. In answer to “who decides” there are any number of possibilities, with the parents presumed to front the queue in virtue of the authority vested in them as parents. Although parental authority has often been portrayed as the granting of power for the best interests of the child rather than an end in itself. This also leads to the issues raised when parents are not in agreement, and to the intervention of the state in resolving the stalemate.

Children themselves could be presumed to be the logical answer to the question, particularly when they have acquired a certain age and/or level of understanding. Under Maltese law the situation at present only contemplates the Courts hearing the opinion of a child aged fourteen and over, **as of right**, in some cases.² Proposals for amendment have been made to the effect that children’s wishes should be considered according to age and understanding.

The other choice rests with an alternative agency, such as a court, taking the final decision however the mode of intervention may not always be clear. Locally, a request for medical procedures without parental consent would invariably be addressed to the Courts where the trend has been to rely heavily on the doctor’s opinion in preference to that of the parent(s). The classic cases involve refusal by parents to consent to a blood transfusion for their child on the grounds of their religious beliefs.³

2. The second query, namely the choice of criteria, is much more difficult to answer. A strongly supported argument holds that all medical decisions affecting individual children should be taken on an individualistic basis applying the welfare principle / the best interests principle / the paramountcy principle – all describe actions taken in the child’s best interests to a varying degree, depending on state legislation.

The opposing argument is founded in the belief that failure to establish reasonably clear criteria can lead to widespread

variations in the treatment or non-treatment of children with broadly similar medical conditions. However it is hard to reconcile this latter viewpoint with the commitment to children's rights.

In the final analysis, most countries refer to their courts to resolve any such difference of opinion. These in turn, do all they can to ensure that due deference is given to the expertise of the medical profession, interfering only on issues perceived as within the domain of fundamental public policy. A British authority on the subject concludes that it has become "clear that the courts will respect the clinical freedom of doctors and refuse to force them to act against their clinical judgement"⁴

Consent

The general premise widely, if not universally, accepted is that the consent of the patient is required for any medical examination or procedure. This principle is founded in the idea of self-determination that gives rise to the immediate query whether a child can be in a position to exercise such self-determination or whether an adult must do this for him or her.⁵

At Maltese law, it is the parents who must make any necessary decisions on behalf of their child and it is only when an emergency situation arises that a third party in good faith may intervene.⁶ Where parents disagree regarding the giving of consent, the court may make attempts to resolve the deadlock and give such directions as it may deem fit in the best interests of the child.⁷ Little, if any, consideration is given to the age of the child so that a seven-month-old, a seven-year-old and a seventeen-year-old are both treated on a par. This issue is currently under review.

Exceptions to parental consent

1. The State may restrict parental discretion directly through legislation or indirectly through the courts.

2. In some legislations the child's own view may prevail over that of a parent in instances where there is a conflict.

3. There are instances where the medical profession may proceed lawfully without parental consent. This follows the doctrine of necessity which allows anyone – not only the doctor – to render first aid.

Capacity

Should parental consent be viewed simply as a **substitute** consent to be made available only when the child lacks capacity, or should it be viewed as an **alternative** consent remaining available despite the child's capacity?⁸ Yet again should both consents be taken into account? And what happens in relation to medical confidentiality?

Competence or capacity is a legal concept imputing decisional authority in a certain domain. Competent patients have the right to decide whether to accept or reject proposed medical care. Children are one of the categories of people, together with the elderly and the mentally ill, that are commonly denied to have competence.⁹ The decision as to capacity must therefore take into account the element of paternalism displayed by the state when the decision proposed by the parents is deemed outside the parameters deemed acceptable in the best interests of the child."the court fuses the principle of child autonomy with the practice of intervention...."¹⁰

International Law

Apart from national legislation, these issues of consent and parental and child rights are regulated by standards of international law.

For the medical profession, the point of departure might well lie with the **Declaration of Helsinki**.¹¹ In 1964 the 18th the World

Medical Assembly made recommendations guiding medical doctors in biomedical research involving human subjects and the association revised the document in 1975, 1983 and 1989. With reference to consent, the declaration makes the position of the doctor very clear, particularly in the light of Article 12.

Article 11

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

Article 12

Whenever the minor child is in fact able to give a consent, the minor's consent must be obtained in addition to the consent of the minor's legal guardian.

The European stand on the subject comes from the much more recent Council of Europe initiative. The Convention for the Protection of Human Rights and the Dignity of the Human Being with regard to the Application of Biology and Medicine known as the **Convention on Human Rights and Biomedicine (BC)** drafted by the Council of Europe Steering Committee and adopted on the 4th April 1997 comes into force on the 1st December 1999.¹² An Additional Protocol to the BC, on transplantation of organs and tissues of human origin is also in the final stages of drafting and the text should be finalised by the end of 1999.¹³

Article 6(1)

An intervention may only be carried out on a person who does not have the capacity to consent, for his or her direct benefit

Article 6 (2)

Where according to law, a minor does not have the capacity to consent to intervention... the intervention may only be carried out with the authorisation of his or her representative or an authority or a person or body provided for her by law... the opinion of the minor shall be taken into consideration as an increasingly determining factor in proportion to his or her age and degree of maturity.

This article does not deal with the refusal of authorisation. Where there is a conflict between the parents and the authority or any person provided for under national law, it will be the responsibility of the authority so provided to settle the problem, bearing in mind the fundamental rights of the child.

Explanatory Report Point 45

"... in certain situations which take account of the nature and seriousness of the intervention as well as the minor's age and ability to understand, the minor's opinion should increasingly carry more weight in the final decision. This could lead to the conclusion that the consent of the minor should be necessary, or at least sufficient for some interventions."¹⁴

The Declaration of Helsinki and the BC must, however be reviewed in consideration of the all-encompassing **United Nations Convention on the Rights of the Child (CRC)**

Article 8(1)

The protection of the child's right to life requires that, despite such justification as may be drawn from the parents' fundamental right to freedom of religion and freedom to manifest this religion and their right to provide their children with religious and moral education in conformity with their own convictions, their refusal

*should not be taken into account by the doctor, even if the patient's immediate survival is not at stake.*¹⁵

Article 12 (1)

The child should have the right to freely express his or her opinion on any matter concerning him or her and the child's opinion should be taken into account according to age and degree of maturity (also referred to as age and understanding).

There should be no dispute regarding the position of the child in the interpretation of all three international documents. Children require an adult to give consent on their behalf in virtue of lack of legal capacity, but their consent must be taken into consideration along with that of the person representing their best interests. Failure to respect this right should be accountable at law but failing legal representation for children makes the situation even more difficult to enforce.¹⁶

Regarding the child who is unable to offer consent or refuses to participate, the Journal of Medical Ethics makes the following point about the CRC :

“ Pediatric medicine abounds with examples of issues which the Convention could not settle without further interpretation. There are, for example many types of case which concern the respective powers of parents and children to grant or withhold consent to medical treatment. If the relevance of the Convention to the medical profession were thought to depend upon its capacity to shed light on these hard cases, then it would be a document with only a slight claim upon the attention of doctors in liberal democracies. Perhaps then, the strongest basis for the Convention's claim on the attention of the medical profession in general, and pediatricians in particular, is in the opportunity it provides for an appraisal of the broader implications and limitations of appeals to children's rights in medical ethics.”¹⁷

This position is also based on the more general principles to be found in the **European Convention on Human Rights (ECHR)**: Articles 2 and 8 and in the **Covenant on Civil and Political Rights**: Articles 6(1), 17 and 23(1).

Conclusion

The dilemma between parents' rights and child rights continues to perplex the medical profession often caught up between the two. Determining whether the patient has the necessary capacity to give consent remains the crucial element to solving the quandary.

While international law is clear on the issue of child and parental rights in the field of consent, the local position still requires clarification and begs reform. Until such time as our law amends the capacity of the child to be interpreted according to age and understanding rather than just age, Maltese doctors will be bound to respect the wishes of parents over children. The fact that our courts have steadfastly stood behind doctors in ensuring that such wishes are truly in the best interests of the child is, at least, some consolation.

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8

SOME PHILOSOPHICAL ISSUES OF THE RIGHTS OF PATIENTS

HENK TEN HAVE

Quality Of General Practice Care

Recent studies concerning the quality of general practice care in the Netherlands showed that both technical and interpersonal quality are important for patients (Jung, 1999). The idea is quite simple: if you want to know what is good care, ask the patients. As regards technical aspects, the most important for patients are: the feeling that the GP is competent, that the GP has good professional knowledge, that the GP diagnoses and treats illness well. The interpersonal aspects of general practice, considered most important for patients, were: the GP guarantees confidentiality of information about patients, takes enough time to listen, talk and explain things, understands what the patients wants from him or her, and tells patients everything they want to know about their illness (Jung, 1999).

The assumption of these studies is that quality of care can be identified by asking the preferences of patients. By presenting their preferences, patients can make an indispensable contribution to defining the quality of general practice care and setting the standards by which to judge it.

In general, the aspects of care evaluated most positively by patients are primarily interpersonal. These aspects can be summarized under three headings: humaneness, informativeness, and competency. These studies also show that the views of patients and GPs in regard to quality of care do not differ substantially. Considerable similarity was found to occur between the preferences of patients and GPs. However, patients tend to give more emphasis on communication, while GPs emphasize

the organisational aspects of care. Nonetheless, for both parties, aspects of the doctor-patient relation are mostly perceived as important and evaluated positively, much more than other aspects of care, such as coordination, management, organisation, accessibility or efficiency. So, the doctor must be competent, of course, but above all he or she should address you as a person.

Emphasis On Rights

In the 30 years history of modern bioethics, much attention has been focused on formulating, differentiating and implementing patient rights. The reasons for these efforts are known. In short, they relate to the criticism of medical power and the need to strengthen the position of patients within a context of paternalism (Ten Have, ter Meulen and van Leeuwen, 1998). At the same time, it has led to a situation where in many countries, the doctor-patient relationship is now strongly regulated within a legal framework. The moral concerns with the fragile position of patients have been translated into a juridical approach. Perhaps this development towards a juridification of medical interactions was unavoidable. But we should also be aware of the price that is paid: the focus now is on the doctor-patient relationship as a contract.

In our country, since 1995, we have a new law on the doctor-patient relationship, regulating the obligations and rights in the contract between doctors and patients. A range of issues is regulated: the right to information, the right not to know, the requirement to consent (oral or written consent; the special case of incompetent patients; the question of patient representatives), the duty to make a record, the period of record storage, the right to destroy the record, the right to consult the record, the duty of confidentiality, the protection of data, the right to privacy. There seems to be an ever growing list of rights and duties in modern health care that are in need of regulation.

The most important legal measure directing contemporary medical practice, is the attribution of an enforceable right of patients to refuse any medical interventions offered, or even stronger, a right not to have to undergo any medical treatment without first having been provided the opportunity to grant consent. A care provider is not only obligated to obtain consent and to respect any refusal, but also to provide all information that may be relevant to the patient in order to make such decisions.

Trust Vs Mistrust, Protection Vs Care

The legal approach to patient rights usually proceeds from the idea of reciprocity of rights and duties of patients and physicians. The general view is that most rights of individuals and duties to individuals are correlative. Every assertion of patients' rights could be translated into statements concerning the obligations of health professionals to patients. For example, if the patient has a right to information concerning his or her condition, it is the duty of the health professionals to provide such information. Philosophers have argued that this focus on patients' rights assumes a parity between health professionals and patients that seldom exists. There is significant difference in knowledge between physicians and patients. Sometimes ill or depressed patients have little choice but to enter a physician-patient relationship. The language of rights is in this perspective necessary to provide protection and safeguards to patients in vulnerable circumstances. But rights language presupposes that there are conscientious and virtuous health care professionals who regard it their duty to care for patients even if the rights are not explicitly formulated and enacted yet.

The idea of patients rights is also closely connected with the notion of doctor-patient interaction as a contract. The notion of a contract has played a prominent role in discussions of the rights and duties of patients and health professionals. A contract is considered as a formal statement of mutually agreed-upon rights and duties.

When doctors and patients enter into a relationship they, at least implicitly accept a contract.

But the professional-patient relationship is more complex than any one-to-one contractual model might suggest. For example, for the sake of community's interest, obligations may be imposed on physicians that conflict with their obligations to their patients, e.g. in the mandatory reporting of communicable diseases.

However, there is also a more fundamental reason why the interpretation of the medical relation as a contract is one-sided.

A Care Relationship

Physicians do not simply provide care because they are contracted to do so. They are engaged in a relationship because they care about the patient. In their professional activity they represent another human being who cares, who is willing to share in the patient's adversity, who goes about seeking an answer, who provides hope, who can be trusted. Patients need to be empowered in the face of medical power. But also the care providers need to be empowered in the face of suffering human beings. They have a right to guide patients. Prudent guidance is never a limitation of a patient's freedom, but opens up new horizons, new options, new possibilities. This is an essential element of care. In the profession of medicine, physicians continuously are trying to promote the patient's good, and therefore in their activities they attempt to balance beneficence and autonomy.

Considering the relationship between doctor and patients primarily as a care relation rather than a contract, also brings the focus on responsibilities rather than rights. Patients' rights are recently developed in legal and moral statements. Professional responsibilities have long been recognized in medical codes. In the context of a care relationship, the physician has the

responsibility to act in accordance with the patient's interests, while he or she is interpreting those interests. In order to have the best perspective on the patient's good, the views of the patient are indispensable. Interpretation of the patient's interests without input from the patient is a contradiction. But acting on the basis of a common interpretation of the patient's good is different from acting in response to the rights-claims advanced by the patient.

The Patients' Charter Of The Malta College Of Family Doctors

At first reading, the Patients' Charter of the Malta College of Family Doctors, provokes the question concerning the status of the document. It has the external characteristics of a quasi-legal statement. But as all self-legislative documents developed by the medical profession, this charter has only the force that the profession chooses to attribute to it. The document therefore is more a promise or pledge than a legal statement.

Secondly, the focus of the document is not on patient rights as well as on professional responsibilities. Of course, I do not know precisely the genesis of the charter, but as I read it, it seems to me to present the ideal self-perception of Maltese family doctors. Nothing is wrong with that. This is how doctors prefer to be viewed within a community. However, it would be overestimating to assume that in this charter doctors would also formulate the rights of patients. They identify the obligations they voluntarily adopt because they regard themselves as members of a profession.

Third, the document also raises the question concerning the relation to general ethical principles. Usually professional statements present themselves as applications of ethical principles. Very often the principles are not very clear. Quite often the statements present rules of conduct, sometimes moral rules, that implicitly appeal to general ethical principles. Interpreting the charter primarily as a statement of professional responsibilities, present a stronger commitment as simply referring to patient rights.

Every right that is postulated and endorsed, needs virtuous and conscientious physicians in order to be enforced in daily practice. This commitment to apply the rights is actually proclaimed in the charter under discussion.

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9 REPRODUCTIVE TECHNOLOGY

Introduction

M.N. CAUCHI

Issues relating to reproductive technology affect perhaps a minority of persons, and yet they loom very large on any bioethic committee's agenda. This is primarily because of the fact that here we are dealing with the very fundamentals of human relationships. Our actions will affect not only us, the current players in the field, but also future generations. That is the reason why procedures that are acceptable when applied to somatic manipulations may not be acceptable when applied to reproductive organs. Included here are procedures which involve growth of a fetus in vitro, the transplantation of fertilised ova, the manipulation of the germinative genome and so on.

Our Committee has been working on a document relating to reproductive technology for several years now. We have been blessed with a plethora of Ministers of Health. In fact we started the document under Dr Louis Galea, then under Dr Michael Farrugia, and thirdly and currently under Dr Louis Deguara. The reason for this is not tardiness on our part, but more importantly intrinsic differences of opinion in our society as reflected within the members of the committee itself.

I am hoping that the meeting today will clarify some issues which arise from this important area of human biology. We shall hear about the biology, philosophy, ethical as well as legal aspects. I am particularly interested in hearing also about the views of all members of the audience today, to try to assess the current views of the Maltese public, and not just the medical confraternity, about these topics.

The function of conferences of this kind is not only to pass information from the selected panel of experts to the general public, but also to glean as much feedback as possible, so that we, as a committee can feel that we are still in touch with the community. I do not believe that any ethics committee can function in too rarefied an atmosphere, detached from day to day developments in the views of society at large.

As a Bioethics Committee we would appreciate suggestions and ideas on where emphasis should be placed and which topics in your opinion deserve the most urgent attention. I feel sure this meeting will be of value to all of us.

10

FUNDAMENTAL ETHICAL ISSUES IN ASSISTED PROCREATION

L.J. GERMAN

The field of human reproduction has proved to be fertile ground for medical technology for, within the span of a few decades, we have moved progressively from 'sex without babies' to 'babies without sex'! The various sophisticated techniques of assisted procreation have brought new hopes to infertile couples, but in the process they have also rocked traditional concepts of "marriage" and "family", and challenged long-established views about the status of the early human embryo and about the significance of the genetic link between parents and offspring.

The development of In Vitro Fertilisation (IVF) is a perfect example of how medical science has outpaced morality and ethics. Reproductive technology, while offering enormous benefits to infertile couples, has opened up a veritable Pandora's box of ethical dilemmas. Louise Brown, now 21 years of age, was the first IVF baby born in England. Here in Malta our first IVF baby was born only a few years ago in what could well be described as a legal and ethical vacuum. For while Science and Technology have forged ahead, Law and Ethics have lagged behind. So, in launching this document on Reproductive Technology (or, should it be Assisted Procreation?), the Bioethics Consultative Committee has taken a decisive step towards remedying this deplorable state of affairs.

Because of time constraints I shall not dwell at length on the various ethical issues raised by Reproductive Technology. I have chosen instead to focus attention on what I consider to be fundamental issues, namely, the moral status of the early human embryo, and the role of bioethics in dealing with controversial issues associated

with assisted procreation. The aim of my presentation, therefore, is not to provide ready-made solutions to ethical dilemmas, but rather to stimulate further discussion on these important topics.

1. The moral status of the early human embryo

The moral status of the early human embryo is of central importance in bioethics not only because the degree of respect which is due to the human embryo depends largely on the status accorded to it, but also because recent advances in reproductive technology have implied questions about the value and protectability of human life in its earliest stages, to which IVF now gives easier access. But before tackling moral status, I want to consider the complex and difficult question concerning the nature of the human embryo, or what it is.

Let us, therefore, review briefly the available scientific evidence and see what we can discern about the nature of the human embryo, given that an entity acts specifically according to its nature. What do we know about the early human embryo? We know that a substantial change occurs at the end of the fertilisation process when the male and female gametes (each carrying 23 chromosomes) transform themselves into a completely different entity (with 46 chromosomes) - the human zygote. Beyond this stage, substantial change does not occur and what follows, as embryological development continues, is a series of accidental changes without any corresponding alteration in the nature of the entity itself.

We know that the human zygote has a complement of 46 chromosomes which characterise the species *Homo sapiens*. We know that the new genetic identity established in the zygote, besides being unique, remains basically unchanged throughout subsequent embryological development and indeed throughout its entire life span.. The changes that do occur represent the 'switching on' and 'switching off' of various genes as embryological

development progresses. We know also that the genetic information contained within the nucleus of the zygote, together with that contained in the cytoplasmic organelles, is ultimately responsible for causing virtually all of the processes throughout embryological development.

Now if the human zygote, with its 46 chromosomes in the proper combination, exists independently as one, unified, self-identical being, then it must be an individual of the human species, even if it later produces more than one individual, for it is naturally capable of doing so. The human zygote, therefore, is not a possible or a potential human being, but a presently existing, real human being, albeit of microscopic dimensions, equipped with the potential to develop into what we will later be calling a 'human person'.

Viewed from this perspective, the distinction between 'human being' and 'human person', which features so often in bioethics literature, is valid only in so far as it reflects different stages in normal functional development of the same human organism. This distinction has its roots in functionalism which claims that personhood is definable only in terms of function or behaviour. Common sense, however, acknowledges the distinction between 'what one is' and 'what one does'; between 'being' and 'function'; and thus between 'being a person' and 'functioning as a person'. It makes no sense biologically to speak of 'human being' and 'human person' as if they were two separate entities. It is because of what we are, because of our nature or essence or being, that we can, and do, function in certain ways. Functioning as a person is a sign and an effect of being a human person. It is evidence that the human being has reached a particular stage of its normal development.

By and large, the way we behave towards nascent human life is a reflection of the value we place on it. In so far as assisted procreation is concerned, bioethical guidelines should therefore respect not only the dignity of the human being, but also the

inviolability of individual human life. Science and technology are there to be at the service of humankind, and not the other way round, and respect for the dignity of the human being should never be sacrificed at the altar of scientific and technological expediency.

2. The role of bioethics

Let us consider a few examples of the kind of ethical problems raised by reproductive technology and examine the role of bioethics in sorting them out. One may indeed ask: Is it ethically acceptable to have an egg fertilised by a donor sperm (or to fertilise a donor egg with the husband's sperm), and then replace the embryo in the uterine cavity? Is it ethically acceptable to cryopreserve embryos for future use? And if so, is it ethically acceptable for the embryos to be implanted in the uterus of a woman who has no genetic relationship with such embryos? Is it ethically acceptable for surrogate mothers to be used where a woman can produce eggs but cannot undergo a pregnancy? And, finally, is it ethically acceptable for 'spare' embryos, produced by IVF but not needed for implantation in the uterus, to be killed or used as tissue for research purposes?

The issue concerning gamete donation presents special problems. Some would argue that, in our culture, marriage is meant to be an exclusive relationship between husband and wife both of whom contribute the genetic elements needed for the procreation of their offspring. Hence, third-party involvement is seen as going against the grain of marriage as an institution, not only because it undermines the exclusivity of the marriage relationship, but also because it raises serious problems concerning the child's genetic identity. On the other hand there are those who find no objection with third-party involvement because they see no significant difference between donation of gametes and such practices as blood and organ donation. Fertilisation using donor gametes would present no special problems in countries where artificial insemination by donor (AID) has already been accepted and

practised for a number of years, since the principles involved are very similar. But I think you will agree that there is a significant difference between donating blood and donating gametes, for it is only the latter that have the potential to generate human life.

Another thorny problem associated with IVF concerns the fate of 'spare' embryos. If 'spare' embryos are killed or used as tissue for research purposes, let us be in no doubt as to what it is that is being destroyed. What is being destroyed is a human being with a claim to life and all the potential of a genetically unique individual. It is impossible to reconcile respect for human life with creating it with a view to using it as experimental material, and then disposing of it as laboratory trash.

In the UK an attempt was made to reach the classic compromise in dealing with the dilemma posed by experimentation on human embryos. Mainly for reasons of pragmatic expediency, the Warnock Committee decided to select Day 14 as the limit beyond which embryo experimentation should be banned. Now pragmatism and compromise are all very well, but I do believe that there are some values which are too important to be relegated to second place unless it is otherwise impossible to prevent harm. And respect for human life must surely rank high among these values.

How can bioethics be of help in resolving these dilemmas? The help which bioethics can provide consists not so much in handing down conclusions as in enabling others to reach them by sound arguments. What is needed is a sound and generally accepted method of argumentation, armed with which those who start with different views can have them discussed in the light of the medical facts and possibilities, hopefully with a view to reaching agreement. The conclusions reached are, to a large extent, conditioned by the ethical theory one embraces as the depository of the basic values underpinning one's arguments. For obvious reasons, however, it may not always be possible to reach an ethical consensus on all controversial issues.

On a practical level, one of the roles of the Bioethics Consultative Committee is to provide ethical guidelines on assisted procreation - guidelines which should respect the dignity of the human being, not simply in isolation, but also in its familial and social contexts. In fulfilling this role, the Committee should also be conscious of its educational commitment, not just towards health care professionals, but also towards society at large. It is in this context that cultural values need to be taken into consideration when drawing up guidelines.

Most scientists naturally resent what they see as arbitrary limits set to their right to experiment. They contend that lay persons are ill-equipped to discuss issues of this sort with them, let alone share control of what they do. They consider these to be highly technical matters which should be left to technical people who understand them. A balance must obviously be struck between Science and Ethics. What needs to be stressed is that human life is too precious a commodity and too valuable an asset, to be left solely in the hands of scientists. Other members of society outside the scientific arena have an equal right to share in decisions over such issues as IVF, experimentation on human embryos, cloning, gamete donation, surrogacy and other procedures which impinge so heavily on the dignity of the human being.

Whatever the technology used, let us not forget that what we are dealing with is a couple who are seeking help from medical science for the treatment of infertility. The human aspects of assisted procreation must not be neglected. The aim should be to treat the couple, and not just treat the diagnosed condition. The couple should therefore be counselled about treatment options and associated risks, about possible solutions and their likelihood of success or failure. The aim is not for them to have a child at all costs. They should also be prepared to cope with the possibility of failure. Without meaning in any way to be insensitive to the genuine suffering of many infertile couples, I would add that infertility, although undoubtedly a blight, is more an absence of a good than

an actual harm, and that marital harmony does not depend solely on begetting children.

Let me conclude with an expression of hope that, in our attempts to expand the frontiers of medical science, we resist the temptation of allowing the so-called 'technological imperative' to cloud the values that should be guiding us in our scientific endeavours. Not everything that is technologically possible is necessarily also ethically acceptable. And before establishing what is technologically possible, and whether it is likely to be safe, let us pause awhile to consider whether we should be doing it in the first place!

11 MORALITY AND PUBLIC POLICY

E. AGIUS

Malta's first so-called "test-tube baby" was born at a private clinic on 15th December 1991, thirteen years after the birth of Louise Brown, the culmination of years of pioneering research by Robert Edwards and Patrick Steptoe. The news of the first successful human artificial fertilisation was given with much satisfaction and pride by a local medical team on 30th May at the Medical School during a lecture on infertility. A video of an ultrasound scan showing a healthy nine-week-old fetus in the womb of its 28-year-old mother after the embryo was produced *in vitro* was shown to the audience. At the same conference it was announced that another fetus, produced by Intra-Tubal Insemination technique (ITI) was several months old.

The publicity given to the first successful human fertilisation raised widespread public discussions, particularly on the local media, on the complex ethical, social and legal issues related to artificial human procreation. Shortly after this breakthrough in local medical history, a parliamentary question urged the National Bioethics Consultative Committee to issue ethical guidelines and called for a legal framework. Though this event caught the attention of the general public, artificial insemination has been taking place in Malta, as elsewhere, for a long time. An article published in one of the leading daily papers announced that the number of Maltese married couples who are having children using donated ova or sperm is increasing.

Nobody contests the fact that human artificial reproduction is not just a matter of science and technology. Because these techniques have primarily been developed to assist infertile couples in their strong desire to become parents, they have become part of our

social reality, and as such, they require the intervention of the political authorities and of the legislator, since an uncontrolled application of such techniques could lead to unforeseeable and damaging consequences for civil society. Daniel Callahan rightly comments that “the moral problems of biomedical ethics are beginning to transcend the narrow context of medicine itself. They are raising fundamental questions about how we ought, to organise our society and think about our life together”.

Today, neither private citizens nor scientists tend to contest the right of public authority to intervene in the techniques to overcome infertility and to review reproductive technologies according to certain values and fundamental moral principles. Nevertheless, two questions are usually raised: When should this intervention occur? On what principles should such interventions be based?

That the intervention of public authority must be inspired by rational principles which regulate the relationship between civil law and moral law is highlighted by the French National Consultative Committee on Ethics, in its report entitled *From Ethics to Law*, as follows:

Concerning the practice of reproductive medicine, it is often said that it is too early to legislate. State law should not interfere, but the responsibility to take decisions should be left to the professional ethics of physicians and scientists. This way of thinking does not take into account that many scientists require legislation for those issues that are not simply professional matters. It ignores the fact that the National Committee on ethics suggested that some regulations should be promulgated ... (p.13)

Then, the report raises the following important question, “How can we not legislate when human artificial procreation places filiation law in question, or when the existence of some fundamental social principles are at risk?” (p. 14) It is therefore the task of civil law to ensure the common good of people through the promotion of public morality.

The Law and Morals Debate

A serious discussion on the relationship between law and morality should commence by avoiding three possible misconceptions. It is sometimes assumed that people seek to ban everything that they regard as immoral. This position, which is often called the *Moral Majority* or the *Moral Right*, is untenable because not every action considered as immoral should necessarily be considered as a criminal act. The opposite is the so-called *Immoral Minority*. It is sometimes assumed that certain people would never ban anything, however immoral, and would prefer to let everyone 'do their own thing'. This position is false because law and public policy must never be regarded as amoral, or indifferent to moral concerns and criticism. Then there are those who argue that the law has nothing to do with morality. This positivist position can easily be argued to be false because many areas of the law in fact reveal moral values beneath their dry exterior.

The question of whether law ought to enforce morality has been an issue of philosophical debate for some time. John Stuart Mill's assertion that the only justification for limiting a person's liberty is to prevent harm to another was the starting point of the Hart-Devlin debate. Lord Devlin, a British judge, disputed the Wolfenden Report's assertion, namely, that "no act of immorality should be made a criminal offense unless it is accompanied by some other feature such as indecency, corruption or exploitation". He argued that society is a "community of ideas" including ideas about morality, that "without shared ideas on politics, morals, and ethics no society can exist". Legislation against immorality is not only permissible but also essential to prevent the disintegration of society. The criminal law exists for the protection of society, not for the protection of the individual.

Lord Devlin suggested four guidelines, all of which are principles of restraint in the way society should use the law to enforce morals:

- i) nothing should be punished by the law that does not lie beyond the limits of tolerance;

- ii) the extent to which society will tolerate (not approve) departures from moral standards varies from generation to generation;
- iii) as far as possible privacy should be respected;
- iv) the law is concerned with the minimum and not with a maximum standard of behaviour.

The American professor H.L. Hart contested Devlin's relatively simple argument. While Hart conceded that some shared morality is essential to the existence of society, he questioned Devlin's conclusion that a change in society's morality would lead to the destruction of society. Hart asserted that society should protect individual differences in morality because it can profit from them. Society, according to Hart, does not require the enforcement of a uniform morality, as Devlin suggested.

In place of Devlin's justification for the full enforcement of morality, Hart developed his own argument for the partial enforcement of morality based on the distinction he drew between immorality which affronts public decency and that which merely distressed others simply because they know that immoral acts are taking place. In Hart's view, society may, for example, outlaw the public expression of prostitution, because it is considered as an affront to public decency, while it would not be justified to outlaw purely private manifestations of this type of behaviour

Thus, both Devlin and Hart argue from different perspectives that law ought to enforce morality. Whereas Hart's focus is on the individual, Devlin's focus is on society. In Devlin's perspective, society ought to legislate on reproductive technologies in order to safeguard public morality. However, only those techniques against which there is a real moral feeling of reprobation should be outlawed. This moral feeling must be so strong that society regards them as an offence. For Devlin, morality is not the product of reason, but is the result either of a divine command or of feelings.

Hart's argument differs from that of Devlin. He maintains that society should never outlaw those techniques of reproductive technology which do not affront public decency. Each individual should be allowed to follow its own private convictions even though others might be distressed when they learn about such practice. This is not a good ground for forbidding it. Moral disapproval of certain reproductive techniques should not lead automatically to legal action.

The debate on law and morals has not been exhausted by the solutions proposed by Lord Devlin and Professor Hart. Since the sixties the debate shifted to relationship between law and religious ethics. To what extent may any religious group inject its beliefs into the formulation of civil laws, without violating the religious freedom of those who do not share those beliefs? Is the right to religious liberty predicated on the assumption that believers are refrained from imposing their beliefs on others by law? Does this mean that religious beliefs are *de facto* excluded from legislative action? Are such beliefs simply private matters without implication for the larger society?

It is inevitable to raise these questions for the following reasons. On the one hand, many Maltese believe that our country is still Catholic and that Catholic values must shape public policy and law. On the other hand, many see any intrusion of religious values into civil life as an assault on individual freedoms and therefore as politically retrogressive and lethal to any genuine conception of freedom in a secular society. In between, there are growing numbers of believers and non-believers who respect the values of religion but who are convinced that people should be free to make their own decisions about euthanasia, abortion or reproductive technologies. What role should religious values play in public choices? Should religious belief influence public policy?

Religious Values and Public Policy

The debate on the proper relation of religious values to public

policy has focused on three perspectives. The first is a liberal democratic stance with secularist implications. John Rawls represents this position in a moderate form. Richard Rorty pushes it to radically secularist conclusions. The second endorses the fundamental presuppositions of liberal democratic theory while seeking to provide greater public space for religion. This is the position developed by Kent Greenawald. The third offers both a philosophical and theological critique of standard liberal democratic theory and seeks to justify a much greater public role for religious convictions. This position is defended by Michael Perry.

a) Liberal theories with secularist implications

The term liberalism refers to a political tradition that developed in the 17th and 18th century in response to the religious and moral pluralism of the emerging world. It affirms human freedom and equality as the central values in public life. Because the citizens of pluralistic societies hold different convictions about God and ultimate moral purposes in human life, if we are to treat them as equals we must protect the freedom of all to hold these convictions. In public life, therefore, theological and metaphysical beliefs cannot be invoked as normative for the way society is organised. To do so would be to violate the freedom and equality of at least some citizens. This has crucial implications for the relationship of religion and politics.

John Rawls calls toleration as a *modus vivendi*. But later on Rawls maintains that a more stable basis for ordering pluralistic society was discovered. He calls this an “overlapping consensus” on a “reasonable political conception of justice” for a pluralistic society.

Rorty is considered more radical than Rawls in affirming that the only criteria of morality are culturally embedded. For Rorty, there are no trans-cultural norms of morality at all, for there is no transcendental knowledge at all. The difference between acceptable and unacceptable behaviour is not determined by

appealing to some universal rational norm. Rather, the distinction between the moral and the immoral is a “relatively local and ethnocentric” matter. Morality is simply what we do and immorality is what we do not do. The appeal to morality is an appeal to a sense of identity that is “overlapping and shared” with other persons who make up the “we” of a particular community. It has no other basis. For this reason, Rorty maintains that notions such as transcendent human dignity and human rights cannot be invoked to stand outside these traditions. Such transcendental norms simply do not exist. Rorty’s liberal perspective attacks the notion of human dignity invoked to defend the sanctity-of-life of the human pre-embryo. He also rejects the notion of the integrity of marriage usually invoked against third party involvement in assisted procreation.

b) The liberal theory supportive of religion

Kent Greenawald, professor at Columbia University Law School, addressed the problem Rawls grappled with in a way that is more promising. His book, *Religious Convictions and Political Choice*, is a reflection of the deep tension in liberal democratic societies towards the role of religion in political life. He characterises the tension in the following way.

First, government is legitimated by the consent of the governed and by its protection of basic human rights. These rights are natural rights and therefore can be understood in non-religious terms. Second, this secular foundation for government implies that government should not seek to promote religious truth, nor should sponsor any religious organisation. Third, for many people religious convictions do in fact have important bearing on ethical choices, including ethical choices about laws and public policies. Fourth, it is a central tenet of liberal democracy that people are free to develop their own values and, at least within limits, styles of life; they are free to express their views not only about political questions but about other human concerns.

The tension Greenawald addresses is that between the principle that government has a secular purpose and a secular warrant and the principle that citizens are free to seek to influence public policy in the light of their own values. When these values are religious the potential for a conflict of principles is real.

How, then is one to deal with this tension? Greenawald agrees with Rawls partially but not completely on this question. Like Rawls, he maintains that the justification of law and public policy must rest on public reason, or in Greenawald's terminology, on "the shared premises and publicly accessible reasons" that prevail in society. Justification must reflect those canons of rationality that are in fact widely shared within society in question. Nevertheless, Greenawald is also convinced that "publicly accessible reasons" do not settle a number of important moral questions relevant to public policy that are hotly debated today, such as the abortion question and issues related to assisted human procreation.

In order to answer these questions, some vision of what it means to be a human person and what value to attribute to non-human beings must be invoked. Such vision must at least contain the sort of metaphysical or religious elements that Rawls wants to exclude from his concept of political justice. Greenawald admits the inability of reason to resolve these questions. Thus public officials cannot be blamed on liberal grounds if they turn to religious convictions for guidance in these areas. They have no other choice.

Nevertheless, Greenawald maintains that citizens who rely on religious convictions to reach their own conclusions on such matters should not appeal to these religious convictions in advocating these conclusions in the public forum. They may rightly discuss policy questions in religious terms with those who share their faith, but they should not do so when engaged in political advocacy in a pluralistic society. Public discourse about political issues with those who do not share religious premises should be cast in other than religious terms.

c) Religion and the limits of liberal theory

In his 1983 book, *Morality, Politics and Law*, Michael Perry, who is a Professor of Law at Northwestern University, maintains that faith and reason are allies, not adversaries. But his views are far from those of Catholics who think that moral principles governing public life are easily known by all persons of good will. Perry takes the historicity and exploratory nature of all human knowledge with deep seriousness. But it is precisely because he does so that he grants much more importance than does Greenawald to the public role of particular traditions, including religious traditions.

For Perry, people - including religious believers - should not enter the public arena simply to negotiate about how best to secure their own privately chosen interests. Democratic citizens should not approach the public arena with this type of argument: "I want X". Rather, they ought to approach the public arena with proposals in this form: "X would be good for the community to which I belong". It is good for a conversation and argument to consider all possible proposals. Perry wants to encourage and open up public space for people to propose visions of what would be good for the larger community. They should be able to do so also when proposals are premised on religious convictions that are particularistic and distinctive.

So Perry challenges the predominant liberal view that conversation and argument about a comprehensive vision of the good life must be fruitless in a pluralistic society. According to Perry, politics is not about instrumental adjustment to competing private interests, but conversation and argument about "competing conceptions of human good, ... questions of how human beings, individually and collectively, should live their lives".

Whereas Rawls argues that such questions are too important to be subjected to the heart of politics, Perry does the opposite. Questions of human good are too fundamental, and the answers

to them too determinative of one's politics, to be marginalised or privatised. In this way, Perry challenges the fundamental presupposition of most versions of liberal politics today, namely, the idea that politics can be neutral about competing conceptions of what authentic human existence is all about. Such neutrality cuts liberal thought off from some of the richest religious resources for thinking about the human. Thus, for both theological and political reasons, religious discourse deserves to be a free participant in the public exchange of a pluralistic society.

It does make sense, according to Perry, to invoke religious ethical arguments in public debates on assisted human procreation. It is not true that the participation of a religious community in the formulation of public policy on reproductive technology would in any way compromise the freedom of others. On the contrary, religious belief ought to be invoked in discussions on assisted human procreation because it is a valid source of inspiration on many fundamental issues touching on human life, sexuality and the family.

***Donum Vitae* and Public Policy**

Perry's perspective on the role of religious belief in public policy is in line with the position defended by the *Instruction on Respect for Human Life in its Origin and on the Dignity of Procreation (Donum Vitae)*. Moral values, especially religious ones, *Donum Vitae* declares, should influence future legislation. The Church's document rightly maintains that these new techniques may be so damaging to society that "recourse to the conscience of each individual and to the self-regulation of researchers cannot be sufficient for ensuring respect for personal rights and public order". In Chapter III of the Instruction which deals with "Moral and Civil Law", the Catholic Church is urged to advocate as much as possible the inclusion of these moral values in all nations' civil law.

According to *Donum Vitae*, “the new technological possibilities which have opened up in the field of biomedicine require the intervention of the political authorities and of the legislator, since an uncontrolled application of such techniques could lead to unforeseeable and damaging consequences for civil society”. The Congregation for the Doctrine of Faith suggests relevant principles which must guide appropriate legislation and regulations. These are: “a) every human being’s right to life and physical integrity from the moment of conception until death; b) the rights of the family and of marriage as an institution and, in this area, the child’s right to be conceived, brought into the world and brought up by his parents”. Though the Instruction admits that sometimes certain procedures in assisted human procreation may be tolerated in order to avoid a greater evil, these two fundamental principles must never be compromised.

The Ethical Considerations relating to Human Reproductive Technology approved by Malta’s Bioethics Consultative Committee is quite clear on the first moral principle defended by the Instruction, namely, the respect of human life from the moment of conception. A consensus has been reached on the respect of embryonic human life: Article one of the ethical considerations states that “since human life exists from the moment of conception, it deserves the respect that is due to a human being at all stages of development”. Moreover, the report of Malta’s Bioethics Consultative Committee maintains that the law should never tolerate that human beings, even at their embryonic stage, be treated as objects of experimentation, be mutilated or destroyed with the excuse that they are superfluous or incapable of development normally. Furthermore, the ethical guidelines of the Malta’s Bioethics Committee prohibit the creation of spare embryos. In fact, article 11 states that “only a minimum number of ova strictly necessary to optimise the success of procreation should be fertilised *in vitro*. All of the fertilised ova are to be transferred to the woman from whom the ova were removed”. Storage of embryos for future use is therefore prohibited. The ethical guidelines forbid also the donation of embryos to another couple.

Third Party Involvement

The report of Malta's Bioethics Consultative Committee fails to reach a consensus on the issue of third party involvement in assisted human procreation. Should the law ban the use of gametes foreign to the party involved to save the institution of marriage and the family? This question has been the most controversial issue in the drafting of ethical guidelines.

Malta's Bioethics Committee followed the pattern of argument adopted by the Italian Bioethics Committee. In its ethical guidelines submitted to the government, the Italian Bioethics Committee includes views both in favour and against third party involvement. Eventually, a draft law endorsing third party involvement was outvoted during its first reading at the Italian parliament. An opinion poll carried out recently in Italy revealed that the majority of people is against third party involvement. Moreover, the Portuguese Bioethics Committee took a clearer position against heterologous artificial reproduction. The committee unanimously rejected reproduction using donors. Objections against heterologous artificial procreation are based in relation to the donor, to the receiving couple and to the unborn child. Furthermore, the 1989 Resolution of the European Parliament on fertilisation *in vitro* and *in vivo* considered also all forms of heterologous reproduction to be undesirable.

On the one hand, the first position endorsed in the ethical considerations presented by the Bioethics Consultative Committee defends as ethically acceptable the donation of gametes under a number of conditions. On the other hand, the second position maintains that the donation of third party gametes is significantly different from other morally lawful practices such as blood or organ donation. Donation of third party gametes changes the significance and value of marriage and the family as the proper context for human procreation and may prejudice seriously the chances of the child to develop a healthy sense of self-identity.

The latter position is in agreement with *Donum Vitae* which affirms that: a) it is through the secure and recognised relationship to his own parents that a child can discover his own identity; b) that the parents find in their child a completion of their reciprocal self-giving; c) that the vitality and stability of society require that children come into the world within a family, and d) that the family be firmly based on marriage. The use of external gametes is contrary to the dignity of the spouses, to the vocation proper to parents, and to the child's right to be conceived and brought into the world in marriage and from marriage.

The Jesuit moral theologian Richard McCormick was the only member of the Ethics Committee of the American Fertility Society who objected to third party involvement because donation of gametes touches on some very basic human values: marriage and the family, parenting, genealogy and self-identity of the child. The American Fertility Society's report, *Ethical Considerations of the New Reproductive Technologies*, released in September 1986, expressed McCormick's dissent in the following words:

“One member of the committee argued that the use of third parties – whether by sperm donation, donor ovum, or surrogate womb – was ethically inappropriate. First, it seems violative of the marriage covenant wherein exclusive, ... Secondly, by premeditation in contrast to adoption – it brings into the world a child with no bond of origin to one or both marital partners, thus blurring the child's genealogy and potentially compromising the child's self-identity. These considerations suggest that the use of third parties to overcome sterility is not for the good of persons integrally and adequately considered. Such risks to basic values outweigh, in a prudential calculus, individual procreative desires or needs. In summary, when calculus involves individual benefit versus institutional risk of harm, the latter should take precedence.”

Moreover, Karl Rahner also faults the anonymity of the donor which represents a refusal of responsibility as father and is an

infringement of the rights of the child. It should be remembered that when Sweden passed legislation giving children conceived by AID the right (at eighteen years of age) to know the identity of their genetic fathers, donor insemination came to a virtual standstill. The same seems to be happening in parts of Australia. Obviously, donors want neither recognition nor responsibility.

Richard McCormick raises two key issues related to third party involvement: a) Does third party involvement (via donation of gametes or surrogate gestation) infringe on conjugal exclusivity? b) Does having a jointly raised child justify such infringement? His answer is yes to the first, no to the second. According to McCormick, the notion of conjugal exclusivity includes the genetic, gestational and rearing dimensions of parenthood. Separating these dimensions (except through rescue, as in adoption) too easily contains a subtle diminishment of some aspects of the human person.

To insist that marital exclusivity ought to include the genetic, gestational and rearing components can be argued in the following way: any relaxation in this exclusivity will be a source of harm to the marriage and to the prospective child. For instance, the use of donor semen means that there is a genetic asymmetry in the relationship of husband and wife to the child, with possible damaging psychological effects. It should also be asked whether the child should know about the method of its birth. If so, how much information should the child have – only that which is deemed to be health-related data or all the other biological information about its heritage that most of us value? Whose interests, whose preferences, whose needs count here? The child may well have serious identity problems at a later time. Does such a possibility have to be seriously considered by those who want to undertake unusual reproductive methods? The interests and well-being of the baby-to-be-made seem to be the last issues considered, and sometimes seem not to be considered at all.

Feasibility of Law on AID

McCormick believes that party involvement is probably not feasible for prohibition by public policy. Morality and public policy are distinct but related. Although morality is indispensable for public policy, it is not sufficient, for policy-makers must also consider a policy's feasibility. Thus, in legislation it is necessary to take into account "the good that is possible and feasible in a particular society at a particular time." Often McCormick related "feasibility" to "realistic" and "sound".

Feasibility is "that quality whereby a proposed course of action is not merely possible but practicable, adaptable, depending on the circumstances, cultural ways, attitudes, traditions of a people." McCormick argued that it would not be possible to ban IVF with donor gametes or AID – even though he contends that it is not ethically justifiable – because of a lack of broad consensus and difficulties of compliance and enforcement. These examples suggest some important standards of feasibility: consensus, compliance and enforcement. "Sometimes morality can be translated into public policy, sometimes not".

Donor Anonymity

Those who argue that AID is ethically acceptable contend that it should be legally permissible under certain conditions. The report of our Bioethics Committee endorses arguments both in favour and against heterologous artificial procreation. The list of conditions to regulate AID, in case it would be legally permissible, includes donor anonymity. This position is not in line with the policy adopted by many European countries that have taken a clear stand against donor anonymity. The child's right to know its biological origin must be respected.

According to a report published by the Danish Council of Ethics, *Assisted Reproduction – A Report*, some members expressed reservation regarding the use of donor sperm. They emphasize that regard to the best interests of the child means ascribing importance to the fact that the complicated formative process may engender identity problems for the child. In some cases, discovering that the man with whom the child is living, is not its genetic father may prove to be a problem for the child. It is further stressed that donation may create dissension in the family and in the relationships between the man and the woman, since one of them is a genetic parent to the child, while the other is not. The one who has not supplied genetic material to the child may eventually feel “left out”, and problems can arise in allocating responsibility for – and commitment to the child. One of the reasons why, despite these reservations, these members were unwilling to recommend a ban on the use of donor sperm is that such a ban is difficult to enforce.

Denmark’s Bioethics Committee feels that donor anonymity must be abolished altogether. Ethically speaking, abolishing donor anonymity can be justified by arguing that, in consenting to donate material for the creation of a child, a donor assumes a responsibility; not in the sense that the person in question can be ordered to assume legal, parental custody of – or provide for – the child concerned, but in the sense that the person concerned must acknowledge his or her instrumentality in bringing a child into the world. That responsibility entails being prepared for the possibility of having one’s identity revealed to the child in question at a given point in time. By the same token the recipient of the donated sperm or egg must assume responsibility and admit that this is how the child was created. The responsibility entails consenting at a specific point in time to give the child the option of getting information about its genetic parents.

Some of the members of Denmark’s Bioethics Committee feel, furthermore, that an important objective in assisted procreation is

to encourage openness in the family regarding the making of the child. The parents should not be supported in the fallacy that the child actually is genetically their own when the truth is different. If donor anonymity is abolished, then according to the majority of members, the parents will presumably be more inclined to face up the truth, both in relation to the child and in relation to themselves.

In Sweden it has been provided by statute that, on reaching sufficient maturity, a child engendered by donor insemination has the right to obtain information about the donor. The social authority is obliged, at the request of the child, to assist in procuring such information. The explanatory memorandum of the Swedish report states that the regulation has taken on board the experience gained from adoption, where children from studies are known to benefit from receiving information about their genetic origins, provided that information comes from people who like them and respect them. Mention is also made of the fact that secrecy entraps the parents in a life-long lie. If the child wishes to have contact with the donor, this takes place through the hospital or clinic where insemination was carried out.

Germany does not admit donor anonymity. In Austria, also, the sperm donor does not have the right to anonymity. From the age of 14, a child born by the use of donor sperm can ask for information on the donor's identity. Fertility clinics are under an obligation to keep records showing the donor's name, place, and date of birth, nationality, address and so on. Moreover, Canada also proposed that records must be kept enabling the donor to be linked with the resulting child, ensuring that the donor or children can be contacted in any contingency of severe medical necessity.

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12 LEGAL ASPECTS OF REPRODUCTIVE TECHNOLOGY

LORRAINE SCHEMBRI ORLAND

Introduction

Is procreation a biological act or an essentially human act? I believe that this is a fundamental question to be addressed when evaluating human reproductive technology. All the more so because assisted reproductive techniques can so easily shift from the therapeutic to the manipulative.

The distinction between therapy and experimentation pure and simple lies at the very core of any analysis of this particular area of study in order to safeguard the integrity of the "person" which is the subject of treatment. I do not only refer here to the patient in the broad sense of the term, but to all parties involved in the reproductive process as well as the human life from inception.

The Need To Legislate

Law is notoriously conservative, yet in this particular area regulation is non-existent save for the mention of DNA testing in paternity litigation - an amendment which was introduced to the Maltese Civil Code in 1993 and left at that. Yet despite the fact that Maltese couples have benefited from new reproductive techniques, the law, unsurprisingly I would say, lives in blissful ignorance, awaiting that first test case which would shake general principles of law at their very foundations!

Comparative Legislation

I propose to approach the subject matter of my talk from a deductive viewpoint - by synthesising the main features of comparative legislation. I believe that this exercise can shed light on the main areas of concern and serve to guide the Maltese

legislator accordingly in formulating a blue print for legislation.

Of the legislation reviewed, I have found the laws of certain Australian States, particularly those of New South Wales, and Victoria and of the United Kingdom, to be particularly comprehensive. I will also refer to legislation in the US State of Louisiana as this State embraces the Napoleonic code as we do and consequently has a legal affinity to our juridical system.

An analysis of these laws immediately indicates the broad spectrum with which countries have chosen to tackle the legal and moral issues attendant on the regulation of reproductive technologies and would, no doubt, obtain a critical response from the Maltese legislator in certain cases.

Primary causes of concern are the issues of consent on the part of the donor, recipient and of the husband, the status of the child born of a reproductive process, and the issue of confidentiality. These constitute main themes in laws and statutes which have sought to provide a framework to regulate the legal relationship between the various parties to an assisted reproductive process.

Definitions

N.S.W.

The relevant legislation in the State of N.S.W. are the ARTIFICIAL CONCEPTION ACT , 1984 and CHILDREN (EQUALITY OF STATUS) AMENDMENT ACT , 1984 No. 6 .

The former deals with artificial insemination which is defined as : *“the artificial insemination of a woman, but does not include, except in section 10, the procedure of implanting in the womb an ovum (whether or not produced by her) fertilised outside her body” (art. 7).*

Artificial insemination and the implantation of a fertilised ovum in the body of a woman are also the areas which are subject to

legislation in other areas of Australia (see for example, the Commonwealth of Australia - Family Law Act 1975),

The Parties

The parties to assisted reproductive techniques are the donor of semen or of the ovum, the woman receiving the semen or implant, the child, and in the case of a married woman - her husband. The medical practitioner is also a party as issues of informed consent, experimentation, and liability are relevant.

Filiation

"Mater semper certa est", but it seems that this is no longer an absolute! Filiation and issues of disavowal of paternity are principal areas of regulation. As I stated in my introduction, Maltese law mentions DNA testing in only one area - that of filiation and even in this case, a Maltese court cannot impose testing on any party to a case in which paternity of a child is in dispute.

A common theme which runs through various laws is that where a married woman has, with the consent of the husband undergone a procedure as a result of which she becomes pregnant, then her husband shall for all purposes, be conclusively presumed to be the father of any child born as a result of the pregnancy (see Australia Capital Territory Artificial Conception Ordinance 1985 s. 5.)

This presumption is absolute.

In N.S.W. the law provides that in respect of the following procedures, namely:

- Artificial insemination of a woman
- Implanting of an ovum produced by a woman and fertilised outside her body
- Semen donated by a person other than her husband
- Semen being a mixture in part produced by her husband and in part by a third party

and where the husband has given his consent, then he shall be presumed for all intents and purposes to have caused the pregnancy and to be the father of the child born as a result of the pregnancy. Furthermore, the legislator does not equivocate on this matter and states categorically that "The presumption of law that arises by virtue of subsection (2) (above) is irrebuttable". (N.S.W. Artificial Conception Act 1984 s.5.)

The same irrebuttable presumptions can be found in other legal systems. In the same manner, a common provision concerns semen used in the procedure which was produced by a man other than the woman's husband. The same absolute presumption has been found to apply provided that the husband would have given his consent to the procedure. (*Art. Concep. Act op.cit*).

The main element for the presumption to apply is the consent of the woman's husband. Once this consent has been given, then for all intents and purposes of law and without any shadow of a doubt, the husband is the father of the child and the donor *shall be conclusively presumed not to be the father*.

It would be wise under the circumstances, therefore, to stipulate that consent must be given in writing.

The determination of paternity and the presumption of status of a child born to a married woman are stipulated in the interests of the child itself. Often, ad hoc amendments have been introduced into Children's Acts and legislation concerning children. The child has a right to certainty of status and society has an interest in regulating the matter in order to avoid doubt and instability.

The NSW act goes one step further and provides that the consent of the husband to the fertilisation procedure is presumed and the burden of proving that he did not, in fact, give his consent lies with the husband. (N.S.W. s. 5.(4))

The same considerations apply to the presumption of maternity where an ovum produced by another woman is implanted . In this case the irrebuttable presumption of maternity is in favour of the woman receiving the implant and the donor is presumed in an absolute manner not to be the mother of the child born from the procedure.(see fo ex. Australia Capital Territory – Art.Conc.Act 1985 s.6)

The legislator would have to provide whether the recipient of fertilisation treatment is to be a married woman or otherwise. This requirement is not essential and some states have provided for the presumption of paternity in the case of bona fide domestic couples. A Maltese legislator would in all likelihood opt for the qualification of marriage once reproduction is considered to be an essential human act resulting from a conjugal union.

Penalties For Abuse

The imposition of penalties and sanctions for abuse should be a feature of comprehensive legislation on reproductive technologies. Again, far reaching law makers have proscribed commercial trafficking in semen and ova, advertising and procuring fertilisation treatment for financial gain.

Trading in semen for example is, in NSW subject to a penalty or imprisonment.

Medical Supervision And Informed Consent

The medical practitioner and his team are professionally responsible for the process of fertilisation / implantation. The NSW legislation, for example, provides for pre-procedure assessments which are obligatory on the medical practitioner who will be performing the technique. The law provides that the practitioner shall , before authorising the procedure give due consideration to the following matters :

- Whether the woman or her partner are infertile
- Their children are likely to be infected by a genetic abnormality or disease
- The welfare and interests of the child born of artificial insemination
- The home environment and stability of the household
- Whether or not counselling is desirable
- The physical and mental health, age and emotional reaction of the prospective parent

Contravention of this section (section 7) is tantamount to misconduct in a professional respect (s. 7(2).)

Other provisions concern certification of donors of semen save that of the husbands, and penalties for false or misleading statements by donors.

Elsewhere, in respect of in vitro fertilisation, it is provided that such procedure may not be performed unless not less than 12 months before the carrying out of the procedure, the woman and her husband have undergone examination or treatment by a medical practitioner, *other than the one who will be performing the procedure* as might be reasonably required to establish the woman's fertility by other means. (State of Victoria Act quoted infra s.10).

Control Of Donated Semen

What happens to unused semen? This matter also requires regulation. Respect is given to an agreement between the donor and the person who is to use the semen. The State of Victoria has legislated on the authority to use an embryo in alternative procedures. The Victoria Act quoted infra provides that where the woman cannot receive the implant due to death, illness or injury, then the embryo shall be made available to another woman with the consent of the donor of the gametes from which the embryo

has been derived or, where such persons cannot be found, with the consent of a person so designated by the Minister responsible in an approved hospital (s. 14). In the case of gametes, a withdrawal of consent would oblige the designated person to destroy them forthwith.

Confidentiality

Confidentiality is essential from a number of aspects. The parties would obviously wish to have their identities subject to strict confidentiality and here, one cannot help drawing analogies with adoptive procedures. The NSW Act places the duty of non disclosure at par with the confidentiality owed by a doctor to his patient but admits of exceptions in the case of a court order, or where the person (other than the child) consents thereto, and other limited cases.

On the other hand, the person undergoing the procedure has a right to non-identifying information concerning the donor in the interests of her health and welfare.

Of significance to the issue of administrative practice is the duty to maintain proper records relating to fertilisation procedures. The Victoria Act is quite detailed in this respect and imposes a long list of particulars which are required to be recorded.

Prohibited Procedures

Legislation enacted in the Australian state of Victoria is relevant to the issue of prohibited procedures. I refer here to the *Infertility (Medical Procedures) Act 1984 No. 10163*.

This Act in Part II stipulates the following to be prohibited procedures:

- Cloning
- The fertilisation of the gametes of a man or women by the gametes of an animal

Such procedures are absolutely prohibited. The Act then provides that certain experimental procedures can be authorised by a Standing Review and Advisory Committee .These experimental procedures which can be authorised refer to research on an embryo even if such research would cause damage to the embryo.

Other Issues

Other issues tackled concern the application of the presumption of paternity to bona fide domestic couples provided neither are married and the issue of status to children born of a widow. In the latter case the presumption of paternity would apply if the husband would have given his previous consent to the procedure and his stored semen would be used in the procedure and, further, that the woman does not become a married woman after his death and before the birth of the child.(see e.g. NSW legislation).

The Victoria Act provides clearly that no person can be compelled to undergo fertilisation procedures and the use of the gametes of a person under the age of 18 is prohibited. Interestingly, a the legislator felt the need to specifically prohibit the use of semen for artificial insemination produced by more than one man.

Not all legislators have provided such comprehensive treatment. In the Canadian Province of Quebec, for example, the Civil Code provides the relevant article which concerns the status of the child and in consonance with other laws, provides that the husband cannot contest paternity if he has given consent to artificial insemination.(Civil Code art. 586). The same treatment is given in the Louisiana Civil Code (art 188).

Surrogate Motherhood

The SURROGACY ARRANGEMENTS ACT 1985 of the United Kingdom defines a surrogate mother as *a woman who carries a child in pursuance of an arrangement (a) made before she began to carry the child and (b) made with a view that the child is to be handed over to, and parental rights being exercised by, another person . (Art.1)*

The Law is made applicable to all such arrangements, lawful or otherwise . The principal purpose of the Act is to prohibit and sanction surrogacy arrangements on a commercial basis.

The Human Embryo

A Louisiana Act (ACT No 964) provides a definition of the human embryo for the purposes of the law as an “in vitro fertilised human ovum, with certain rights granted by law, composed of one or more living human cells and human genetic material so unified and organised that it will develop in utero into an unborn child” (Chap 3 s .121). This law prohibits research on human embryos as well as the sale of a human ovum, a fertilised human ovum, and a human embryo.

Article 123 provides that:

“An in vitro fertilised human ovum exists as a juridical person until such time as the in vitro fertilised ovum is implanted in the womb, or at any other time when rights attach to an unborn child according to law.”

This implies that the fertilised ovum is to be identified specifically and is not to be deemed in any manner to be the property of the physician or medical facility in which it is stored. The physician is at law the *guardian* of the ovum unless the identity of the fertilisation patients is expressed. In the latter case they acquired the rights of parents. If such parents renounce, then the ovum will be available for adoptive implantation.

Art 129 further provides that *a viable in vitro fertilised human ovum is a juridical person which shall not be intentionally destroyed...* but further clarifies that an in vitro human ovum which fails to develop further over a 36 hour period except if in a state of cryopreservation, is considered non-viable.

Regarding inheritance rights, the solution adopted by the Louisiana legislator is that such rights will only flow once the ovum develops into an unborn child that it born in a live birth (art 133).

The status of the unborn child raises ethical considerations. As we have seen, the unborn child can be the subject of rights . However, international human rights documents have been notably reluctant to recognise the unborn child as a subject entitled to the guaranteed protection against violation of fundamental human rights. *A contrario sensu*, no international legal norm actually states that the right to life only attaches to persons already born. Such norms are couched in terms which refer to the "individual" or to "the integrity of the human person" (see for example, *The Universal Declaration of Fundamental Human Rights at art. 3, and the European Convention on Human Rights and Fundamental Freedoms at art. 2*).

The European Commission has, however, affirmed that the European Convention in article 2 does recognise the right to life of the foetus but a subject to certain implicit limitations, primarily the right to life and the protection of the health of the mother during the initial phase of pregnancy. (see *X vs United Kingdom* Dec. 13.5.1980 and *Bruggemen and Schuten vs The Federal republic of Germany* Dec. 12.7.1977). The Commission based its reasoning on the consideration that the life of the foetus was inextricably linked to that of the mother .

The European Court of Justice of the European Union has stopped short of recognising a the right to abort on the part of the mother as a fundamental human right whilst sanctioning State interference

which prevented the dissemination of information on the availability of abortion procedures in other member states of the EU.

On the issue of consent, the European Commission on Human Rights in a decision given in 1979 considered the complaint that the state legislation denied the father of a foetus the right to be consulted about a proposed abortion by his wife, which, it was argued, constituted a denial of his right to respect for private and family life. The Commission recognised the right of the pregnant mother as the person primarily concerned with the pregnancy, its continuation and termination and referred to the decision above mentioned. The Commission stated that *having regard to the right of the pregnant woman, it could not find that the husband's and potential father's right to respect for his private and family life could be so widely interpreted as to embrace such procedural rights as claimed by applicant, i.e. the right to be consulted or the right to make applications, about an abortion that his wife intended to have performed on her.*

The Moment of Conception

The Parliamentary Assembly of the Council of Europe has, in various Recommendations, called for Respect for the embryo and foetus which are to be treated with the respect owed to human dignity (*Recc Nos. 934 (1982);1046 (1986) and 1100 (1989).*

However, the applicability of the right to privacy in international Human Rights documents is more in keeping with the judgment in *Roe vs Wade* (410 US 113 (1973)) than with the contention that the foetus has a right to life.

This landmark judgement of the US Supreme Court was reformulated more recently. In *Roe*, it was held that a State could not proscribe abortions in the first trimester of pregnancy. In *Planned Parenthood of South-eastern Pennsylvania vs Casey* this trimester was rejected and it was held that the test throughout

pregnancy was to be the same, namely, that the State could not impose an *undue burden which should have the purpose and effect of placing a substantial obstacle in the path of a woman's choice.* (505 US 112 S.Court. 2791 (1992).

Our legislator would argue with this judgment. Life begins from the moment of conception, although again, experts are not even in agreement on the definition of this term. Certainly, the moral issues are fundamental and on this matter, the law must protect life itself.

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TRANSPLANTATION

Introduction

M.N. CAUCHI

Transplantation has become an everyday occurrence, and yet it is a procedure which still gives problems at an ethical level. Even though we may not have indulged in the excesses associated with the sale of organs, or even the kidnapping of potential donors for the purpose of stealing organs for transplantation, we still, in Malta are faced with a number of ethical problems which the Committee has tried to resolve.

Unlike the issue we discussed previously, this is not one which should provide widely varying points of view. We have concluded a draft document, a copy of which has been circulated.

In this document we deal with various issues, including the issue of informed consent, including transplantation from those who are not in a position to give consent, the rights of the donor and recipient, the role of confidentiality and so on. We are of course always happy to receive any comments relating to this document.

In the panel today we have speakers who will talk on various aspects of this topic, philosophical and ethical issues as seen from the points of view of the various actors in this play. This includes the views of the lay person, which, as usual, should be given due importance. I must admit that I was taken aback at a recent lecture to the University of the Third Age when I asked whether the views of the person carrying a donor card should over-ride those of the family when it comes to donation of cadaver organs. All were in favour of this logical procedure. However, in our document we were too squeamish to make it categorical that this should be the case. You may want to give your views on this matter also.

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ORGAN TRANSPLANTS:

The Ethics of Donation

PROFESSOR G. GRIMA

There is perhaps no other medical technology which has changed our self-perception more than organ transplant technology. Now that the procedure has by and large passed the experimental stage and it is becoming increasingly safer to apply, patients requiring an organ replacement can justifiably hope for a longer and healthier life. Yet the promise which medical progress holds in this respect depends, in the circumstances, very much on human generosity.

The core philosophical problem, relating to organ transplants, as I see it, originates precisely from a particular state of dependence in which a certain category of patients has been placed. These patients have no claim to anybody's organs. They can only wait until the organ or organs which they require is or are actually given. Yet is it not true that the greater the need the higher is the demand and the stronger is the claim for help! If people's needs play a crucial role in a theory of justice, one may find it hard to draw the dividing line between justice and generosity.

In the history of moral philosophy and theology the place of both justice and love is acknowledged. There is room for both principles because people are distinct from each other and yet they are bound with each other by the bond of common human fellowship. Justice regulates relations between people in so far as they are individual subjects of rights and duties. Love articulates the requirements of human fellowship. Justice is motivated by the respect for the rights of the other; love is motivated by the solicitude one is expected to show for the other person in need of help. The demands of justice can be enforced, while one can only appeal to human generosity.

The way we talk about the procurement of human organs assumes

that the practice should be regulated by the logic of love rather than that of justice. Organs should neither be sold nor bought, as the exchange is not of a commercial kind. Organs can only be donated. By definition, a gift cannot be enforced; it is not given, because there is a claim to it. It is given perhaps as a sign of appreciation, as a token of gratitude or simply as a concrete manifestation of solidarity with the suffering. In the case of organ donation, the freedom of disposing of one's organs is exercised in the interest of a worthy cause. It is a sign of moral and spiritual maturity when individual freedom is exercised in a responsible manner. But should we call the free response to the summons of responsibility an act of 'love', without any qualification? If there is any obligation at all of heeding to the suffering of the most vulnerable, what sort of obligation is it and in what way and to what extent should it elicit social concern?

I propose to look at this issue from the standpoint of what can be called the paradigm of ownership and that of stewardship. The general tendency is toward the former but, as I shall be arguing, it is the latter paradigm that can adequately explain the nature and scope of our responsibility in offering or procuring human organs for transplantation.

2. The Ownership Paradigm

The ownership paradigm assumes that we have some kind of right over our body, because it is our own property. In a sense this is a valid assumption, as there is nothing else which can be described as ours more than our own body. Of course, a dualistic conception of man, dividing the human being into body and soul, as if these were two separate principles, is philosophically untenable, even though it prevailed in modern philosophy and may still be implied in our view about certain medical procedures, including organ transplants. The human body is not something extrinsic to ourselves. We do speak of our body, as we speak of

our house, but the possessive pronoun does not have the same meaning in one context as it has in the other. My body is a constituent part of myself; my house belongs to me but it can be transferred to somebody else.

One can at best only speak analogically of the body in terms of private property. This is why this kind of talk has to be qualified. Some of the more obvious qualifications are the following.

The right over our body is not to be understood as a right to self-mutilation and, much less, to self-killing or suicide. It is a right implying the obligation to care after oneself and after one's physical integrity. Behind this view there is a long-established tradition. It explains the initial negative reaction to organ transplants from living donors. Removing a sick organ is obviously not the same as removing a healthy one. But removing a healthy organ to give it to someone who needs it desperately does not amount to self-mutilation but can well be quite a heroic expression of love, provided that the life and health of the donor is not jeopardised. The right over one's body, therefore, is exercised in a meaningful manner to the extent that it takes the form of care for oneself and care for the other. It does not entitle the individual to destroy or even to waste any part of himself. I shall return to this crucial point later in my elaboration of the stewardship paradigm.

The right over one's body has another, as it were in-built, restriction to which I have already indirectly alluded. Human body organs are not a commodity which can be bought or sold. The various organs of a human body should not be exchanged for money. The market is not the avenue to be sought for their procurement and distribution. In the words of the North American philosopher, Michael Walzer, they fall within the category of blocked exchanges. They are not marketable not merely on consequentialist grounds. Indeed, if human organs could be procured against payment, the consequences would be highly undesirable. The practice is very likely to give rise to discrimination in favour of the richer and

exploitation of the poorer sections of the population. But beyond these, morally unwanted, consequences there is another, even more fundamental, issue to consider. This is the principle to be followed in trying to do justice to both the patients and the actual or potential donors. In the economic sphere justice presupposes freedom of exchanging money for a good or a service. Performance in the market depends on initiative as much as on the financial resources at one's disposal. Economic justice is, however, only one form of justice. When we pass to the sphere of security and welfare, the needs of the individual, on the one hand, and the responsibility of society to make adequate communal provisions to help its weaker, sometimes, suffering members, on the other, have paramount importance.

The ethical and legal measures generally adopted against business in human organs surely presuppose that the market is ill-suited for procuring them and make them accessible. They are, nevertheless, based on justice, because in the field of security and welfare contribution according to one's means and distribution according to one's needs constitute the basic parameters of justice. The norm that human organs should only be donated and should, therefore, be subject to no financial considerations does not necessarily render talk about justice, say, in procuring human organs superfluous. Concern for the health needs of others is a constitutive principle of justice in health care. What can you and I as well as society as a whole contribute to make human organs more available for transplantation is also a matter of justice.

The demands of justice in so far as the procurement of human organs for transplantation is concerned are usually narrowed down basically to one demand. This is the respect for the freedom of the donor. The ethical guidelines, adopted by the Bioethics Consultative Committee, require that in the case of living donors:

“Free, informed and specific consent is to be given in writing before an official body or person...”

“The doctor removing the live organ must take reasonable measures to ensure that no undue psychological or moral pressure has been exerted on the donor, and that the consent is indeed free and informed.”

“A donor is free to withdraw consent at any time prior to intervention.” “Refusal to give consent must be respected at all times.”

Given the obvious importance of respect to the freedom of donors, the relative guidelines provide also for the setting up of a special Board “to ensure that all potential donors are adequately informed, and that no undue pressure is brought to bear on the donor”. Besides, they prohibit as a rule transplantation of organs from persons incapable of giving consent, although in exceptional circumstances, children under the age of maturity may donate organs subject not only to the consent of their parents or, in their absence, to the authority of a competent court and to the approval of the special Board, but also on condition that they are adequately informed and are free to give consent.

The reason for requiring, in so categorical terms, free and informed consent from living donors, I believe, is not founded merely on the modern awareness of individual autonomy as a basic human value, but also on the consciousness that the body is mine in a unique sense. Any interference with it is only morally legitimate if I consent to it. The fact that the relative ethical guidelines prohibit individuals, who are incapable to give consent, from being considered as potential donors confirms the seriousness with which the matter of free and informed consent is taken. There is nothing to argue about on this point. Living donors have unquestionably the right of determining what to do with those organs of their body they can give, without serious prejudice to their life and health.

As transplantation of organs from cadaver donors gradually becomes the rule, ethical attention has to focus more and more on this manner of procuring human organs for transplantation. The most sensitive issue in this respect has been the criteria to follow in certifying an individual to be dead. I do not intend to raise this issue, because it is too complex to deal with in the context of this short paper. I am interested rather in the other conditions for removing organs from cadaver donors, particularly those relating to consent, which again feature prominently in ethical guidelines. This is certainly an important ethical issue to address. In fact, once the individual is dead, why should it be unjust for any organs to be removed and given to those who need them? The principle of respect for individual freedom is obviously in-applicable. What one can require is, at best, to find out whether the individual has given or refused consent during his or her life-time. Having a properly signed donor card can be taken as an expression of consent on the part of the deceased. But what happens in the absence of any previously expressed wish? One way of solving this problem is to refer the matter to the relatives of the deceased person. This is the solution which the Bioethics Consultative Committee is actually proposing.

Now relatives do occupy a very important place in the whole picture. They are the ones who generally suffer most, particularly in cases of premature death, very often through some accident. In practically every culture the family, as a basic unit of society, enter, generally on a very profound level, into all the major transitions of the individual life-cycle. It is particularly present at the final phase. Removal of organs from a deceased person, however laudable it may be in itself, without asking for the consent of relatives, will harm our deepest feelings.

There is another side of the picture, however, which is equally significant to look at. These are the needs of patients who can benefit from medical progress only if there are enough human organs available. When one argues, as is generally the case, from

the stand-point of the right of the individual over his or her body, the right of the individual to dispose any of his or her organs as one thinks fit has to be affirmed. This principle is assumed to imply the right of the individual to determine what use is to be made of the body after one's death and, in the absence of any expressed intention, this right is extended to the relatives. It is, in my opinion, the ownership paradigm which is making such an emphasis on individual consent, even in the case of cadaver donors, plausible. But is not the right of ownership itself, even in matters related to one's body, subject to a higher norm? Do not the goods which we happen to own have a universal destination? Are they not meant ultimately to serve the interests of all? Are not property arrangements that exclude people from those goods that they need, at the cost perhaps even of losing their life, unjust? The ownership paradigm should be seen in the light of the paradigm of stewardship to serve as a basis for sound ethical guidelines on organ transplants.

The Stewardship Paradigm

The stewardship paradigm assumes that what we have is entrusted to us to manage and administer in the interest of ourselves and of others. Strictly speaking, we are not owners of anything - a discourse which, I concede, is not altogether meaningful outside a religious context in which life is acknowledged as a gift from God. On this premise, we are bound not to waste anything but to make the best possible use of it, taking into account our own needs and those of others.

An obvious conclusion that can be drawn from this paradigm concerns the philosophy that should animate the education of the public on the need of organs for transplantation. By all means, appeals to generosity should continue to be made but they can be more educationally effective, if generosity is presented as a virtue which is itself anchored in justice. The image of ourselves as 'trustees' of anything we happen to possess can bring out clearly

and forcefully enough the link between love and justice, organ donation as an expression of generosity and, as a requirement, of justice towards others.

The implications of the stewardship model for public policy may be harder to draw out and draft into appropriate legislation that takes seriously into account the responsibility of society to provide its sick members with the health care they need. That there should be the strictest possible measures to guarantee full respect to the freedom of living donors is too obvious to argue for. It is the issue of consent relating to cadaver donors that can be controversial. With the help of educational programmes which explain that behind every act of love there is also sense of justice to be acknowledged, the way can be opened for more effective social intervention in the procurement of human organs for transplantation. For instance, one may consider that in those cases where a deceased person had not expressly forbidden the removal of his/her organs, consent is to be presumed. This may hurt the feelings of relatives but it may also relieve them of a burden to have to decide themselves, very often in not so ideal circumstances.

Conclusion

The responsibility of donating organs for transplantation may lose most of its ethical relevance in the coming years with the development of animal - to - human organ transplants. Of course, the procedure needs to be developed not only from the technical side. The technique itself will have also to be assessed from an ethical viewpoint. This point I have not discussed here. Reports such as that produced recently by the Nuffield Foundation on the principal ethical aspects involved in this kind of technology are a helpful source. In the meantime, patients requiring an organ transplant will have to rely on human generosity. Generosity is a species of love. But love presupposes and perfects justice. Recognising that an act of free giving is also an act of justice does not make the gift less worthy of praise and thanksgiving, for whatever else it is, love for the other is also a duty.

15

ETHICAL ISSUES OF KIDNEY TRANSPLANTATION

DR E. FARRUGIA

Historical background

Up to 1982, in Malta there was very little choice available for persons with advanced renal disease. Some patients went overseas seeking a transplant abroad. In 1982 the first haemodialysis was performed, but only on patients who were scheduled to receive a living donor transplant from a family member. From 1984 onwards were included young non-diabetic end-stage renal failure patients who were candidates for a renal transplant not necessarily from a living-related person.

In 1989 the first non-transplantable non- diabetic patients were also accepted

From 1992 elderly persons (below the age of 74 years) as well as diabetics were also included in the programme.

Over the years there has been an upward trend in dialysis and transplant usage in Malta, as seen in the adjoining table.

The success rate of kidney transplants is now approximately 90% (1 year graft survival). The most pressing problem is the availability of adequate numbers of transplantable organs. Various options have been discussed in attempts to increase the number of organs available. This paper discusses, in simple terms, the inevitable ethical concerns raised by organ donation.

The **general principles of medical ethics** stress the need to do as much good to the patient whilst doing the minimal amount of harm. Patients need to be given full information in a manner that allows them to make up their mind about a proposed line of treatment. Their decision should be made, as far as possible, free

from undue external pressures. Finally, treatment should be available, and be given in a fair and just manner.

Table: Dialysis and transplant in Malta:

	1992	1993	1994	1995	1996	1997	1998	1999
<i>Acceptance</i>		29	28	35	46	47	49	41
<i>Point Prevalence*</i>	31	43	45	61	78	98	114	104
<i>Transplants</i>		8	7 (3LRD)	4	14	7	7 (1 LRD)	10 (2 LRD)
<i>CAPD Prevalence*</i>	4/31	14/43	18/45	28/61	39/78	44/98	52/114	46/104
<i>% CAPD*</i>	13	33	40	46	50	45	46	44
<i>Acceptance PMP#</i>		82	80	100	115	118	123	103
<i>Dialysis for ARF</i>		9	12	17	14	19	18	9

*As of the 31st December of the particular year

PMP = per million population: based on 0.40 million persons in Malta

(ARF: acute renal failure; LRD: living, related donor)

Reported incidence of dialysis in 1996 according to EDTA statistics (personal communication):

Western Europe: 111 per million persons (ca 80 % of centres provided data)

Southern Europe: 109 per million persons (ca 49% of centres provided data)

Specific ethical issues in cadaveric kidney transplantation include:

1 Definition of death

The legal and ethical acceptance of the brain death criterion has legitimised the salvage of organs whilst restricting the supply from irreversibly comatose persons (eg anencephalic infants, persistent vegetative state).

2 Consent for organ donation

This can fall in one of two main types: express consent or 'opting in' and presumed consent or 'opting out'. Debate continues on to

what extent is consent necessary and how can it be obtained in the case of a cadaveric donor.

3 Interventional ventilation

This refers to ventilatory support for patients with major intra-cranial haemorrhage on the verge of respiratory arrest, solely and exclusively in order to allow the patient to be declared brain dead and thus to become an organ donor. Duty-based ethics and utilitarianism are in conflict when trying to solve the ethical problems of consent and the possibility that ventilation may be followed by a persistent vegetative state. A practical issue is that the lack of intensive care facilities may determine the adoption of interventional ventilation in many hospitals.

Two situations can be envisaged:

1. Semi-elective situation, where cardiac arrest may be anticipated. Patients may be on ventilator. After certification of death the patient is immediately moved to the operating theatre for kidney removal.
2. Emergency situation: e.g. sudden, unexpected death in Casualty. In situ kidney cooling through insertion of a femoral artery double balloon catheter is done and then the patient is transferred to the operating theatre.

Explicit consent from relatives is required for both the cooling procedure as well as the kidney harvesting.

4 Non-heart beating donors

In centres using this programme, no major ethical objections have been raised. However, consent from relatives for both the cooling procedure on a dead body and also for kidney harvesting is very difficult to obtain in patients who die unexpectedly and suddenly, usually at Casualty.

5 The allocation of cadaveric organs

Ownership of organs rests with the State, which delegates its authority to the hospital and transplant team. Relatives are not in a position to dictate how the organs are to be used. Best possible use of kidneys is based on the principle of distributive justice, fairness, equality and impartiality. Not only must justice be done, it must be seen to be done. There is no perfect allocation system but whatever system is used, it must take note of clinical need. It should:

- ensure that there is significant clinical benefit in prolongation of life, reduction in suffering, improved quality of life,
- Fit in closely with the traditional patient-doctor relationship,
- Distinguish clinical need from clinical desire.

It is understood that this procedure may not be precise as it may rely on subjective criteria that cannot be standardised.

Two groups of patients cause particular difficulty: those with self-induced disease and those who are non-compliant with their treatment.

In **live donor transplantation**, ethical concerns centre almost exclusively around the donor. Despite problems and anxieties, it is widely accepted that donation of a kidney from a close relative is acceptable. A donor may be subjected to external pressures (family pressure to help the recipient, bribery, coercion), and internal pressures ('to do the right thing' or to 'not let down the recipient'). Consent problems also arise in children and in mentally incompetent individuals. The use of non-related live donors has become increasingly common and emotionally related donors (for example spouses) have been shown to give results at least as good as those obtained with well-matched cadaver kidneys. However, there is a slippery slope argument, namely that this

practice can lead eventually to outright commercialisation of live donor organ donation. The sale of organs has been rejected by the Western-dominated transplant community. On the other hand, it has been argued that a well run, well controlled system of payment for live donors may on balance do more good than harm.

Problems associated with informed consent.

One of the issues associated with informed consent is to ensure that this is freely given. The reasons for doubt in this area include:

- Information may not be available.
- Potential donors may make up their mind very early and then not “hear” any of the further information given.
- External pressures: family pressure to help the recipient, bribery, coercion and manipulation.
- Internal pressures: ‘to do the right thing’ or to ‘not let down the recipient’.
- ‘Way out’ for donors: invention of medical contra-indications.
- Consent problems with children and mentally incompetent.

There are several reasons for encouraging donations from **emotionally-related live kidney donors (ERLKD)**. These include:

1. There is an increasing waiting list for cadaveric kidneys.
2. There is a success rate at 1 year in excess of 90 %.
3. There is strong motivation in the donor.
4. Often there is a direct personal advantage for the donor, especially if this is the spouse.
5. There is the possibility of bypassing dialysis completely.
6. There are fewer psychological problems than in transplantation between siblings.
7. There are fewer ethical objections from staff compared to cadaveric transplants.

On the other hand there are several objections to this procedure, namely:

1. It is contrary to the principle of *primum non nocere*: there is an early complication rate, peri-operative mortality as well as late complications (0.2 – 0.5 %).
2. There is a lack of insurance coverage in the case of a catastrophic scenario.
3. There may be doubts as to whether the donation was really “voluntary”. If a partner says “no” to a transplant, this may be interpreted as lack of love and solidarity.
4. There may be the implication that the donation of this great gift might imply the obligation of eternal gratitude and fidelity.
5. There could be immunological objections to the transplant (e.g. poor HLA match).
6. The ‘slippery slope’ argument implies the possibility of commercialisation of organ transplantation.
7. There is also the fear that this might result in a further decrease in availability of cadaver kidneys for transplantation.

Should there be **payment for organ donation**?

It is generally accepted that there should not be any financial inducements to organ transplantation. The arguments in this respect include:

1. That such a practice is intuitively repugnant and immoral;
2. That it will exploit the poor and divide society; it could inhibit cadaver and living related donation,
3. Removal of an organ from a healthy person is not therapeutic for the donor.
4. A poor person may be induced to sell an organ to help his/her family.
5. The ‘slippery slope’ argument
6. Regulation: it would be very difficult to regulate paid donations.

On the other hand there are those who would support the concept of paid donations. Their arguments can be summarised as follows:

1. Every person has a right to self-determination – a paramount principle in secular Western society. This is related to the principle of autonomy.
2. From the utilitarian point of view, such practice would increase the number of available organs for transplantation, and thus increase societal good .
3. It may be easier to ensure the voluntary nature of the donation if the donor is not a relative to the recipient.
4. The act of selling kidneys is not necessarily degrading. It could be considered altruistic if the aim is to save the life of a family member.
5. Slippery-slope arguments are philosophically unsound as basis for public policy.

With regards to **xenotransplantation**, the discussion can be reduced to one fundamental issue: do animals have rights, and are they the same rights that we accord to humans? For those who believe that the answer to this question is 'no', that a human life is intrinsically worth more than that of an animal, then given due regard for the details (conditions in which pigs are kept, possible of transmission of animal infections to humans, and so forth), xenotransplantation will be seen as a development that offers life to patients who otherwise would die - and is therefore acceptable. Until such time as this has been shown to be the case, it is wise to move with the utmost of caution.

16 THE LAY PERSON AND TRANSPLANTATION

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Introduction

The work I will be presenting in this paper is part of a project carried out by a group of people coming from different disciplines. The aims of the project were four. These were:

1. To create greater awareness of organ donation among the public;
2. To provide information about organ donation;
3. To foster positive attitudes towards organ donation and decrease negative ones;
4. To increase the number of donor card holders.

To reach these objectives we decided to launch a national campaign on organ donation. The campaign was based on the Social Marketing Model proposed by Kotler (Kotler & Roberto, 1989). The formative research carried out before the campaign consisted of a national survey with a quota sample of 400 people, 12 interviews with doctors, donor families and recipients and five focus groups. In this paper I shall only present the results of the survey. I shall also discuss briefly the results of two other surveys carried out after the campaign.

The project started in 1995 and came to an end this year in 1999, covering a span of five years. In 1995, twelve years after the first kidney transplant in Malta, organ donation was still a relatively new concept for the majority of the Maltese people. Many had

heard about it but very few knew what it meant or what it involved. Many people had never heard about the donor card. It was therefore decided that one of the first investigations should be a survey of attitudes of the Maltese public about organ donation.

The Survey

In order to be able to compare the results with research carried out in Britain, the questions asked were a translation of those used in a survey commissioned by the British Kidney Patient Association and carried out by Gallup Ltd. (Social Surveys (Gallup Poll) Ltd., 1994). The survey consisted of eight questions which were asked in Maltese. The responses to these questions are compared with the British data. Some questions are analysed in more detail using chi-square tests of independence, and hierarchical log-linear analysis.

Methodology

The survey was carried out with a sample of four hundred persons aged eighteen years and over living in Malta and Gozo. The only exclusion was of persons living in an institution at the time of the survey. MISCO International was commissioned to administer the questionnaire. They were given the set of questions and they provided the collected data on diskette. The questions were pre-tested with a sample of 20 people to ensure that the questions were clear and understandable. As a result of the pre-testing, minor adjustments were made to the wording of some questions prior to submitting them to MISCO.

The Maltese survey was carried out in twenty areas randomly selected within the six regions as given in the "Demographic Review of the Maltese Islands" (Central Office of Statistics, Malta 1994). Sixteen trained interviewers carried out face to face interviews in the respondents' homes according to a quota representative of the age and sex of the Maltese population.

Fieldwork was carried out between 27 April and 10 May 1995. All the responses to the questionnaire were classified by gender, age and socio-economic status of the respondent. Age was coded into one of three categories (18-34 years, 35-54 years and 55 years or more) and socio-economic class was recorded in one of four categories (A-B, C1, C2 and D-E categories).

Results

Each response is analysed first by comparing the results obtained in the Maltese survey with the corresponding response obtained in the British survey held by Gallup in 1994. This analysis is somewhat brief and limited in scope because only basic tabulations from the Gallup survey are available and not the actual data. But following this comparative study, the data for the response of the Maltese survey is then, where appropriate, subjected to more detailed statistical analysis. Details how this is done are given below when the relevant question is being analysed.

(i) Awareness of Organ Donation

The first question respondents were asked was the following:

Question 1. Are you aware that you can leave your organs to be used by somebody else after your death?

Table 1 compares the responses obtained to this question in the Maltese survey and the Gallup survey carried out in Britain in 1994. In the Maltese survey, 93.5% of the respondents had heard about organ donation. This figure was surprisingly high since it was even higher than that registered in the British survey where the corresponding percentage was 73%. This could be due to two factors. One is the social desirability bias where respondents want to appear in good light with the interviewer. The other was a TV programme on organ donation which had been screened during prime time some weeks before the campaign.

Table 1: Responses to Question 1 - Maltese and British figures

	Malta 95	United Kingdom 94
Yes	93.5%	73%
No	6.5%	16%
		10% (Do not know)

(Base for percentages: All respondents)

Analysis of the Maltese data in more detail was carried out by performing the chi-square test of independence on each of the following contingency tables: (i) response (awareness of organ donation) by socio-economic class, (ii) response by gender and (iii) response by age.

A strong association was found between awareness of organ donation and socio-economic status (Chi sq=9.8, df=3, p=0.02). As can be seen from Table 2, the percentage of those in the D-E categories who were unaware of organ donation was 10.4%. This proportion varied considerably with socio-economic class, with everybody in the A-B categories saying that they had heard about organ donation.

The association between awareness and gender or age was not found to be significant.

Table 2: Responses to Question 1 - Analysis of Maltese sample by socio-economic class

Ever heard about organ donation	Socio-Economic Classification				Total
	A-B	C1	C2	D-E	
Yes					
Count	71	79	103	121	374
Column percentage	100.0%	96.3%	92.0%	89.6%	93.5%
No					
Count	0	3	9	14	26
Column percentage	0.0%	3.7%	8.0%	10.4%	6.5%
Total					
Count	71	82	112	135	400
Row percentage	17.8%	20.5%	28.0%	33.8%	100.0%

Chi sq=9.8, df=3, p=0.02

(Sample base: All respondents)

(ii) Willingness to Donate Organs After Death

Respondents were then asked the following question:

Question 2: Would you agree to donate your organs after your death?

The responses indicated that the majority of the Maltese sample approved of donation. When asked whether they would agree to donate their organs after their death, 55% of the respondents answered “Yes definitely” and 26% answered “Probably yes”. This compared well with the 72% reported to be in favour of donating their organs after their death in the Gallup survey carried out in Britain. Only 14% of the Maltese respondents said that were against organ donation and would not give their organs after their death. The percentage of British respondents who were against organ donation in the Gallup survey was 18%. (See Table 3.)

Table 3: Responses to Question 2 - Maltese and British figures

	Malta 95	United Kingdom 94
Yes definitely	55%	72% (In favour)
Possibly yes	26%	
No	14%	18%
Do not know	5%	10% (Neutrals+Do not know)

(Base for percentages: All respondents)

To analyse the Maltese responses to this question in terms of socio-demographic characteristics, it was decided to filter out the responses of those who, in answer to the first question, had said that they had never heard about organ donation (26 respondents out of 400). Therefore only responses of those who had heard about organ donation are considered in the following more detailed statistical analysis (374 respondents).

Again separate chi-square tests of independence were carried out for the contingency tables classifying the response to this question (willingness to donate organs after death) and each of the three socio-demographic characteristics. Yet again, the strongest association found was that between the responses to the question and socio-economic class (Chi sq=16.6, df=9, p=0.06). Although this association is not as significant as the one noted above for the awareness question, one can still discern from Table 4 that positive attitudes towards organ donation are strongest amongst the A-B classes and become weaker amongst the D-E classes.

Table 4: Responses to Question 2 - Analysis of Maltese Sample by Socio-economic Class

	Socio-Economic Classification				Total
Willing to donate after death	A-B	C1	C2	D-E	
Surely yes					
Count	49	52	60	59	220
Column percentage	69.0%	65.8%	58.3%	48.8%	58.8%
Possibly yes					
Count	12	21	27	36	96
Column percentage	16.9%	26.6%	26.2%	29.8%	25.7%
No					
Count	7	5	9	21	42
Column percentage	9.9%	6.3%	8.7%	17.4%	11.2%
Do not know					
Count	3	1	7	5	16
Column percentage	4.2%	1.3%	6.8%	4.1%	4.3%
Total					
Count	71	79	103	121	374
Row percentage	19.0%	21.1%	27.5%	32.4%	100.0%

Ch sq=16.6, df=9, p=0.06

(Sample base: All respondents aware of organ donation)

The associations measured between willingness to donate and gender and between willingness to donate and age were both not significant. However, this question, dealing with respondents' willingness to donate organs, is very crucial especially from the point of view of designing a campaign in order to promote donation. It was therefore felt that this data warranted a multivariate statistical analysis in order to probe more deeply into the relationship between the response and the socio-demographic characteristics and to discover any significant higher order associations.

It was therefore decided to carry out a hierarchical log-linear analysis (running the HILOGLINEAR procedure from the SPSS package) on the variables in question, that is, the response to the question (willingness to donate organs after death), gender, age, and socio-economic class. Hierarchical log-linear analysis constructs multi-way cross-tabulations involving all the variables and provides many procedures to help unravel complex relationships which might exist between the variables. The backward elimination variable-selection method was employed. With this method HILOGLINEAR removes interaction terms which are not significant until it reaches a model containing interactions of the variables which best fit the data.

The result of running this procedure indicated that, apart from the association between the response and socio-economic class which was noted and considered above, an interaction between gender and age could have an important contribution in explaining the associations amongst the data. This question was explored further by analysing contingency tables of response by age for male and female respondents separately. It was found that although for males the association between their willingness to donate and age was not significant, it became highly significant for females (Chi sq=14.0, df=6, p=0.03). Table 5 indicates that the younger females tend to be more willing to donate their organs after their death than older ones.

Table 5: Responses to Question 2 - Analysis of Maltese Sample by Age for Females

	Age			Total
	18-34 years	35-54 years	55+ years	
Willing to donate after death				
Surely yes Count Column percentage	48 76.2%	47 67.1%	25 45.5%	120 63.8%
Possibly yes Count Column percentage	11 17.5%	14 20.0%	17 30.9%	42 22.3%
No Count Column percentage	3 4.8%	6 8.6%	10 18.2%	19 10.1%
Do not know Count Column percentage	1 1.6%	3 4.3%	3 5.5%	7 3.7%
Total Count Row percentage	63 33.5%	70 37.2%	55 29.3%	188 100.0%

chi sq=14.0, df=6, p=0.03

(Sample base: All female respondents aware of organ donation)

The findings were similar to those found by other researchers, for example, Perkins (1987) and Manninen and Evans (1985).

(iii) Donor Cards

Respondents were then asked the following question:

Question 3: You may know that people carry a donor card which they can fill in to say which organs they would like to donate after their death. Will you look at this card and tell me which answer applies to you?

The responses to this question are summarised in Table 6 below which also compares them with the Gallup survey. The percentage of Maltese respondents who said that they have donor cards was only 7% when compared to the 35% reported in the Gallup survey carried out in Britain in 1994. Those who had not heard about the donor card in the Maltese sample was 23%. No corresponding figure was given in the British sample.

Table 6: Responses to Question 3 - Maltese and British figures

	Malta 95	United Kingdom 94
Have donor card, carry it	5%	26%
Have donor card, do not carry it	2%	9%
Do not have but consider getting one	38%	26%
Do not think I could carry a donor card	8%	8%
Don't think it's worth carrying one	4%	9%
Do not want to carry card	5%	17%
Not sure	15%	5%
Never heard about it	23%	

(Base for percentages: All respondents)

In order to analyse the responses of the Maltese sample to Question 3 in terms of socio-demographic characteristics, a filtering out of some respondents was again effected. Only the responses given by those who had heard about organ donation (Question 1) and those who had expressed willingness to donate their organs after death (Question 2) were considered. This gave a total of 316 respondents. This was done because it was assumed that people who were against organ donation would necessarily be against carrying a donor card. For the purpose of this analysis the responses to this question were classified under the following categories:

1. *Have a card.* Those who said that they have a card and they carry it and those who have a card but do not carry it (8.9%).
2. *Consider getting a card.* Those who do not have a card but have often thought about getting one (46.8%).
3. *Would not carry a card.* Those who do not think they would carry a card, those who see no sense in their carrying a card, and those who do not want to carry a card (14.2%).
4. *Uncertain.* Those who were not sure which options best described their opinion (12.7%).
5. *Never heard.* Those who had never heard about the donor card (17.4%).

Again separate chi-square tests of independence were carried out for the contingency tables classifying the response to this question (opinion about donor card) and each of the three socio-demographic characteristics. The strongest associations found were that between response to the question and socio-economic class (Chi sq=26.4, df=12, p=0.01) and that between response and age (Chi sq=16.5, df=8, p=0.04). As usual, those from the A-B and C1 classes and the younger respondents had a more favourable attitude towards the donor card.

This question asking respondents their opinion about the donor card is another very crucial one, especially with regard to the planning of a campaign promoting donor cards. Therefore multivariate techniques were also used here. A hierarchical log-linear analysis was again carried out in a way similar to that used above for Question 2. This analysis indicated that an interaction between age and socio-economic class was important in explaining associations between the response and socio-demographic characteristics of the sample. In fact, on further analysis it was found that for the youngest (18-34 years) and the oldest (55 years and over) age groups the association between attitudes on the donor card and class was not significant whereas it was very significant for the middle age group (chi sq=26.2, df=12, p=0.01), that between 35 and 45 years.

Table 7: Responses to Question 3 - Analysis of Maltese Sample by Socio-economic Class (35-54 years)

	Socio-Economic Classification				Total
	A-B	C1	C2	D-E	
Opinion about donor card					
Have card					
Count	5	6	2	3	16
Column percentage	23.8%	18.2%	5.0%	10.7%	13.1%
Consider getting card					
Count	9	16	21	9	55
Column percentage	42.9%	48.5%	52.5%	32.1%	45.1%
Will not carry card					
Count	2	6	3	5	16
Column percentage	9.5%	18.2%	7.5%	17.9%	13.1%
Uncertain					
Count	5	4	2	3	14
Column percentage	23.8%	12.1%	5.0%	10.7%	11.5%
Never heard about card					
Count	0	1	12	8	21
Column percentage	0.0%	3.0%	30.0%	28.6%	17.2%
Total					
Count	21	33	40	28	122
Row percentage	17.2%	27.0%	32.8%	23.0%	100.0%

chi sq=26.2, df=12, p=0.01

(Sample base: Respondents aware and willing to donate, 35-54 years)

This could imply that the youngest respondents are more generally in favour of getting the donor card and the older ones are generally against, irrespective of class. However, for the middle age bracket, the general tendency to have a card or to be considering to get one is more significantly felt amongst the A-B and C1 classes than amongst the C2 and D-E classes (see Table 7). The same

applies for those who had never heard about the card.

Those who were in favour of organ donation but were against carrying a donor card (45 respondents) were asked to give their reasons. (This question was not asked in the Gallup survey.) Many of the respondents (40%) could not explain why they would refuse to carry a donor card. Other respondents voiced the fear that if they carry a donor card and are involved in an accident, doctors would not try to save their lives but would prefer to let them die in order to give their organs to somebody else. Others were afraid that doctors would take their organs before they are actually dead. Other reasons for not carrying a donor card were the fear of being mutilated, not knowing who would take the organs and forgetting to carry the card. These responses are summarised in Table 8.

Table 8: Responses to Question 4 - Reasons for Not Wanting to Carry a Donor Card

	In favour of organ donation but against carrying a card
Afraid not really dead	18%
Will not try to save my life	16%
Will not know who takes organs	2.2%
Do not like being cut up	4.4%
Because I forget	24%
Other (unspecified)	40%

(Base: 45 respondents; each could give more than one answer)

(iv) Discussion with Family

In an effort to find out what helps respondents come to a decision in donating the organs of a family member, the respondents were asked whether or not they would want to donate the organs of a relative who had just died. They were presented with three different situations. These were the following:

Suppose you had a relative who died and the doctors asked you your permission to take the organs. Would you give permission in the following situations?

Question 5 (Situation 1).

Your relative was not carrying a donor card and had never made his or her views clear.

Question 6 (Situation 2).

If this time your relative was not carrying a donor card, but had made it clear that he or she was willing to donate their organs.

Question 7 (Situation 3).

If this time your relative was carrying a donor card but had not made it clear that he or she was willing to donate their organs.

In the first scenario 35% said they would definitely agree to give the permission while 32% thought that they would probably say yes. The data collected in the Gallup survey showed that a higher percentage (58%) answered “yes definitely”.

In the second scenario the percentage of Maltese respondents who answered that they would agree to give permission to doctors to remove organs (56%) was higher than in the previous scenario. An additional 34% answered that they would probably agree. These figures are similar to those found by Gallup in Britain.

The results for the third scenario were very similar to those in the second. This indicates that for most respondents, knowing a person’s view about organ donation carries the same weight as knowing that the person is a donor card holder.

The percentage of respondents who would not give permission to doctors in the first situation is 29%. This is much higher than the percentage of those who are against organ donation (14%). This means that there are many people who though willing to donate

their own organs would not donate those of a member of their family unless they know specifically that it was their wish.

Table 9: Responses to Questions 5,6,7 - Maltese and British Figures

	Malta 95	United Kingdom 94
Question 5 (Situation 1)		
Yes definitely	35%	58%
Probably yes	32%	
No	29%	31%
Do not know	4%	11%
Question 6 (Situation 2)		
Yes definitely	56%	89%
Probably yes	34%	
No	7%	6%
Do not know	4%	5%
Question 7 (Situation 3)		
Yes definitely	53%	82%
Probably yes	36%	
No	9%	9%
Do not know	2%	9%

(Base for percentages: All respondents)

(v) The “Opting-out” System

There are two major systems of organ procurement. The one which is practised in Malta is that of “opting-in”, where the persons who wish to donate organs after their death fill in a donor card and have their names registered in a National Organ Donor Register. On the other hand, some countries like Spain, France and Belgium, follow the “opting-out” system. In these countries the doctors do not need to ask the permission of the relatives of the person who has just died before they remove the organs unless the person had made it known during his or her life that they are against it.

To find out respondents’ reactions to the two systems they were asked the following question:

Question 8. In some countries one way which is used to increase the number of donor organs is to say that organs could always be taken from adults who had just died, unless they had specifically forbidden it. Do you agree that this procedure be adopted in Malta?

In the Maltese sample 52% said that they would not be in favour of the opting-out system. This percentage was slightly higher than the percentage of British respondents (48%) who were against this system (see Table 10).

Table 10: Responses to Question 8 - Maltese and British Figures

	Malta 95	United Kingdom 94
Yes definitely	18%	43%
Possibly yes	25%	
No	52%	48%
Do not know	4%	9%

(Base for percentages: All respondents)

This general disagreement with the opting-out system was quite uniform across the socio-demographic spectrum of the sample, and no significant association between the response and age, gender or class was found.

Discussion

This survey gave a first picture of the attitudes of the Maltese people towards organ donation. The major points which emerged were that:

1. Most respondents (81%) had positive attitudes towards organ donation and were willing to donate their organs after their death even though some of these people had many unanswered questions and fears.
2. While many were in favour of organ donation, few of the respondents (7%) had a donor card. Moreover a high proportion

- (23%) did not know about the existence of the card.
3. While many of the respondents were willing to donate their own organs after their death, they found it more difficult to donate the organs of their relatives. Only 67% said that they would give permission if they did not know the relative's wishes about the matter. This difficulty seems to be greatly resolved if the dead person had talked about his or her wishes before dying. 90% said that they would allow donation of organs if they knew that the dead relative had wanted to be a donor.
 4. More than half of the respondents (52%) were against the opting out system and felt that organ donation should be voluntary and should not be taken for granted by the state.
 5. There was no significant difference between males and females in their willingness to donate their organs after their death.
 6. Respondents from the A-B and C1 classes tended to have more positive attitudes towards organ donation.
 7. The respondents who were most favourable towards carrying a donor card were those in the 18-34 age bracket and those in the A-B and C1 classes.

Post-campaign Surveys

Between April and May 1996, about three months after the end of the campaign, the second national survey was carried out. With the exception of two, the questions asked in this survey were the same as those asked the year before, in May 1995. The questions investigated awareness of organ donation campaign, attitudes about organ donation, donor cards and the "opting-out" system.

The survey was again conducted with a sample of 400 persons aged 18 and over and living in Malta and Gozo.

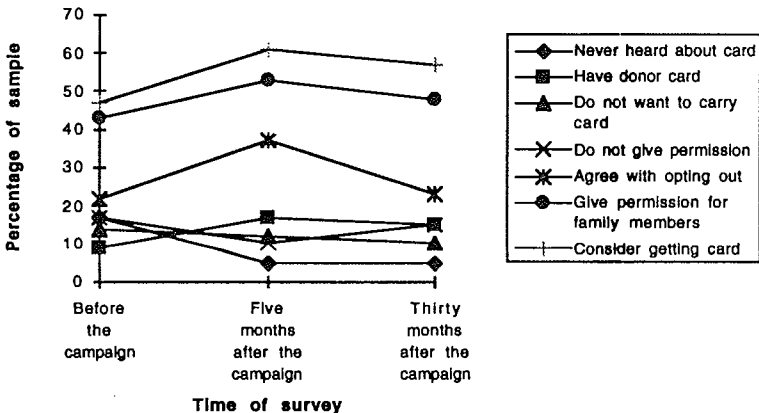
The following points briefly summarise the main differences between the two surveys.

1. In the first survey 46.8% said that they are considering getting card. This figure went up to 60.8% in the post-campaign survey.
2. The proportion of respondents who had never heard about the donor card went down from 17.4% to 4.5%.

3. In the pre-campaign survey, 18% of those who were willing to donate their organs but were against carrying donor card gave as a reason the fear that they would not really be dead when the organs are removed. This proportion went down to 8% in the post-campaign survey.
4. In the pre-campaign survey, 43.4% of participants said that they would donate the organs of dead relative without knowing his/her intention about organ donation. This proportion went up to 53.2% in the post-campaign survey.
5. The proportion of those who said that they were definitely in favour of the opting out system went up from 22% to 36%.

A third survey with the same sample size was held 30 months after the campaign to assess the longer term effects of the campaign. The same questions were asked and this survey showed that, although the improved perceptions were largely maintained, there was a downward trend in some aspects (see Figure 1).

Figure 1: Changes in Public Perception Regarding Organ Donation



The greatest change occurred in the percentage of people who had never heard about the donor card. Before the campaign 17% of those in favour of organ donation had never heard about the card (95% confidence interval: $17\% \pm 4\%$). This percentage went down to 5% ($\pm 2\%$) in the second survey and when surveyed again 30 months later this percentage remained 5% ($\pm 2\%$). (All these and subsequent intervals are 95% confidence intervals.)

This change was accompanied by a considerable increase in the number of people who said that they were considering getting a donor card. The percentage went up from 47% ($\pm 6\%$) to 61% ($\pm 5\%$) after the campaign. In the third survey this figure declined to 57% ($\pm 5\%$). The difference in proportions between the first and third surveys was still significant ($z=2.76$, one-tailed $p<0.005$). In the long run therefore, the effects of the campaign were maintained but declined from the peak achieved immediately after the campaign. The number of people who were definitely in favour of the "opting out system" increased significantly from 22% ($\pm 5\%$) to 37% ($\pm 5\%$) in the first survey carried after the campaign. This percentage went down to 23% ($\pm 5\%$) in the third survey. Again, this could indicate that unless the issue is kept in the public sphere, the salience and therefore the support for the issue tends to diminish.

Other changes registered by the surveys were a change in the number of respondents who said that they would certainly give permission to doctors to take organs from a family member after death even when not knowing the deceased's views on organ donation. This figure went up from 43% ($\pm 5\%$) to 53% ($\pm 6\%$) in the second survey and then went down again to 48% ($\pm 5\%$) in the third survey. Whereas the difference between the first and second survey was statistically significant ($z=2.58$, one-tailed $p=0.005$), the difference between the first and third survey was not statistically significant ($z=1.30$, one-tailed $p=0.10$).

The percentage of those who replied that they would not give

permission to donate organs of their relatives in this situation went down significantly from 17% ($\pm 4\%$) to 10% ($\pm 3\%$), but in the third survey this went up again to 15% ($\pm 4\%$).

A significant increase from 9% ($\pm 3\%$) to 17% ($\pm 4\%$) ($z=3.08$, one tailed $p=0.001$) took place in the number of respondents who had a donor card. This increase was largely maintained in the third survey with 15% ($\pm 4\%$), the difference between the first and the third survey remaining statistically significant ($z=2.38$, one-tailed $p=0.01$). These figures are summarised in Table 11.

Table 11: Changes in Public Perception of Organ Donation

	1st survey	2nd survey	3rd survey	Difference between 1st/2nd surveys: p values	Difference between 1st/3rd surveys: p values
Never heard about card	17%	5%	5%	<0.0001	<0.0001
Have card	9%	17%	15%	0.001	0.01
Do not want to carry card	14%	12%	10%	n.s.	n.s.
Consider getting card	47%	61%	57%	0.0001	<0.005
Would give permission to remove relative's organs	43%	53%	48%	0.005	n.s.
Would not give permission	17%	10%	15%	<0.05	n.s.
Agree with opting out system	22%	37%	23%	<0.0001	n.s.
Sample base for percentages: All who had heard about organ donation and were in favour	316 res-pondents	314 res-pondents	328 res-pondents		

Conclusion

The survey carried out in May 1995 was part of the formative research for the Organ Donation Campaign held between October 1995 and January 1996. The two post-campaign surveys served

to measure the success of the campaign in terms of changes in people's attitudes towards organ donation.

Apart from these surveys a number of other investigations were carried out in order to delve more deeply into the Maltese public's view of organ donation, of particular importance being ten focus groups (five held before and five after the campaign). These investigations gave a more detailed picture of how organ donation is represented amongst the Maltese lay person and will be presented in another paper.

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17 CONCLUDING REMARKS

DR RAY BUSUTTIL

This three day conference organised by the Bioethics Committee has been the third of its kind. In the past years similar conferences were held on 'Informed Consent' and last year on 'Bioethics and the Disabled'. The conference this year was more ambitious because it tackled three topics. Each topic could in its own right have been the sole subject for a conference of this nature. The reason all three topics were held in one conference was because of the impending demand each is imposing on us in this period.

Patient Rights

With the planning of a Charter for Patient Rights it was time to open the debate to the wide scrutiny of the public and the medical profession. Although the conference on Informed Consent had set the pace for discussion of rights, confidentiality, truth telling etc, all of these individual topics had to be put under one blanket. When we speak of Patient Rights we are not only tackling the philosophical issues of truth telling and confidentiality; we are also tackling the social problems which present themselves and how therefore these rights have to continue to be respected. I have in mind cases such as the elderly. With an increasingly ageing population old people will continue to be patients presenting specialised problems and may require certain decisions to be taken. In taking these decisions we need to do away with utilitarian philosophies and think deontologically - that a person is valued for what he or she is and not according to the utility he or she holds.

I must commend the Malta College of Family Doctors for writing a neat Charter for Patient Rights. As was stressed by the Minister in his introductory speech I would encourage all medical bodies

to work closely with the Bioethics Consultative Committee to develop charters for patients and guidelines for their members. We are also contemplating to develop a Charter in this respect and future meetings will continue to be dedicated to this important area of health care.

Reproductive Technology

The Bioethics Committee has been working for a number of years on the Reproductive Technology Document. It was unfortunately hindered by two elections, each time seeing some changes in the members of the committee. I thank and congratulate the present committee (under the chairmanship of Prof. Maurice Cauchi) which has worked very hard to finalise such a document. There are many problems with a reproductive technology document. Although all committee members have shown an open-mindedness on all issues, including third party sperm donation, such matters continue to be very sensitive. Definitely, there is room for further public debate in this area. Taking final decisions means finding a balance between advancing medical technologies while respecting the cultural and religious values of a people. This is after all what Bioethics is all about. The Bioethics Committee has shown itself very professional in this respect but its word can only be that of an advisory body. It is not final and further scrutiny has to be taken on from here. This decision is of great social impact. Although the document sets the pace and the atmosphere for work to begin, we must still continue to consider and if necessary re-consider issues such as third party sperm donation. There are those who believe that on the verge of the beginning of the third millennium we must provide people and doctors with a right to this technology. But our culture may tell us otherwise. For this we need further public fora. I am sure the Bioethics Committee will play an increasingly important role in organising more specific debates related to this area in the near future.

Transplantation

The issue of organ transplantation may at first seem more straight forward. However, there are areas which need further scrutiny. Recently there was a proposal for introducing transplant surgery for foreigners in private hospitals. Although in theory there is nothing wrong with this and indeed such a proposal may be commended, one needs to scrutinise such requests from all ethical points of view. In particular we do not want Maltese patients to be at any disadvantage and we need to take part in the ethical process of any surgery which occurs in Malta. Ethical scrutiny from abroad is not enough. We need to see that organs obtained were not bought and that the person making the donation has not been under any influence or undue pressure.

Last but not least, we need to embark heavily on educating people about the altruism of donating organs after their death.

In conclusion this seminar can be seen as having set the ball rolling for further debate in all these three areas. It is hoped that even up to two such conferences can be organised every year. I encourage and hope that all bodies work closely together. This not only saves time but encourages wider debate. It is hoped that medical bodies, for example, develop their own advisory committees rather than relying on the input of one individual. This is an era of ethical debate and we need to handle it seriously. In this respect I also hope to see Bioethics being included and taught on all medical and nursing curricula. Ethics is not a side line. It is the area of medicine which keeps all technology on a human level. We need to discuss issues which are already heavily under way abroad - such as genetic screening, insurance for health care, and allocation of scarce financial resources. These discussions must start with courses at student level. Our present students will be the doctors of tomorrow. Courses in bioethics should not be limited exclusively to health professionals, but should also be included in the curriculum leading to a doctorate of Law as well as

courses concerning sociology. Only in this way can we continue keeping up with medical technology and advancement whilst at the same time respecting our cultural identity and human values.

BIOGRAPHICAL INFORMATION

Rev Dr Emmanuel Agius is senior lecturer in philosophical and theological ethics at the University of Malta. He studied philosophy and theology at the University of Malta and at the Catholic University of Leuven, Belgium, where he obtained an M.A. and Ph.D. He pursued post-doctoral research in the field of bioethics at the University of Tübingen, Germany as a fellow of the Alexander von Humbolt Stiftung, at Georgetown University, Washinton, D.C. as a Fulbright scholar, and at the University of Notre Dame, Indiana. He is the author of three books and co-editor of five publications on future generations. His articles have appeared in a number of international journals.

Dr Sandra Buttigieg is the Director of the Institute of Health Care, University of Malta.

Sandra Buttigieg graduated as a Medical Doctor from the University of Malta in 1987, later obtaining a Masters in Public Health Medicine. She is currently reading for a Masters in Business Administration. She is also a Fellow of the Salsburg Seminar, sessions 292 and 356, related to Health Care. Between 1987 and 1998, she served as Vice-President and later International Secretary of the Medical Association of Malta. Dr Buttigieg's previous post was that of Medical Superintendent at St Vincent de Paule. Dr Buttigieg is a member of the Bioethics Consultative Committee, the St Luke's Hospital Management Committee, and the Board for the Professions Supplementary to Medicine.

Professor Maurice N. Cauchi, A.M., M.Q.R., M.D., M.Sc., Ph.D., F.R.C.P.A., F.R.C.Path

Professor Cauchi graduated M.D. (Malta, 1991) and furthered his education at the University of London, Monash and Melbourne. He is professor of Pathology, University of Malta, and Chairman, Gozo Health Council. He is Chairman of the Research Ethics Committee (Medical School, University of Malta). He represents Malta on the Bioethics Committee of the Council of Europe. He has written and edited several monographs and papers of a

scientific nature. He has also several articles relating to bioethics to the local press. He is currently Chair, Bioethics Consultative Committee.

Dr Emanuel Farrugia MD Dip Neph (Lond), MRCP (UK), FACP FRCP (Lond) is Consultant Physician and Nephrologist at St Luke's Hospital since 1992. Dr Farrugia is also Senior Lecturer in Medicine and Examiner in the Faculty of Medicine and Surgery at the University of Malta. Dr Farrugia received training in nephrology, dialysis and transplantation medicine at the Royal Postgraduate Medical School in London and at Mayo Clinic, Rochester, Minnesota, USA. He has numerous publications in peer-reviewed journals and has participated in various congresses abroad. Dr Farrugia is also a member of the Research Ethics Committee

Dr Ruth Farrugia graduated LL.D. (1984) from the University of Malta. She has served as Deputy Registrar of the Superior Courts and Advocate, at the Office of the Attorney General. Dr Farrugia has followed an M.A. in diplomatic studies a diploma course in Canon Law at the Ecclesiastical Tribunal, and human rights studies at the University of Strasbourg as part of a United Nations Fellowship in Human Rights. She has published in local and international legal journals and formed part of several law commissions. Dr Farrugia also practices family law before the civil and ecclesiastical courts, and is chairperson of the Children and Young Persons (Care Orders) Board and consultant to the Ministry for Social Policy on Child Law.

Dr Lino John German was born in 1931. He qualified M.D. (Malta) in 1955 and specialised in Obstetrics and Gynaecology in the United Kingdom, obtained his MRCOG in 1962, and was elected FRCOG in 1977. In 1996 he graduated MPhil. (Malta) in Ethics. He was Hon. Secretary MAM (1973 - 1988). Dr German has been Vice President (European Region) of the Commonwealth Medical Association since 1989 and has been involved in a CMA project on Medical Ethics and Human Rights. He is currently a Member of the Bioethics Consultative Committee and Ethics Officer of the Medical Association of Malta.

Professor George Grima studied for the B.A. and the Licentiate in Theology at the University of Malta and for an M.A. in philosophy and a Doctorate (S.Th.D.) in Moral Theology at the Catholic University of Leuven Belgium. He has spent a long period of research in Christian social ethics at the Faculty of Catholic Theology, University of Tubingen Germany. He is Professor of Moral Theology and Dean at the Faculty of Theology at the University of Malta. He is a member of the Malta Bioethics Consultative Committee.

Mary Anne Lauri holds a B.A. (Hons) in Psychology from the University of Malta and an M.Sc. in Social Psychology from the University of London. She co-authored the fourth edition of a secondary school textbook on Media Studies, and is currently finishing work for a doctorate at the University of London. Her research interests include the effects of campaigns, attitude change and the social psychology of mass communication. She is an assistant lecturer in the Department of Psychology at the University of Malta

Dr Pierre Mallia graduated M.D. in 1993 and M.Phil. (Bioethics) in 1998. for which he obtained a distinction. He is currently secretary to the Bioethics Consultative Committee and lectures part-time in Bioethics at the University of Malta whilst being a full-time GP. He has written articles on Bioethics in a number of international journals and presented a number of papers in international meetings. Currently he is about to publish a book on patients' rights in Maltese. His M.Phil. thesis on Principles of Biomedical Ethics is also being published (Kluwer Academic Publishers). He is reading a PhD in Bioethics at the Catholic University of Nijmegen, Holland, under Prof. Henk ten Have.

Dr Lorraine Schembri Orland was educated at the Convent of the Sacred Heart. She graduated to the Doctorate of Laws from the University of Malta (1982), and holds a Masters degree in European Law, as well as a Diploma to serve before the Ecclesiastical Tribunal. Her Doctorate thesis dealt with problems of carrier liability in container carriage whilst her Masters thesis

Union dealt with “The Doctrine of Direct Effect” of the law of the European Union.” Dr. Schembri Orland was President of the National Council of Women(1988-1990), an elected member of the Executive of the Conseil International des Femmes (ICW), Chairperson of the Inter-governmental Committee on Violence Against Women (1990-92), and Vice-Chairperson of the Commission for the Advancement of Women (1989-1996). She is co-drafter of the family law and adviser on amendments concerning Domestic Violence. She is also a Salzburg Fellow and a recipient of the USIA International Visitors Programme. She has represented Malta at the Council of Europe, at the UN General Assembly and at the 1995 UN World Conference in Beijing. She was an Expert advisor to the Commonwealth on women’s issues (1993-1995). She was a Director of Middle Sea Insurance Co. Ltd. (1992-1996), a Committee member of the Camera Degli Avvocati (1998), and is currently a Director of Sea Malta Co.Ltd. She is married to George Schembri Orland and has one son, Kevin

Dr Denis Soler: Family Physician, Qualified MD, Malta (1973), elected Fellow of the Royal College of General Practitioners (UK 1992). He is Founder President, Malta College of Family Doctors, Chairman, Dean’s Advisory Committee on Family Medicine, (University of Malta), Council Member, European Society of Family Medicine, Member Council of Health. He is presently reading for a Masters in Public Health (University of Malta).

Cecilia Xuereb graduated in law, humanities and education management at the University of Malta. She has been active in various fields including gender and family issues, music and the arts, and education planning and administration. She was chairperson of the Manoel Theatre Management Committee between 1988 and 1991, and President of the National Council of Women between 1994 and 1997. She is currently an assistant head in a church school. She has published a number of papers in local and international journals related to her fields of interest, and is a regular music critic for the Sunday Times of Malta.

PATIENT CHARTER: YOU AND YOUR DOCTOR

A Commitment to your Care

Your doctor provides services to meet your needs and expectations, regardless of age, sex and religious beliefs.

You can expect:

1. To be treated with care, consideration and respect;
2. To have the right service at the right time and place;
3. To discuss and help decide the care and treatment that's right for you;
4. Be given clear information about any treatment or care proposed, including any risks and any alternatives, and to have your own wishes taken into account as far as possible;
5. Be kept informed about your progress. Your relatives and friends are also entitled to be informed, subject of course to your own wishes;
6. Give or withhold your consent to medical or other care and treatment;
7. Choose whether or not you wish to take part in research or student training;
8. See any reports made for insurance or employment purposes and information held about you on computer.

You have the right to:

1. Be registered with a family doctor of your choice and to change to another doctor if you wish.
2. Be seen by a hospital consultant acceptable to you, when your GP thinks a referral is necessary;
3. Be referred for a second opinion if you and your GP agree that this is desirable; and
4. Have access to your health records which are treated as wholly confidential.
5. Be treated with courtesy at reception

6. Be satisfied with the waiting time for an appointment
7. Be satisfied with the waiting time in surgery
8. Feel your problems are assessed
9. Be given time during the consultation
10. Feel that you have been listened to.
11. Feel satisfied with the information given.

You can help to improve your own health through:

1. Not smoking;
2. Eating a sensible and well balanced diet;
3. Taking regular exercise;
4. Reducing the amount of alcohol you drink to the recommended limits.

There are a number of ways that you can help your doctor:

1. Keep appointments made for you or notify the doctor as soon as possible if you are unable to attend;
2. Whenever possible go to your doctor's surgery rather than ask your doctor to visit you;
3. Do not say that a visit is urgent unless in an emergency,
4. If you do need a home visit, try to let your doctor know before 8.00am;
5. Do not expect a prescription at every visit; many illnesses are short term and do not require medication.

ETHICAL CONSIDERATIONS RELATING TO HUMAN REPRODUCTIVE TECHNOLOGY

Preamble

In the field of human sub-fertility there is a great and increasing need for assistance in procreation. There are now a variety of techniques available which are meant to be of value to those couples who for some reason cannot achieve a normal family through natural methods.

Problems have been raised in this context, involving ethical, societal, psychological and legal issues which must be faced by those involved in these procedures. The interests of the embryo and future child remain of primary importance.

These issues have already been discussed at considerable length by previous National Bioethics Committees, and a document "Reproductive Technology: Ethical and Legal Considerations, Report of the Sub-committee, National Bioethics Consultative Council, 1992," relating to this was approved by the previous committee. This document was extensively discussed at two separate seminars held at the Department of Health. The present document reviewed the original document, taking into account issues raised during these seminars.

Although this document owes a considerable amount to "Human Artificial Procreation" issued by a Committee of the Council of Europe (CAHBI, 1989), a number of other documents have been consulted, including:

- Recommendations for Ethical Guidelines in Human Artificial Procreation, issued by the Malta College of Obstetricians and Gynaecologists, October 1994.
- Convention for the Protection of Human Rights and Dignity of

the Human Being with regard to the Application of Biology and Medicine: Convention of Human Rights and Biomedicine. Oviedo, 1997.

- Ethical and legal problems of genetic engineering and human artificial insemination, European Parliament, 1990.
- Assisted Reproduction - A Report, The Danish Council of Ethics, 1995.
- New Guidelines for the Use of Semen for Donor Insemination, American Fertility Society, 1986.
- La Fecondazione Assistita (Documento del Comitato Nazionale per la Bioetica), 1995.

General Considerations

1. Techniques of human artificial procreation are to be used:
for the benefit of a heterosexual couple within a stable legitimate relationship;
To ensure the over-riding right and well-being of the future child.

Since human life exists from the moment of conception, it deserves the respect that is due to a human being at all stages of development.

2. Such techniques are to be used only:
when other methods of treating infertility have failed or are inappropriate, or
when there is a possibility of preventing the transmission of a grave hereditary disease to a child.

In every case it has to be ensured that the procedure has a reasonable chance of success, and there is no significant risk to the health of the mother or child.

These procedures should be undertaken only for serious conditions such as treatment of infertility and prevention of problems for future children, and not for trivial matters such as selection of gender, hair colour etc.

3. Informed consent should be given in writing by those participating in these procedures following appropriate information and counselling from competent professionals.

4. There should be a designated Authority for the purpose of regulating the practice associated with these technologies.

5. These procedures should only be undertaken by institutions or qualified practitioners registered by the Authority.

6. Members of staff shall not be forced to participate in these procedures if they have an objection on grounds of conscience.

7. The physician and the person responsible for the institution where these procedures are carried out must keep adequate records of information relating to these procedures. Whilst confidentiality must be respected, information must be made available to the person who wishes to know who was the donor used for his/her fertilization.

Storage of Gametes

8. Storage of gametes may be carried out only in establishments licensed by above Authority.

9. Storage of gametes for one's own use:

9.1 This is allowed only if there is a risk of infertility or other hazard that may impair procreative capacity.

9.2 Where the donor of gametes dies, cannot be traced, or withdraws his/her consent, stored gametes shall not be used for artificial procreation.

10. There should be a time limit on storage of gametes.

Fertilisation in vitro

11. Only the minimum number of ova strictly necessary to optimise the success of procreation should be fertilised in vitro. All of the fertilised ova are to be transferred to the woman from whom the ova were removed.

Storage of embryos

12. Embryos shall not be stored for future use.

Donation of Gametes

13. Donation of third party gametes is not desirable because it may create social and psychological problems.

13.1. One position is that the practice is ethically acceptable and that it should therefore be legally permissible under the following conditions:

- i. There is verified irreversible sterility in either of the couple.
- ii. There is a serious risk of major malformation or other abnormality.
- iii. All other possibilities have been exhausted prior to resorting to use of third party gametes.
- iv. There should be written consent of both partners.
- v. It should take place only following adequate counselling and confirmation of their suitability, and after they have been informed on the varying views on this matter.

- vi. There should be adequate donor selection screening. All reasonable measures should be taken to ensure that the donor is free of transmissible diseases.
- vii. Donation of gametes should occur only to married couples .
- viii. No payments should be made for the donation.

13.2 The other position maintains that it is a mistake to assume that donation of third party gametes is not significantly different from other morally lawful practices such as blood or organ donation. In fact it may change the significance and value of marriage and the family as the proper context for human procreation, and may prejudice seriously the chances of the child to develop a healthy sense of self-identity. Hence, while legal provision on the matter should take into account the distinction between law and morality, they should recognise the importance of sustaining the integrity of married life and uphold the right of the child to be born and to be raised in a family environment that is conducive to the development of an unimpaired sense of self-identity.

14. The number of children born from the gametes from any one donor should be strictly limited.

15. A donor of gametes may not be subject to any discriminatory conditions. The donor is free to withdraw permission to donate gametes at any time prior to their use.

Donation of Embryos

16. The donation of embryos to another couple shall not be allowed. Likewise the transfer of an embryo from the uterus of one woman to another shall not be allowed.

Anonymity

17. The identity of the couple(s) and donor(s) shall be kept strictly confidential.

Determination of maternity and paternity

18. A child born as a result of artificial insemination by donor may, at an appropriate age, have access to information relating to the manner of his or her conception including the identity of the donor.

19. The rights of the child and lawful parents following artificial procreation should be respected at all times. There should be a clear understanding relating to the status of the donor of gametes, and any obligations to the future child that a donation might entail must be enunciated. These should provide for:

19.1. Informed consent of the couple and confirmation of their suitability, in accordance , by analogy, with regulations governing adoption, including provision relating to the anonymity of donors.

19.2. A ban on disavowal of paternity in the case of artificial insemination by third party donor

19.3. There should be no legal obligations (including maintenance obligations) as a result of being a donor of gametes.

Surrogate motherhood

20. Techniques of artificial procreation shall not be used to provide a pregnancy for a surrogate mother.

Procedures on Embryos

21. Surgical and medical procedures to correct specific abnormalities and diagnostic tests on the embryo may be allowed provided that:

- 21.1. they are intended solely for the benefit of the embryo,
- 21.2. the purpose cannot be achieved by any other method,
and
- 21.3. the consent of the mother has been given.

In addition, one must ensure that:

- 21.4. there is no undue risk to the embryo or the mother;
- 21.5. the expected benefits justify the risks associated with the procedure.

22. An intervention seeking to modify the human germ cell genome is not acceptable.

23. The placing of a human embryo in the uterus of another species or vice versa shall be prohibited

24. The fusion of a human gamete or embryo with that of another species shall be prohibited.

Use of embryonic tissues for research and therapy

25. The creation of embryos for research purposes shall be prohibited.

26. Research on embryonic tissue obtained after a natural miscarriage is acceptable provided that such research has been approved by the appropriate ethics research committee and the consent of the couple has been obtained in writing.

27. The use of embryonic tissues for therapeutic purposes is acceptable provided that:

27.1. This is the result of a natural miscarriage.

27.2. All the relevant conditions and criteria laid down in the document “Ethical Guidelines Relating to Transplantation”, including authorisation by the Specific Board as established in that document will be observed.

EXPLANATORY MEMORANDUM

Preamble

Artificial reproduction technology includes a number of procedures including:

artificial insemination of a woman by sperm.
intra-tubal insemination
in vitro fertilisation
embryo transfer
direct sperm injection (micro-insemination, *ICSI*)
transfer of gametes into the Fallopian tube
preservation of gametes and embryos
surrogate motherhood.

The following principles should serve as a guideline in this difficult and rapidly changing area.

General Considerations

Re Article 1: Professional guidelines are not meant as casual restrictions on reproduction technologies that offer enhanced options for producing a pregnancy. Rather, guidelines should be set out that detail how the technologies may be offered with safety and ethical appropriateness, while giving due consideration to individual rights.

These guidelines fall into four categories:-

- i) Those that apply to technologies at the research stage.
- ii) Those that delineate some of a physician's responsibilities in his or her clinical practice.
- iii) Those that determine the family relationships among the couple, the children and any third party, donor or surrogate who aids in non-coital reproduction.

iv) Those that may affect payment to donors.

This article emphasises the importance of limiting these procedures to couples in a *stable* relationship. It excludes provision of services to homosexual couples. It does not, however, exclude their application to couples within a *de facto* relationship.

Re Article 2: Techniques of artificial procreation may be justified in the prevention of disease, such as the prevention of sex-linked disorders (e.g haemophilia, which is carried by the female X chromosome and affect only the male issue). Such techniques must not be used merely to select the sex of the child, or particular (accidental) characteristics when there is no such risk of disease transmission.

This article also emphasises the fact that the risk to mother and fetus should be taken into consideration prior to the implementation of these procedures. Procedures which are considered to carry undue risk to either should not be encouraged.

Re Article 3: Informed Consent: A broad legal mechanism - informed consent - protects the participants in the reproductive technologies, no matter what type of institution or clinic provides the services, and no matter whether the procedure is experimental or standard practice. Physicians must present information to patients in a form that they can understand, so that they may accept or reject a proposed procedure.

Physicians must discuss the patient's condition, the nature, risks and benefits of diagnostic procedures or treatments, and the availability, risks and benefits of alternatives. Informed consent protects patients by giving them the opportunity to refuse treatments that they consider to be too risky. Provision of information can be of physical and psychological benefit to the patient.

Information must also be given with respect to genetic risks in child bearing.

Re Articles 4 and 5: Clinics/hospitals providing reproductive technology must be monitored by a specially set up Board. Anyone conducting these procedures must file half yearly reports with the Department of Health that give the names of everyone conducting or assisting the process; the location where fertilisation takes place, and the names and addresses of persons or institutions sponsoring and involved in the procedures.

Re Article 7: In the case of AID, a physician must obtain and keep the husband's consent form. This can only be shown on a court order. The process must be done by a physician in possession of a medical license.

It is important that full details are kept of all procedures and persons involved, including the names of donors of gametes, number of women given sperm from any one donor, the number of eggs fertilised from any one donor etc.

Confidentiality could present problems in the situation where a child resulting from these technologies requires information, e.g. relating paternity. It is current opinion that every effort should be made to ensure that such information must be made available. While it is understood that this requirement will put an extra strain and difficulty in procuring donor sperm, for instance, this has to be counterbalanced by the rights of the future child for information.

Re Article 8: Storage of gametes: The provision for storage of gametes is made on the assumption that all the requirements set in these principles are met, and on condition that there are valid medical reasons for storing these gametes, e.g. that the husband is to undergo chemotherapy which could affect the viability of his sperms.

The cryo-preservation of human sperm is ethically and medically acceptable. The cryo-preservation of ova is likewise acceptable, however, since the safety and efficacy for application to human beings is not yet fully determined, the fertilisation and/or transfer of cryo-preserved eggs should be considered as a clinical experiment after the preliminary research has been completed.

Protective procedures have to be respected. Sperm bank facilities have to be reliable. Proper donor selection and medical screening procedures should be provided. Known carriers of genetic diseases, genetic defects or neural diseases are prohibited from being sperm donors.

An area of concern is the use of frozen gametes when the original intent has changed e.g. after the death of the husband or after divorce. In the latter case the stored sperm should be destroyed and under no circumstance can use be made of such sperm. An exception may be made in the case where specific written consent had been made to donate sperm in such an eventuality.

A donor of gametes may not be subject to any discriminatory conditions. The donor is free to withdraw permission to donate gametes at any time prior to their use.

Re Article 10: The length of time for which gametes can be frozen is left indefinite in this article. While it appears reasonable *a priori* to assume that gametes should not be kept frozen indefinitely, there is no definite scientific evidence in favour of a single cut-off point. It is therefore left to local legislation to determine what is a reasonable length of time that gametes can be frozen. This will be different for ova vs sperm, and will vary according to advances in technology.

Re Article 11: The Committee finds that basic IVF is ethically acceptable.

Artificial Insemination by husband (AIH) is acceptable if it is used as an extension of the couple's coital activity. It is acceptable for demonstrated indications: where the husband is unable to achieve ejaculation within the vagina for whatever reason, including psychogenic or organic impotence, severe hypospadias, retrograde ejaculation, drug induced erectile dysfunction, or vaginal dysfunction. AIH may be acceptable also in certain cases, such as cervical mucus abnormalities that cannot be corrected by other means, cases of oligospermia, poor sperm motility, and/or anti-sperm antibodies which may be corrected with the use of various swim-up or washing techniques and intrauterine insemination.

AIH for gender selection is to be prohibited

Re Article 12: Storage of Embryos: Pre-embryos shall not be stored for future use. All fertilised ova are to be transferred to the woman from whom the ova were removed. In arriving at this conclusion, the Committee has kept in mind

1. The risk of possible injury to the embryo resulting from the freezing technique.
2. The ethical problems associated with excess embryos. Destruction of such embryos or their donation are both fraught with ethical problems. A limit must be placed on the number of ova that can be fertilised in one attempt - say four in one IVF cycle and six in one ICSI cycle - this will reduce to a minimum the number of multiple pregnancies in excess of triplets.

Re Article 13 Donation of Gametes:

This article provided extensive discussion and the Committee could not reach a consensus. The two different points of view are stated here (Articles 13.1 and 13.2). In all circumstances, it was agreed that there should be strict regulation relating to donation of gametes by a third party.

Paternity of the child: the legal parents are the sperm recipient and her consenting husband.

The identity of the donor shall be kept strictly confidential. (See however the possible conflict of interest arising from the rights of the child as discussed above under Article 7). A (third party) sperm donor must never be held responsible for supporting the child. A child born as a result of artificial insemination by donor, at an appropriate age, may have access to information relating to the manner of his/her conception. Also, such a child should be able to get information to exclude consanguinity with a prospective spouse (Articles 18 & 19).

Donor sperm in *In Vitro* Fertilisation

It is ethically acceptable to use donor sperm for IVF in cases where the woman is normal but the man's fertilizing capacity is unknown or uncertain. Donor sperm should not be used during the initial IVF cycle attempt and should be used only if fertilisation attempts with the husband's sperm consistently fail.

Donor Eggs in *In Vitro* Fertilisation

The use of donor eggs is ethically acceptable for some conditions. Several guidelines should apply. There should be no compensation to the donor of the eggs. This does not exclude the reimbursement for expenses and inconvenience entailed with the donation. Anonymity must be respected. Donation among parties known to each other, such as relatives, should not be precluded.

The confidentiality and record keeping provision applied to an artificial insemination donor (AID) also should apply to egg donation.

So that the possibility of the transmission of a genetically defective egg can be reduced, younger donors should be used, and except

in unanticipated situations, all donors should be screened. In addition, so that problems of infection are minimised, donors should be screened according to the same procedures as for male donors.

Re Article 13.8: Re-imburement of expenses: Only loss of earnings, and other expenses associated directly with the donation may be refunded to the donor.

Re Article 17: Anonymity: Information on the genetic characteristics of the donor can be given in the interest of genetic counselling. However, see note re Article 7, above.

Re Article 20: Surrogate Gestational Mothers: Surrogate gestational motherhood is unacceptable and techniques of artificial procreation shall not be used to provide a pregnancy for a surrogate mother.

Re Article 21: Procedures on embryos: The aim here is not to prohibit sampling of tissue and blood for purposes which would be of direct benefit to the embryo and future child.

Re Articles 25 - 27: Use of embryonic tissues for research and therapy: All research involving human subjects must be approved by a specially set up Review Board such as the Institutional Research Ethics Committee. Regulations should specify what the Review Board should consider when reviewing a proposed research project. The guidelines should specify that research must be designed so that risks are minimised and reasonable in relation to anticipated benefits, the selection of subjects is equitable, informed consent is gained according to specific guidelines, and is documented, the data are monitored to ensure the safety of the subjects and the privacy of the subjects and the confidentiality of data is maintained.

In the case of IVF research, there must be adequate criteria for selection of potential subjects and monitoring of the actual consent process.

An application for research must be reviewed by an Ethics Advisory Board.

No fetuses, other than those procured as a result of natural miscarriage, can be donated for purposes of research or experimentation, and only provided the mother/parents has/have given her/their consent, and provided such research has been approved by the appropriate Ethics Research Committee.

The creation of embryos for research shall be prohibited. A woman shall be prohibited from selling a fetus for purposes of experimentation or other reason.

Embryonic tissue may be used for therapeutic purposes, provided that:

1. This tissue is not the result of abortion procured for the purpose of obtaining embryonic tissues for therapeutic use.
2. All the relevant conditions and criteria laid down in the document "Ethical Guidelines relating to Transplantation", including authorisation by the Specific Board as established in that document, be observed.

Placental tissues obtained after normal delivery of a full term infant or miscarriage for research and possible therapeutic purposes can be used as long as there is the appropriate approval from the institutional research ethics committee. In such cases, the consent by the woman from whom the placenta had originated is not specifically required.

Recommendations for Legislation:

1. Accreditation and licensing of clinics where such techniques are carried out.

2. The creation of adequate structure for the supervision of facilities and practices carried out in such clinics.
3. The provision of free, informed, specific and written consent by all persons involved in donation or receipt of gametes in the process or artificial procreation, following adequate counselling.
4. Provision for keeping detailed records of all procedures, to be available for inspection by the competent authorities.
5. Provision of effective and appropriate penal sanctions.
6. Provision relating to the length of time that gametes can be kept frozen.
7. Provision of adequate legal protection for persons involved in the process or artificial procreation, including the legal status and rights of any offspring resulting from procedures involving gamete donation.
8. The following procedures to be declared illegal:
 1. production of embryos specifically for experimental purposes.
 2. experimentation on the human embryo.
 3. cross-species embryo transfer involving human beings.
 4. manipulation of the human germinal genome.
 5. donation or preservation of human embryos.
 6. breeding hybrid embryos (chimeras) involving human cells.
 7. commercialising and profit making from donation of gametes.
 8. surrogacy.
 9. induction of post-menopausal pregnancy.
 10. donation of stored sperm from dead donor (including husband).

ETHICAL GUIDELINES RELATING TO TRANSPLANTATION

Preamble

Organ donation is one of the finest gifts one human being can give to another, and donation of organs from both living and dead donors is to be encouraged. Transplantation should be the last resort when no other equally effective treatment is available, and when there is reasonable hope that the transplant will be successful.

In the transfer of organs and tissues, a number of ethical issues are involved, relating to donors, recipients, and their families, as well as the inter-relationship of the medical teams involved in the procedures.

It is absolutely crucial that at no stage during the procedures involved in transplantation is there a loss of respect for the human body. In particular, it is imperative that the human body does not become a source of profit as if it were a mere commodity.

The aim of this document is to highlight the several ethical issues involved in transplantation, relating to the donor (living or dead), the recipient, the medical aspects, as well as the use of fetal and animal tissues for transplantation.

1. Transplantation of organs from living, adult donor capable of giving informed consent.

- 1.1 There must be adequate medical and psychological assessment of the donor.
- 1.2 Adequate counselling from professional staff should be given.
- 1.3 Donors should not expect any financial or other reward from

donation of organs. The sale of organs and its advertising shall be prohibited.

- 1.4 Free, informed and specific consent is to be given in writing before an official body or person (e.g. notary public or commissioner for oaths, or a Board as described further below). This should also include an explicit declaration that no financial gain is involved.
- 1.5 The doctor removing the live organ must take reasonable measures to ensure that no undue psychological or moral pressure has been exerted on the donor, and that the consent is indeed free and informed.
- 1.6 A donor is free to withdraw consent at any time prior to intervention.
- 1.7 Refusal to give consent must be respected at all times.
- 1.8 Prospective donors have a right to confidentiality which must be respected at all times.
- 1.9 A Board for organ and tissue donation and transplantation should be set up to ensure that all potential donors are adequately informed, and that no undue pressure is brought to bear on the donor, (see Paragraph 9 below).

2. Transplantation of organs from living donor not legally capable of giving consent

- 2.1 As a rule transplantation of organs from persons incapable of giving consent should be prohibited. However, in exceptional circumstances, and with the specific approval of a specially instituted Board (paragraph 9 below), children under the age of majority may be considered as donors of organs subject to conditions mentioned above and with the consent of their

parents or, in their absence, by authority of the competent court. In all instances the informed consent of the child is also required.

2.2 The Board will have no direct links with the transplant team.

2.3 No organ may be removed from an individual who by reason of mental disorder does not have the capacity to give consent.

3. Transplantation of organs from cadaver donor

3.1 Every effort should be made to ensure an enlightened public opinion relating to the necessity of organ transplantation.

3.2 The consultant in charge of the Intensive Therapy Unit should, where appropriate, ask relatives for donation of organs.

3.3 The body of a dead donor must be treated with the utmost respect. Every effort must be made not to offend individual sensibilities.

3.4 Issues relating to consent:

3.4.1. Previously expressed consent is said to occur where the deceased had during his/her lifetime expressed the wish to be a donor (e.g. having a donor card).

3.4.2. As a general rule, where there is a discrepancy between the previously expressed wishes of the dead person and the relatives, then the views of the latter shall over-ride the presumed wishes of the deceased.

3.4.3. Where a deceased person had not expressly forbidden the removal of his/her organs after death, this shall not be taken as consent, in the absence of express consent from the relatives.

4. Brain death concept

- 4.1 Certification of brain death according to current scientific criteria should be made by two experienced independent practising medical practitioners and who form part of a panel chosen for the purpose by the Director General of Health from among medical practitioners who in his opinion are qualified for the purpose. They should be independent of the transplant team.
- 4.2 When death has been certified, the whole body or parts thereof may be artificially maintained for a reasonable period of time with a view to transplantation.
- 4.3 Seriously ill patients who are being considered as likely potential donors should not be put on life-prolonging procedures if this is not considered to be in their best interest.

5. Recipients

- 5.1 All persons should be treated as equal in terms of their right to receive an organ transplant.
- 5.2 The final decision relating to selection of recipient must be based primarily on medical criteria.
- 5.3 There should be free and complete disclosure of selection criteria being used.
- 5.4 The informed consent of the recipient must be obtained in writing.

6. Relating to the Institution where transplants are carried out:

- 6.1 Removal and transplant of organs should take place in officially

licensed institutions having adequately trained and experienced staff and proper equipment. Such institutions must be specifically authorised to perform these procedures by the competent authorities

6.2 A register of transplant procedures, to include details relating to donor, organ removed, organ recipient and surgeons and anaesthetists concerned, is to be kept by the institution where the procedure has taken place. Full records relating to informed consent must be kept.

6.3 Anonymity: The wishes of the donor and recipient regarding anonymity should be respected as far as possible.

7. Other considerations:

7.1 Transplantation of organs from animals to human beings is permitted, so long as it is recognised as a therapeutic and not experimental procedure. Special counselling would be required, and informed consent obtained.

7.2 Transplantation of organs from fetuses should only be carried out subject to their compliance with criteria preset by the Board.

8. Transplantation of regenerative tissues

8.1 Free and informed consent shall be given by the donor in writing.

8.2 In the case of minors, transplantation of bone marrow to close family members will be allowed, provided that there is no other compatible donor. Consent is required as provided above (See Section 2.1).

8.3 Research procedures involving donor regenerative tissues must have the prior approval of the institutional research ethics committee and the informed and written consent of the donor.

9. Structure and functions of the board

9.1 There should be a Transplantation Advisory Board. The Board should include the following:

9.1.1. a medical practitioner

9.1.2. an ethicist

9.1.3. a representative of the Office of the Attorney General

9.1.4. a layperson

9.1.5. a representative of the Director General of Health.

The chairperson of this Board shall be selected from among the members of the Board.

9.2 The members of the Board shall be nominated by the Minister responsible for Health.

9.3 The functions of the Board shall be to ensure that:

9.3.1 the proper information relating to medical procedures has been available to all persons undergoing medical intervention;

9.3.2 when consent is required, this is duly and freely given in writing;

9.3.3 there is no undue pressure brought to bear upon a donor;

9.3.4 where there is no direct genetic relationship between donor and recipient, to ensure that the nature of the personal relationship is one that is acceptable;

- 9.3.5 there is no financial incentive of any kind benefiting the donor;
- 9.3.6 no transplantation involving a person below the age of consent is carried out without the prior approval of the Board;
- 9.3.7 the criteria of donor selection are clearly set out and available to the patient;
- 9.3.8 a Register as envisaged under Para 6.2 is duly kept by the Institution where the transplant is taking place;
- 9.3.9 any complaints relating to any procedures associated with transplantation are properly and adequately investigated.

EXPLANATORY MEMORANDUM

Re 1.1: Persons giving advice should be adequately trained. Advice given should include medical, psychological and ethical considerations.

Re 1.3: Financial gain referred to here does not include reimbursement of expenses incurred.

Re 2.1: In general donation of organs by children should be prohibited. However, in exceptional circumstances, and in older children only, situations may arise when one desires to donate an organ to a brother or sister which could be a life-saving situation. The purpose of this clause is to ensure that a mature older child (of say 17 years) of age should not be prohibited under all circumstances from giving an organ for transplantation.

Re 3.1: It is the first and primary duty of the medical practitioner to save the life of the patient. However, he is also the person who

is best placed to approach the relatives to discuss the issue of organ donation. It is obviously assumed that this is done with the utmost tact and discretion, and respect for the emotional pressures that relatives are likely to be suffering from at the time.

Re 3.4.2: Until such time when a donor card will have legal binding, the wishes of the relatives are to be given priority by the Board. However, it is recommended that the previously expressed wishes of the dead individual should be respected by the members of the family.

Re 3.4.3: Presumed consent refers to the situation where a deceased person has not expressly forbidden the removal of his/her organs after death. Although this is not necessarily unethical, it would seem inappropriate at the moment to promote such a concept. This could be reviewed in due course.

Where relatives are not available, it is inadvisable to proceed to obtain organs from a dead person on the basis of presumed consent.

Re 4.3: A doctor can only act in the interest of the dying patient. A doctor may apply life support treatment if he/she believes that the patient may benefit from such treatment.

Re 5.2: Selection criteria: The selection criteria to be considered would include:

1. Medical reasons: Some of the medical criteria which currently guide the designation of a donated organ are:

- the degree of need,
- the likelihood of rejection,
- the blood type,
- other indicators of compatibility, physical size, probability of success.

Diseases which limit the quality of life may affect the overall decision.

3. Age: Young age could be a consideration not only because of the probably absence of degenerative disease but also because of the significant improvement in longevity with good quality life that could be achieved.

4. Relatives: The existence of relatives who wish to donate a kidney for transplantation might be considered as sufficient reason not to give priority to these patients on a waiting list for cadaveric transplantation.

5. Directed organ transplantation, i.e. when the relative of a dead donor insists that the organ be given to a particular recipient. It is considered undesirable that such direction be encouraged. The choice of recipient should remain the duty of the transplant team, as discussed earlier.

Re 5.4: The patient must be fully informed of the physical and psychological issues involved in the transplant procedure.

Re 6.3: While every effort should be made to preserve anonymity in relation to identity of donor and recipient, it is recognised that in a small country like Malta this is not usually practicable. However publicity should not be encouraged.

Re 7.1: Xenografts (i.e. transplants from animals to man) are permissible as long as they do not produce changes in personality.

Re 7.2: The production of fetuses specifically for the procurement of organ donation is to be prohibited.

It is possible for doctors to establish the diagnosis of brain death when respiration has ceased in anencephalic infants. Organs from such infants can be used for transplantation purposes.

Since scientific knowledge cannot clearly determine brain death in infants suffering from severe brain injury, these infants shall only be ventilated in their own interest, and no organ removal should be carried out.

Re: 8: Regenerative tissues refer to those tissues which can rapidly multiply and replace any donation in relatively short time (e.g. bone marrow), and therefore do not constitute long-term loss. This term does not include germinal tissue from reproductive organs, usage of which is dealt with separately. (See Code relating to Reproductive Technology). It also does not include blood and blood components.

The Bioethics Consultative Committee, Malta

The Bioethics Consultative Committee was originally set up (under the chairmanship of the late Dr Joseph L Grech) by the then Minister for Social Policy, the Hon Dr. Louis Galea. It is now appointed by the Minister of Health on an annual basis.

The functions of the Committee include the assessment of bioethical issues relevant to the community, and formulation of advice to the Minister. Over the years it has taken a keen role in highlighting issues relating to the ethical practice of medicine within our community.

Through its participation in the Council of Europe, the Committee ensures that Malta is well aware of advances in the field of Bioethics, and contributes to the formation of the relevant policies. The most recent development in this area has been the Convention of Bioethics which Malta will be signing in the near future.

The Committee has drawn up several Protocols relating to bioethical issues, namely: Informed Consent, Transplantation, and Reproductive Technology. These documents should serve as discussion documents and eventually as a basis for future, legislation.

Over the years, the Committee has published several publications, namely:

- **Bioethics: Responsibilities and Norms for those involved in Health Care** (ed. Toni Cortis 1989).
- **Informed Consent: Proceedings of a Symposium for Medical and Paramedical Practitioners** (ed. M.N.Cauchì, 1998).
- **Proceedings of the Conference on Bioethics and Disability** (ed. M.N.Cauchì 1999).

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