Proceedings of the Conference
organised by
The Bioethics Consultative Committee,
Ministry of Health,

Bioethical Issues at the Beginning and End of Life

Editor: M.N. Cauchi

The Bioethics Consultative Committee
Malta 2002

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Foreword

The Hon. Dr Louis Deguara, Minister of Health

The Bioethics Conference has now become an annual event. It gives us an opportunity to reflect on issues relating to health which are at the very root of medical practice.

This year, this Conference has dealt with two very important issues, relating to the beginning and end of life. There is no need to emphasise the importance or the topicality of these issues.

Genetic testing has been with us for decades, but it is only in recent years that advances in molecular biology has made it possible to tease out the fine details of the human genome and relate these changes to disease processes and even to character traits. Our genome is a very personal bequest and needs to be guarded very carefully.

It is for this reason that genetic testing is not at all like any other diagnostic test in that the results obtained may affect not only the individuals who submit themselves for the test, but also the whole family and even more remote relatives of those persons. The question of informed consent, important in all medical issues, is particularly essential in the case of testing for genetic disorders. A case could be made that no genetic test should be performed unless the whole family has received adequate counselling about the possible consequences of a diagnosis.

Performing a genetic test is not like testing oneself for cholesterol or anaemia. We have to be very clear in our minds why we are performing genetic tests, because the results of these tests will remain attached to us for the rest of our lives.

It is also quite likely that further research might show relationships not only between genetic make-up and tendency to disease, but also associations relating to behaviour, and other psycho-social characteristics which should not be the concern of anyone, perhaps not even the individual himself or herself.

It is for this reason that stringent precautions have to be taken to ensure that information relating to genetic studies is obtained only under strict guidance, and that such information is protected from the prying eyes of third parties who could obtain financial benefit from such knowledge. The Data Protection Bill currently being considered by Parliament goes some way towards ensuring such privacy and protection.

Coming now to the other end of the spectrum of human existence, we find a number of issues that also raise questions relating to the ethics of behaviour. A number of speakers will be discussing the role of palliative care for the terminally ill, and balancing this against euthanasia, which in some countries is considered to be another option. In a pluralistic society we have to be prepared for a diversity of views and resultant expectations and requests. Ideas relating to euthanasia are not absent even in our largely catholic society. The man or woman in the street may sometimes be heard to remark that they would not be prepared to go through what a relative had gone through - indicating that they would take more drastic steps to bring things to a definite conclusion. It is important to clarify that while the end is inevitable, pain and suffering are not necessarily so. Hence the importance of this Conference relating to the significance of spiritual values and the role of palliative care.

None of these questions are easy. None can be resolved by glib statements and rash judgements. Moreover, there will always be those who hold opposite views to those held by the

practitioners of the health professions. It is none the less incumbent on us to make sure of a number of things:

Firstly that the relevant information is available for all those who seek it, and particularly for those requesting a specific test or a procedure.

Secondly that we, as members of the health professions have informed opinions on these issues. This involves not only a solid scientific application of established practice, but also a sensitivity to local cultural mores and expectations. It also assumes that we ourselves have a mature opinion of these issues, which comes from knowledge and reflection. Conference and publications by the Bioethics Committee, including that of a regular Newsletter, should also help in this respect.

I believe it is also imperative that guidance on such matters should come from those in authority. The Data Protection Bill I mentioned already is a step in this direction. I am also now in a position to report that the Government, after consultations with all interested parties, will shortly be deciding to sign the Convention of Bioethics and its Protocols. This Convention would ensure that issues mentioned today relating to the use of genetic data, as well as other issues relating to bioethics and health will be respected.

Finally, I would like to thank all speakers for their participation in this important meeting, which I am sure will clarify several of the issues I have merely touched on. We all look forward to read and reflect on their comments when the Bioethics Committee will publish these Proceedings as has occurred in previous years. I would also like to thank the members of the Bioethics Committee for the work they are doing.

Introductory Remarks

M.N. Cauchi, Chairman

One of the functions of the Bioethics Consultative Committee is to disseminate information and encourage discussion about issues relating to bioethics. Every year now for the last five years we have organised an annual conference to discuss issues of relevance to the health professions and to the general public.

Another venture this year has been the publication of a Newsletter. Two issues have been published so far, and they are also available to you.

This year we have decided to tackle two very important issues, namely those that relate to the beginning and end of life. There are several ethical issues arising from genetic testing, particularly at a time when advances in the field are going ahead at a rate never dreamt of even a decade ago. The human genome has all but been unravelled. The genetic constitution is seen as the key to the analysis of a vast array of human disorders, including not only physical diseases, but also every shade of behavioural disorder as well. We are all worried that eventually big brother will know more about each and every one of us than we really would like him to know. Every day new tests are being dished out claiming specificity for identification of one or other gene of relevance to medicine. In fact, it is becoming clear that no practitioner can afford to lose contact with these advances. Dr Chis Scerri will be dealing with some aspects of these advances in his talk: *The Current Practice of Genetic Testing.*

On the other hand, these advances raise questions which need to be answered. The first of these is the rationale of testing an embryo before implantation. Such a practice

presumes a choice, selection of one embryo against another. In a country like Malta where such practices are not allowed, we have to have very clear reasons why we embark on pre-implantation diagnosis. Professor A. Felice has been working in this area for several years and I am sure that is the right person to talk to us about these issues. He will be talking on *Ethics of Pre-implantation Diagnosis.*

The special nature of genetic testing, including confidentiality, will be discussed by Professor Alfred Cuschieri and Dr P Mallia. There is no doubt that, while it is true to say that all tests should be performed only when there is full informed consent on the part of the patient, and an assurance of confidentiality given by the practitioner, in the case of genetic testing this assumes a far greater importance. Unlike other pathology tests, genetic testing reveals an intimate part of ourselves that remains with us for the rest of our lives. It is part of our blueprint, and therefore needs special protection. It involves also members of the family in so far as they share that genome with the patient concerned. It could even be argued that no genetic test should be done unless informed consent is obtained not only from the individual concerned, but from all the members of the wider family circle who might have a stake in the findings revealed in these tests.

The legal issues that are bound to rise in the practice of this delicate branch of medicine are discussed by Dr L.Schembri Orland, who has taken part in a number of previous discussions organised by the Bioethics Consultative Committee. Her talk on *Legal Issues in Genetic Testing* will emphasize some of the issues involved in this increasingly complicated area.

Finally, our guest, Professor Ruth Chadwick will be discussion genetic issues which are of current interest in Europe in her talk: *Ethical Issues and the Euro-Screen Project.* Professor Chadwick has been involved in issues relating to bioethics for a long time.

End of Life Issues involve ethical issues which sooner or later we all have to face, issues which affects close relatives, and eventually ourselves. *"A gentle, peaceful and easy death"* which is the title of the talk of Dr Moira Camilleri, is something that we all would look forward to, but is not always available. It is an unfortunate fact that very often we are faced with painful terminal conditions which tax our medical capabilities to the utmost. Many patients faced with these problems beg for release. Many health professionals anxious to do the best to their patients are often at a quandary as to what is the best route that they should follow. This is attested to by the current spate of legal proceedings against medical and other health professionals who have seen euthanasia as the only solution. That this is not the case will be attested to by the papers presented by a number of speakers who emphasize the need for palliative care for the terminally ill.

1.
The Current Practice of Genetic Testing

Chris Scerri

The completion of the draft sequencing of the Human Genome has opened up new horizons in the diagnosis, prevention and treatment of genetic disease. The genome of an organism constitutes the whole "blueprint" where all the instructions for all the functional proteins of the organism are stored. The human genome is divided into 22 pairs of autosomal chromosomes together with two X chromosomes in females and an X and a Y chromosomes in males. The genetic compliment is situated within the nucleus of each cell of the body. The chromosomes themselves can be further divided into individual genes that code for individual proteins. The genes (and thus the chromosomes) consist of tightly coiled threads of deoxyribonucleic acid (DNA). DNA is itself formed of smaller subunits made up of one of four nitrogenous bases (adenine, guanine, thymine and cytosine), covalently attached to a deoxyribose moiety and a phosphate group. The bases are covalently linked through phosphodiester bonds between the carbohydrate groups. In addition, two strands of DNA polymer, bind to each other through hydrogen bonds between the nitrogenous bases. This arrangement is analogous to a ladder where the upright sides are represented by the carbohydrates linked by phosphodiester bonds whilst the bases linked through the hydrogen bonds are analogous to the rungs of the ladder. The binding of the bases by the hydrogen bonds is not haphazard but definite pairs of bases always bind together; thus adenine always binds with thymine whilst guanine will always bind with cytosine. This complimentarity forms the basis of both cell division and replication as well as protein formation.

During meiosis one copy of each chromosome pair segregates in the individual oocyte or sperm. This effectively means that each oocyte or sperm has half the compliment of chromosomes (23 and the X or Y). Thus, following fertilisation, the proper compliment of chromosomes is assured. During mitosis, the DNA strand unwinds and each single strand acts as a template for a new, complimentary strand. Thus each daughter cell receives a strand derived from the mother cell and a new complimentary DNA strand. Thus whilst meiosis ensures that the embryo has a normal compliment of chromosomes and that it receives half its compliment from the mother and the other half from the father, mitosis ensures that all the cells of the body contain identical copies of all the chromosomes.

Human Genes

In general, a gene can be divided into five general areas:

1. upstream sequences to the gene/s of interest that regulate the transcription of the same gene/s;
2. the initiation codon that signifies the start of translation of the protein;
3. exons, the coding regions, that alternate with the introns, the non-coding sequences, of the genes;
4. the stop codon signifying the end of translation of the protein;
5. downstream sequences that have important regulatory and RNA stabilisation functions.

Any mutations, even single base mutations, in any of these 5 areas, have a potential to disrupt the normal function of the gene. This forms the basis of genetic disorders.

Inheritance

Genetic disorders can be classified into two main groups:

1. genetic disorder that show a Mendelian type of inheritance
2. genetic disorders that show a non-Mendelian type of inheritance

In Mendelian inheritance, the phenotype is dependent on the genotype at a single locus. Examples of Mendelian inheritance include thalassaemia, cystic fibrosis, Duchenne muscular dystrophy and gangliosidosis.

In non-Mendelian inheritance, the phenotype is dependent on at least two genetic loci with greater or lesser contribution from environmental factors. Examples of non-Mendelian inheritance include ischeamic heart disease and cancer.

Genetic Tests

Genetic tests involve the identification of mutations either within the genes of interest or in their regulatory sequences. This is done by scanning the individual's DNA sequence for possible mutations. The indications for genetic tests include:

- carrier screening,
- newborn screening;
- presymptomatic testing for predicting adult-onset disorders such as Huntington's disease;
- presymptomatic testing for estimating the risk of developing adult-onset cancers and Alzheimer's disease;
- confirmational diagnosis of a symptomatic individual;
- forensic/identity testing;
- and where acceptable prenatal diagnostic testing.

For these tests, the DNA can be obtained from any nucleated cells though in general the sample is either obtained from blood or from internal cheek cells (mouth wash sample).

The testing strategies

One has to understand that though we speak of a genetic test, the testing strategy can differ between genetic disorders and in most cases can be very time consuming. In the case of a disorder characterised by Mendellian inheritance and the gene is known, the initial step following DNA extraction is that of gene amplification. Gene amplification is the term used when the gene or parts of, are selectively amplified in-vitro. This is done by adding a pair of synthesised, short, oligonucleotide strands (primers) that flank the area of interest. One of the primers is complimentary to one strand whilst the other primer is complimentary to the opposite strand. Together with these primers, nucleotides, an appropriate buffer and a thermostable DNA polymerase are added. The whole solution is then passed through repeated cycles of heating to 95°C (denaturing), cooling to a temperature usually ranging between 55°C and 65°C (annealing of the primers) followed by heating at 72°C (elongation of the primers by the DNA polymerase). This set of temperature changes are cycled up to 30-35 times. At the end of these cycles, the area flanked by the two primers would have been preferentially amplified in an exponential manner i.e. if one starts with one copy theoretically one would end with 2^{35} copies of the area of interest. This is called the polymerase chain reaction or PCR.

Following PCR, the fragment can be sequenced directly and the sequence compared to the normal sequence, or else allele hybridisation-based techniques can be used to probe the gene of interest by short oligonucleotide probes complimentary to either the normal strand or the mutated strand. These techniques can be utilised in the service-oriented setup either if the gene is small (2000-4000 base pairs) or if the prevalent mutations within the community are known and their number is small (8-10). If the gene is large and the prevalent mutations are not known, then sequencing becomes impractical due to

cost (one sequencing run can read up to 700 bp) and at the same time allele hybridisation-based techniques cannot be used. In such cases, one enters the realm of research, as techniques (e.g. single strand conformational polymorphism, SSCP) are utilised to identify possible areas within the gene that are mutated following which sequencing is performed on the identified areas.

If the disorder is characterised by Mendelian inheritance, the gene is known but most of the mutations are large deletions, then the technique that is normally utilised is one of restriction enzyme digest followed by hybridisation to labelled probes. Restriction enzymes are bacterial enzymes that digest DNA at particular DNA motifs. Thus, once total genomic DNA is digested by restriction enzymes, the resultant DNA is fragmented into specific fragments of particular size depending on the spacing of the particular motifs in the DNA. These DNA fragments can be separated in a gel depending on size and then blotted on to a membrane. Once blotted, the DNA fragments are transferred on to the membrane. The blotted DNA fragments are then hybridised with a labelled probe complimentary to the gene of interest. Depending on the size of fragment to which the probe has hybridised, one can deduce if a large deletion has occurred in or very near to the gene of interest. As one can already imagine the procedure is quite time consuming, can be difficult to interpret and due to the fact that the best results are obtained by radiolabelled probes, there is the problem of radioactive waste.

In the case of a disorder characterised by non-Mendelian inheritance but some or all of the involved genes are known, then a risk assessment can be achieved by one or all of the above mentioned techniques. On the other hand if the disorder is characterised by either Mendelian inheritance or non-Mendelian inheritance and the gene/s is/are not known, then a risk assessment can be made by an extensive family

examination through the utilisation of single nucleotide polymorphism (SNP's, sometimes called markers) can be obtained. In this way, with the help of particular SNP's that are co-inherited with the disorder a predictive risk assessment for an apparently unaffected individual can be produced.

Conclusion

It should be clear that this short discussion of genetics and the major testing strategies utilised in the identification of genetic disease does not cover all the possible testing strategies. In addition, testing strategies do not only depend on the particular disorder or gene but also on the amount of basic research done towards the identification of the prevalent mutations within an ethnic community or region. Thus it should be emphasised that prior to the setting up of genetic testing for a particular disease, a properly conducted genotyping research study on the particular disorder should be undertaken. Unfortunately, in Malta this has only been accomplished in thalassaemia, which up to this date is the only genetic disease in Malta that is fully characterised. In addition, some information has been gathered on the prevalent mutations for cystic fibrosis, ganglioasidosis and dihydropteridine reductase deficiency (DHPR or atypical phenylketonuria). Though considering our size and financial constraints, these results can be described as relatively big leaps, one hopes that further attention and funding be committed especially in the field of the polygenic disorders such as familial cancer, heart disease, asthma and diabetes.

Genetic tests seem to confer the ability to diagnose genetic disease with relative ease but one has to keep in mind that these are very particular and special tests. It should be remembered that the result of a genetic test, especially in predictive or carrier testing, can be very devastating to the patient, could result in stigmatisation, and can involve the

family as a whole. It should be clearly emphasised that these tests should be carried out only after full and accurate information is offered to the client together with pre- and post-testing counselling. Proper and informed consent - the emphasis being on the word informed - has to be obtained from the client and some would even argue, from the family. It should thus be obvious that such information and testing should preferably be done through a properly organised clinic that apart from the clinical specialists should also include counsellors and psychologists. The client should be made to feel that he has all the support that is necessary, that this support can be given at all times, and that he can obtain the most recent and up-to-date information. To quote from the first newsletter of the Bioethics Consultative Committee, "it would be a great pity if it was misused as many screening tests have been misused in the past."

2.
THE ETHICS OF PRE-IMPLANTATION GENETICS DIAGNOSIS.

Alex. E. Felice

Two procedures are being used in many genetics centers for Pre-Implantation Genetic Diagnosis (PGD). In Embryo Biopsy, a single cell from the 4 - 8 cell blastula is aspirated and tested. This implies a post conceptional diagnosis by which fertilized embryos are selected. Only disease-free ones are transferred for uterine implantation. Thus, it suffers from the same moral, ethical and legal constraints that termination does in this country. The alternate procedure, Polar Body Biopsy, merits closer scrutiny in a community such as ours. The genetic testing by which disease-free oocytes are selected for In Vitro Fertilisation (IVF) is done prior to conception. PGD by Polar Body Biopsy has become a viable alternative for couples at risk of having children effected by hereditary disease but who refuse termination or any post-conceptional manipulation. It also improves the outcome of IVF among women of advanced maternal age. World wide, over 2500 PGD cycles have been conducted in the last decade. Five hundred successful disease-free births have been recorded with an error rate of only 1.8% and the same prevalence of malformations as in the general population.

Of course, PGD by Polar Body Biopsy leads to IVF after selection of disease-free oocytes. However, neither the technology nor the ethics of IVF will be considered in this paper.

Genetic factors account for about one-third to one-half of morbidity and pathogenesis in many disorders. One's health or sickness depends on the interplay of genetics, environment

and life-style choices. In the last few years there has been great progress through molecular biology and genetics to understand physiology, to understand pathology, and to provide powerful diagnostic tools through DNA analysis. We have done extensive studies on a condition known as thalassaemia. It is a hereditary disorder common in Mediterranean and other peoples. In thalassaemia, the production of the red substance in blood cells known as haemoglobin is decreased. The genes and the changes in DNA sequences or 'mutations' responsible for this have been identified, mapped and thoroughly sequenced. The gene defects (mutations) that cause thalassaemia in the Maltese population are well known. A single mutation, so called the beta+;IVS-I,6C in the beta globin gene accounts for over two-thirds of all thalassaemia mutations in Maltese patients. In fact, and as is the case with other genetic disorders, only a small number of DNA mutations cause most cases of thalassaemia among the Maltese as among other populations. For instance, if one looks at the distribution of thalassaemia mutations in the DNA of patients from across the Mediterranean littoral, one finds that as in Malta, in most countries, three or four mutations account for most disease. One can also observe a gradient in the molecular epidemiology with the IVS-I,6C mutation being the commonest one in the west and the IVS-I,110A being the commonest one in the east of the entire Mediterranean basin.

This information, which is concurrently being collected for a variety of genetic diseases is a tool in our hands with which to characterize patients and their relatives. It helps to confirm diagnosis more precisely than other blood tests, to make predictions on the future course of disease or to choose between alternate therapy based on the balance of risks and benefits. DNA analysis helps to identify asymptomatic carriers i.e. healthy heterozygotes and couples at risk in which both parents are heterozygotes. Unfortunately, however, although

we can do extremely well with diagnosis, I think we do extremely poorly when it comes to management or specific treatment of disease. There is, of course, great anticipation that within the next few years, perhaps in five to ten years, that gene therapy techniques finally give us equally powerful tools to do therapy as well as we can do diagnosis. In the meantime, there has been progress in certain diseases such as haemophilia with the production of recombinant products such as coagulation factor VIII to replace those congenitally missing from blood. Correction of certain sequences with specific types of short DNA molecules is making good progress and there is some good progress also with the use of drugs to stimulate foetal or alternative proteins which replace the defective adult proteins in certain diseases. The production of foetal haemoglobin to treat beta thalassaemia is a good example. We have some preliminary satisfying results with this. There is some progress with use of gene transfer in cancer, but in general, gene transfer for hereditary disorders still does not work because safe and effective molecular tools to do it well are not yet available.

Consequently, thus far, the standard of care in genetics has remained that of prevention by counseling or by termination of pregnancy following ante-natal diagnosis. Classically, counseling has been employed to modify the reproductive behaviour of couples at risk if they wished so. On the whole, in most communities, the outcome of this approach has been disappointing. This is the problem that very often confronts us.

It becomes pressing to ask; what are the options available to a couple at risk, i.e. in which both parents are heterozygotes albeit healthy and wanting children ? They are heterozygotes, carriers of a known disease with a mutation which we can identify at the molecular, that is, at the DNA level. Every time they conceive a child together, they run a 25% chance of bearing a homozygote who has inherited both abnormal genes from each parent and is often a sick child.

Up to recently we could offer very little. Even with the best possible use of genomic resources, the best that could be offered was ante-natal diagnosis with or without the option of termination. Knowing what the constraints and thinking in our community are, I will not spend much time on this. However, although often presented together, ante-natal diagnosis and termination of pregnancy are, according to most professional guidelines, actually separate and distinct procedures. It is wrong to assume that one inevitably leads to the other. In fact, quite the opposite is true. At least three-fourths of the time, ante-natal diagnosis saves termination. Furthermore, one has to understand that those couples at risk that have a legitimate access to ante-natal diagnosis and termination end up having a much larger number of healthy babies than those which do not. Admittedly, many couples find termination repelling. They can now turn to alternate procedures such PGD, preferably through Polar Body Biopsy.

The physiological process of female gametogenesis leads to the production of a mature oocyte which is then fertilized by a mature spermatocyte. The precursor oocyte with a normal, diploid, quantity of DNA (2N) first duplicates its DNA (4N). It then goes through two reductive divisions, during which the quantity of the DNA and the number of chromosomes is successively halved and assorted in equal amounts to one or other daughter cells which end up with 1N of DNA each. Only one of the products of these cellular divisions continues down the path of development into a mature oocyte. The others are expelled as polar bodies. The first polar body is the result of the first reduction division, and the second polar body is the result of the second reduction division. In the heterozygous oocyte, with one of the two parental genes being normal and the other one being not, both are first duplicated. Then, the two copies of both the normal and the abnormal genes are assorted to the daughter oocyte or polar bodies. After the first reductive division, the abnormal alleles may be both

distributed to the oocyte or both to the first polar body or one into each. If both copies are detected by DNA gene testing in the first polar body, then one can infer that the primary oocyte has retained only the two normal alleles and one may proceed to IVF with husband's sperm. The outcome of this fertilization may be a healthy foetus with only normal genes or a healthy heterozygote like its parents. It can be seen that, if one knew beforehand the particular DNA mutation in the mother, by testing the first polar body and, ideally from a technical point of view also the second polar body, one can particularly select oocytes with which to proceed. The chances of a couple at risk such as these of having any sick babies practically decreases to zero from the theoretical 25%. They can be rewarded with the joy of a healthy baby in conditions of genetic risk.

Both chromosomal abnormalities such as trisomy 21 and DNA sequence alterations such as those of thalassaemia and many others can be tested with advanced molecular biology techniques. Fluorescent In situ Hybridization (FISH) on chromosomes or DNA sequencing with fully automated methodology are currently available in state of the art facilities. Most major single gene disorders whether autosomal recessive or dominant, mitochondrial disorders, and those due to tri-nucleotide instabilities that result in conditions like Huntington's disease can be done. The only ones that are not suitable to be approached in this way would be the ones that are male-linked. The latter are extremely few and extremely rare.

One technical drawback that has precluded most laboratories working in this field from using exclusively test analysis of the first of the two polar bodies is known as "allele dropout". Only minute quantities of DNA can be obtained from a single cell such as the first polar body. One can imagine that it is possible for only one of the two alleles to be detected and this could result in false negative judgements. The problem can be

overcome by including analyses of the second polar body, which increases the accuracy, and by testing for additional DNA sequences flanking the known mutation.

Having considered the procedures involved, I think that there are two main issues to discuss with respect to PGD. It seems that the procedure, as such, down to the stage of the first polar body, does not raise any moral or ethical dilemma of any great significance. I mean, there is a continuity of life. The two cells, the oocyte and the fertilizing spermatocyte originated in a prior human organism. They are a sort of vehicle in the generation of a new life and subsequently a new human person. If one is ascertained of the stringency or the reliability of the diagnosis based on the DNA of the first polar body, then, in my way of thinking, there ought not be any major issue to consider. However, most workers in this field are not happy stopping at the first polar body. One would like to have the comfort or the assurance of a confirmatory diagnosis from the DNA analysis of the second polar body. This raises a different issue because, unlike other organisms, the second polar body in the human is most commonly produced only after fertilization. This brings up questions about the beginning of a new human life and human personhood. There are various views on the transition of human life to the establishment of a new human person. The main issue with regard to the good conduct of PGD would be to ask and hopefully answer the question "when, during the process that starts with the fertilization of a single oocyte by a single spermatocyte, and ends with the fusion of both parenteral pronuclei with the formation of a new diploid genome does a new human life begin ?"

At what stage can one determine, can one ask, a new human being has begun to exist ?

I think it would be nearly irrational to assume that this can happen ever before one has acquired a new diploid genome. By diploid I mean, the DNA that has been derived from both parents; one half from the mother, and one half from the father. Although there is some evidence that some of the separate DNAs may be active, I think this is trivial. For a period of time after fertilization they are separate, and then they have to come together to form a new diploid genome and conceive a new human being.

The second issue is perhaps less demanding intellectually or philosophically, but there is in PGD a tool with which couples could, if so wanting, design a baby for particular means. Couples may seek offspring with certain tissue markers suitable for the donation of organs in transplantation. Consider a family that has a sick child who needs an organ transplantation for a cure of a condition such as a leukemia or a thalassaemia. Possibly, there is within the concept of Christian sacrifice a legitimate way to reconcile the couple and their sick child with the possibility of deriving curative tissue from a loved "designer baby"

These are not easy questions. One tends to look at them from different perspectives especially when one is closely involved in practice with these problems. These, I think, are the two questions that need reflection with respect to the good conduct of PGD. Otherwise, PGD offers suitable means with which couples at genetic risk can seek to have healthy offspring.

3.
Confidentiality, Privacy and Genetic Testing

Alfred Cuschieri

Introduction

About 25 years ago, when I first began practising clinical genetics in Malta, I wondered why I rarely saw cases of Huntington's disease. It was not because they did not exist or were rare, but because they were not referred for genetic counselling. Psychiatric consultants counselled me that if I wanted to see cases of Huntington's disease, I should visit Mt. Carmel Hospital. At that time Huntington's disease was considered to be a terrible affliction that happened to strike a particular individual, and often the family conveniently overlooked the occurrence of similarly affected relatives. The existing risks were often hidden from children, even when they grew up to be adults and themselves passed on the disease. It was not right to discuss such matters within the family, and much less outside it. This was an example of strict observation of the individual's and the family's privacy. The presence of Huntington's disease in an individual was highly confidential information and was frequently camouflaged by the presence of pulmonary, cardiac, or malignant diseases, which were often quoted as the causes of death.

This extreme picture of confidentiality and privacy has changed dramatically as people became more knowledgeable about health, and hereditary diseases, about genetic testing, prevention of genetic disease, gene therapy, the human genome project, assisted fertilization and cloning. Genetic testing is now being increasingly employed for diagnostic purposes in a wide variety of conditions ranging from

congenital defects in babies to adult onset neurological disorders. It is used for pre-natal and pre-implantation diagnosis, pre-symptomatic diagnoses in persons at risk, for identification of asymptomatic gene carriers, and for prediction of susceptibility to certain diseases such as breast, lung, and colon cancers cardiovascular accidents and other common diseases. Genetic testing is, in a way, different from other medical laboratory tests because it has profound consequences regarding present and future health and longevity, far-reaching social effects regarding marriage and offspring, and most importantly broad implications relating to whole families rather than to individuals [1]

Many people are willing to have genetic tests to provide information about their health status, although they might not fully understand the profound implications of the test results until these are explained to them. The people who want to know are not only the individuals affected by a disease condition, but also their relatives their sons and daughters, the fiancées of engaged offspring, uncles, aunts and cousins and even totally extraneous persons or bodies, such as insurance companies and employers. Depending, of course, on the circumstances of particular cases such individuals may claim that they have a legitimate right to information that directly or indirectly relates to them. The ethical problems regarding confidentiality and privacy are to decide whom to include within the limits of confidentiality and under what circumstances they to be included. The relatives of an individual who tested positive for a genetic condition not only claim that they have a right to know of any results that could affect them but they themselves become entitled to their own privacy and to the confidentiality of their own test results.

Confidentiality of patient records

Emphasis is now being placed on the inclusion of every detail of investigation and therapy in a person's medical history. It is unethical not to record the results of clinical examination, of clinical laboratory, radiological or other investigations and of surgical interventions. Medical records should include all information about a patient including genetic results, as these could be important in the care of the patient and of other family members in the future (2). However, it has also been argued that certain genetic test results should be excluded from the patient records by virtue of their delicate nature and their far-reaching implications relating both to the persons involved and to their families. Persons who had certain genetics tests performed on them have also expressed fears about the confidentiality of their results. Do such fears on the confidentiality of sensitive issue being included in the medical records imply that the confidentiality of these records is not in fact being adequately safeguarded? The ethical issue of safeguarding the confidentiality of patient records needs to be carefully assessed. The currently prevailing attitudes of all those involved in safeguarding this confidentiality need to be evaluated and certainly will have to change. There appear to be several serious misconceptions regarding confidentiality of patients' records. Confidentiality means that the information belongs to a particular individual and is available only to authorized person. However, this may not be the prevalent concept of confidentiality. It is enough to look at the cover of patients' medical records of the Health Service in Malta that warns in bold letters "CONFIDENTIAL: NOT TO BE HANDLED BY THE PATIENT". Does this mean that everyone else, except the patient, is entitled to see the records?

Although genetic testing is sometimes considered to raise special ethical issues regarding confidentiality and privacy, these are not really different from other confidentiality issues

in medical practice. The general principle that the patients' confidentiality and privacy are to be respected applies also to the results of genetic testing. The criteria regulating disclosure of the results of genetic testing is not much different from disclosure of other forms of medical information. Genetic information is certainly a new concept arising from a new science but it raises the same old dilemmas regarding disclosure of information, value of the information, and who owns the information (3)

Ownership of genetic information.

There can be no doubt that the results of genetic tests belong to the individual tested. Individuals have the right to control the use of all medical information about themselves, including genetic information (4). The individual, or his or her legal guardian in the case of children, have a right to determine to whom that information is passed on. This might seem clear enough but problems and conflicts do arise. In paternity testing the person paying for the tests might think that he or she has ownership of the test results and may therefore think that he or she has the right to determine whether or not to pass the information to the partner. In fact this is not so. Both partners who have consented to being tested have an inalienable right to know the test results. The father is not free to withhold the information from his partner if she has participated in the testing procedure. It is also unethical for a person to perform paternity genetic tests regarding adolescent sons or daughters without their specific consent, although the alleged father may be the legal guardian of the individuals who are officially considered as minors.

Informed consent

Doctors may feel quite secure that they are authorised to disclose information if they have the consent of the individuals

tested, particularly if this is in writing. If fact, however, one must be aware that having a written consent might convey a false sense of security. It is entirely dependent on whether the individual consenting to the disclosure of the information fully understands the implications of his or her consent. An individual giving consent to a genetic test might not realise the implications of that test to the rest of the family or its implications in taking a medical insurance. This means that consent should be truly informed, that the doctor has explained that revealing the test result might work against his or her own interests, and might result in discrimination by insurance companies or at work by failure to be find employment or to be given a promotion. The doctor has the responsibility to point out these potential consequences even if the doctor might not be involved in the actual passing on of the information at a later stage.

A signature at the bottom of a statement agreeing to a genetic test does not constitute informed consent. It is merely a measure of protection for the doctor and not for the patient whose interests we are in duty bound to observe, if only by virtue of the ancient principles enclosed in the Hippocratic oath. Consent is merely the confirmation that one agrees to have a particular test or other procedure being done. It does not provide any confirmation that the individual understands its possible consequences or dangers. Very often an individual turns up for genetic testing with a particular purpose, perhaps to obtain definitive confirmation of a clinical diagnosis or to qualify for some particular aid or benefit, but does not usually realise that the test might not provide the conclusive information that was desired. An individual who agrees to have a genetic test is unlikely to anticipate the problems that may arise concerning his or her family, but the doctor who is consulted has the responsibility of anticipating the problems that commonly arise and inform the client accordingly. The information that accompanies the consent is a moral

responsibility of the doctor and is an integral part of ensuring the privacy of an individual.

Confidentiality in relation to third parties.

Third parties who may be interested in obtaining information concerning the test results of others may be divided into two broad categories: (a) employers, insurance companies and other agencies; (b) relatives and family members. The reasons for which the two groups require the information is vastly different. In the first it is related mainly to business and profit-making of the third party, while in the second it is a matter of personal health.

Currently, any insurance company or employer has a right to request a genetic test, just as they have a right to request a medical examination. Informed consent is always required. The problem of privacy does not arise provided there has been truly informed consent, and that the test is used solely for the purpose for which the consent was given. The ethical implication of genetic testing for insurance companies and employers is that they may encourage or perpetuate discrimination against individuals, making the issue of confidentiality of genetic information even more important (5,6). It is not the purpose here to question the ethics of insurance agencies in demanding genetic information, on the basis of which an insurance policy may be refused or subjected to a heavier premium. However, I must point out that the danger that discrimination against an individual or even a whole family might sometimes be based on apparent or perceived risks, resulting from unknown significance of a variation from the 'normal' genotype. The relevance and consequences of possible discrimination varies in different countries depending on existing laws and systems and alternative provisions for health care and pensions.

Confidentiality in relation to other family members.

In genetic disorders we are confronted with the situation where the discovery of a genetic condition in one individual has health and social implications for other family members. Do the other family members have a right to know of the risks to their health in order to enable them to undertake preventive or therapeutic measures? Here is a situation where an individual's right to privacy and the right of others to know both weigh heavily, and it is not possible to discard one in favour of the other. Fortunately such situations do not commonly arise. As part of the counselling procedure, affected individuals are told of the importance of volunteering the information to their relatives who might be unaware of the risks facing them. In many cases the individuals comply with the recommendation of informing their relatives, who can then seek medical help. However family feuds unfortunately exist, and sometimes one is faced with the situation where an individual does not want even his sons or daughters to be informed or his own brothers or sisters to know of the genetic risks affecting the whole family. The situation here is a very delicate one, which requires careful assessments of the how great is the risk to the health of the relatives, and how urgent it is to take immediate steps. There is no simple answer to these dilemmas and one has to act very discretely according to the circumstances of each case and adopt a carefully selected strategy to inform relatives of their risks while preserving the confidentiality of the individual tested.

Sometimes, however, the conflict of interest between relatives does not stem from animosities. A person who is at 50% risk of being affected with Huntington's disease may not wish to undertake any pre-symptomatic tests and to prefer to let nature take its course and to worry about the condition only if and when it strikes. This attitude is quite understandable. On the other hand, the person's son or daughter, being of

marriageable age, may wish to know decisively their genetic status prior to marriage. A positive result would imply a positive result also for the parent, and would thus constitute a breach of his privacy. Such a situation can often be resolved by careful and sensitive counselling adopting once again a careful strategy for preserving the privacy of both parties. However a hard core of difficult cases may still persist.

A problem of confidentiality and privacy also crops up when the affected individual cannot, for some reason, pass on the information to his or her relatives, but gives his informed consent and authority to the doctor to convey the risks to the relatives. The confidentiality of the tested person has not been breached but imparting the information to relatives who were previously unaware of the condition may be interpreted as a breach to their privacy. This situation acquires even greater relevance when one considers that in some disorders, notably familial mental retardation, the relatives might be pre-mutation carriers, who are still developing a mutation that has not manifested itself as a clinical disorder, and will not manifest itself in the offspring of the individual but will certainly occur in subsequent generations. It is not a foregone conclusion that unsuspecting individuals may want to know that they are at risk, even if remedial or precautionary measures are available. In some cases the presence of a genetic risk may still be interpreted as a family stigma bearing with it undesired social consequences that an individual would rather live without.

The concept of genetic stigmatisation is still consciously or unconsciously present. Although we may declare ourselves strongly against it, the underlying fear of discrimination lingers in the minds of affected persons and prejudice in the minds of others. The changes brought about by genetic tests and by the whole burst of genetic knowledge necessitates a corresponding shift in pubic education. Fears have been expressed that "privacy as we know it is dead", (7) and that

the combination of scientific breakthroughs, commercialisation of the genome, and ways of dealing with medico-social problems will accelerate the use of genetic data with the result that others may come to know more about an individual than that person knows of herself or himself. However, our genome does not destroy our privacy. Confidentiality and privacy are social issues and it is up to us to preserve and develop the existing ethics of responsibility to care and to extend the existing ethics of privacy to keep pace with the increased knowledge of the Human Genome. (8)

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4.
Is There Anthing Special About Genetic Tests? - Genetic Essentialism And Information

Pierre Mallia

Innovation in medicine almost always creates feelings of moral unease; especially in religiously oriented countries. Evidence to this are technologies such as those of organ transplantation in the 1950s and assisted procreation in the 1970s. Medical Genetics and the investment in the Human Genome Project has created the concern that we may tamper with the very essence of life - our DNA. Whilst on the one hand medicine strives to cure genetic ailments such as Tay Sachs disease, Sickle cell anaemia and Huntington's disease, the prospects of genetics go much further and reach into the realm of enhancement and cloning. Having genetic information at our disposal, can itself affect our very essence by giving us the opportunity to choose who will live or die, and possibly by fostering new eugenic attitudes. But medicine, by its very nature, has always thwarted the natural order. In this light it is appropriate to ask whether there is anything special about genetic tests and whether this follows directly from genetic essentialism.

Genetic Essentialism - a false statement?

Genetic essentialism is the idea that we are our genes, that the nature, or essence, of the human being is in his or her genes.[1] Yet by changing our environment we constantly go against our essential nature. We take folic acid in order to decrease the chance of neural tube defects in babies; we treat all sorts of ailments, including genetic diseases. On a more social level we try to influence our environments by

optimising our chances of survival and competition. We pay money to attend good schools. Parents do their utmost to have the perfect baby. Even contraception is a way of maximising our efforts for those children born into the family. All these environmental factors, let alone the factors over which we have no control, change the outcome which would otherwise result. Thus when it comes to using genetic information to influence the outcome of our babies, some may feel this is a natural responsibility which parents have to carry. Glenn McGee, in his pragmatic analysis of genetics has argued that the attractiveness of genetic intervention is that it allows parents to participate scientifically and systematically in the construction of 'the perfect baby', which all wish to have.[2] He exposes this as a natural extension of parent's efforts to participate in the moulding of their offspring, as is education. He warns, however, of the special complexities of reproductive decisions such as expecting too much from a child who was genetically 'chosen' to have a better brain for education or a better body for sport. Parents may put undue pressure on their offspring to satisfy their chosen genetic traits.

But is there a special nature to genetic tests themselves other than defining the moral boundaries in which they may allow us to traverse. It is in the category of 'predictive' and 'pre-symptomatic' testing that most difficult issues arise.[3] By pre-symptomatic one implies a belief in the certainty of a positive result; something which is not the case for all 'predictive' testing. In predictive testing the risk of the disorder occurring is reduced but not entirely eliminated. This is probably the case for the Breast Cancer genes BRCA1 and BRCA2. Yet the lack of certainty has certainly induced enough fear in many women to seek radical mastectomies.

Are the Ethical Dilemmas raised by Genetic Information new?

This question has been raised by the British Medical Association in their publication on genetics.[4] Many of the ethical dilemmas raised in the genetic sphere are the same as for those raised in other areas of medicine and concern confidentiality and acting in the patient's best interests and to avoid harm. The publication argues however that when applied to genetic technology, the usual imperative of maximising benefit and decreasing harm may be seen from a different angle. Our increasing understanding of how an individual's genes can cause or predispose towards a disorder, *widens the scope of decisions to try to bypass or pre-empt nature by terminating pregnancies or by surgical removal of tissues. Moreover genetic choices are more likely to touch the lives of others.* This is the main ethical concern where genetic technology differs from other areas of medicine. The individual's priorities and autonomous choices may not be the sole determinants for performing the tests. Another member of the family may be denied insurance, because a brother, say, had a genetic test in the past.[5]

But how is genetic 'information' different from other medical information in the eyes of insurance, say? Certainly it would constitute discrimination if not all people were asked to undergo genetic testing. But the problem with having all people undergo testing is that they lose their right *not to know* about medical information. A person who has a brother with Huntington's disease may not feel it in his interest to know about the outcome of his future life.

It has been argued that if genetic essentialism is true, then this implies that there is indeed something special about genetic tests, because they tell us something about our very nature. In order to answer whether there is anything special about the nature of genetic tests we must first, therefore, ask

whether genetic essentialism is in fact true, and secondly, whether this directly implies that genetic tests are special. We can thus formulate the questions as follows:

a. What do we mean by the essence of genetic tests?
b. Is genetic essentialism a contingent truth, a necessary truth or a falsity?
c. Are genetic tests special?
d. Does 'c' depend on 'b'.

Clearly by essence we do not simply mean that DNA is structurally made of nucleic acid molecules. It is the *arrangement* of these molecules into codons which constitutes the *structural reality* of DNA. The essential reality is therefore the information it carries. We can interfere both in the correction of bad mutations and in the inclusion of genes. This choosing indeed interferes with the essential nature of DNA which is to combine randomly as well as by removing a selected amount from the pool of future genes.

Clearly the human individual is not only his or her genetic program. An large number of environmental factors have a role in influencing the outcome of the individual. Whilst the genotype is a specific arrangement of codons, the phenotype it a range of possibilities within which the individual can develop and over which the environment can have a say. To change the limits of the phenotype one needs to change the genotype.

Therefore the problem of essence lies where we want to put our definition: is essence the *range of possibilities* which the environment has on the phenotype, or simply the resultant *status of* the individual, that is one of several outcomes of the phenotype? In other words if my phenotype predisposes me to obesity will my essence in this respect be that of a lean individual if I diet continuously, or that of a lean individual predisposed to growing fat if not careful? It is quite obvious

that the essence of the individual lies not only in what result the environment has had, but in all the range of possible results of different environmental scenarios. This *potentiality-of-being,* so to speak, is in effect the phenotype. It is this phenotype which lasts forever unless in some way the genotype is affected *a priori* (by modification of the germ cells) or *a posteriori* (by modification of the somatic cells). Arguably even these interventions are environmental factors, and the environment continuously effects the genome. Nevertheless it is the genome which ultimately defines the possible phenotypes. In this respect one must conclude that genetic essentialism is true. Moreover one has to conclude that it is thus a natural truth that the genotype affects the phenotype; it is a contingent truth that the environment affects our essence. It can only do so at the whim of the genotype.

We must now ask ourselves whether this makes genetic information special. In other words, is the *predictive* nature of genetic information of relevance to this genetic essentialism? It does not follow that genetic essentialism gives a straightforward claim that genetic information is special. If it does so at all, we must show why.

Let us consider two predictive tests, the Breast Cancer gene and blood cholesterol, a phenotype test. Clearly the distinction is that the latter is only a phenotype *possibility.* A healthy diet with or without medication may bring cholesterol down and thus reduce my risk of heart disease or stroke. Conversely the BRCA result is there to stay. Research may show that the genetic removal of this gene may or may not have an outcome on phenotype - the appearance of the malignancy. Conversely a change in environment (a mastectomy) will practically eliminate the risk of cancer. So both kinds of tests are affected by a possible environmental solution. But the BRCA result tells the woman something of her essence. It tells the woman she has a definite increased statistical risk of developing breast

cancer. Natural environment will not change this; only intervention would. But the same can be said for cholesterol, since this phenotypic manifestation is also dependent on the genotype.
Therefore one cannot say in this respect that there is anything special about the tests. Even for prenatal diagnosis there are non-genetic tests, such as alpha feto-protein, that may induce us to eliminate high risk fetuses. Yet the broad aspect of genetic tests gives us a greater potential for not only eliminating affected fetuses, but also for choosing a priori what individuals we want to survive. This *geneticisation* is the main factor pointing to the special nature of genetic tests.

Geneticisation

The 'Cyprus Paradigm' is a clear example of this.[6] Hoedemakers and ten Have have argued that medical professionals (in Cyprus) do not only consider the burden of a disease on the patient but the future burden of the treatment itself. Paternalism appears in different forms-strategies are used to convey the importance of preventive measures for the prevention of the disease (in this case beta-thalassaemia). This results in social pressures that limits free choice. Responsibility is put on couples as well as on health professionals in reaching their decisions. Quality of life arguments are used to justify remedial actions, such as selective abortion, which became part of general medical practice and acceptable for target groups. This approach was condoned by the World Health Organisation.[7]

Clearly for the large section of the human population who uphold the status of the embryo, this geneticisation plays a crucial role in placing a special status on genetic tests and that this depends on the contingent or natural truth of genetic essentialism.

The 'power' factor

Therefore, the speciality of genetic tests lies in their potential to give us the *power* to choose our offspring. It can extend our medical goals to another 'Race Hygiene'. *But this power is a moral value, rather than a special nature of the test itself.*

There is no way of telling how genetic information used through selective screening of fertilised ova or fetuses will be used. It will invariably involve future generations who were 'made' through such selective processes, and who might in their turn select different traits in their offspring in an effort to avoid those traits which may have rendered their lives a misery.

A significant problem at the root of all this is our comprehension of the status of the embryo. Yet it must be stressed that this is a problem of moral weight on the elimination of 'unfit' potential humans. Of equally significant concern is the pressure which society can put on these selected people and the pressure which these in turn would induce in their offspring. Life would have turned from merely trying to provide your children with a better future and security than you had in your childhood to an induction of, or protection from traits which society has imposed on you, the selected. If giving our children a brighter future means adding to the existent pressure of family size, another pressure of selecting genes, we are removing the liberty in our children to explore their own potentialities. If it can be argued that this does not make genetic information anymore special than other tests, then it could be argued that there is nothing special about genetic information. To pragmatically argue that selecting a child's genetic make-up through information and elimination of other potential children is equivalent to trying to give your child a better education by selecting a better school is being simplistic to say the least. One can only conclude that in today's cultural/scientific ambience, what one does with a test is full of value-laden

choices. It is these choices which render genetic tests special, not their essential nature, nor genetic essentialism.

If, because of the wide-spread use of genetic tests, insurance companies will change the way they work, employers will request tests for safety, and parents will eliminate disabled fetuses and/or choose genetic traits they deem desirable for their offspring, then there is indeed an argument for the special nature of genetic screening and testing.

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5.
LEGAL ISSUES in GENETIC TESTING

Lorraine Schembri Orland

Medical science is advancing rapidly in the field of genetics. Scientists are at the threshold of developing treatments where individual genes may be altered to the benefit or the detriment of the individual. Cloning will allow for a genetic identical twin to be produced.

Information from genetic testing can affect the lives of individuals and of their families. Genetic testing is a complex process and individuals may wish to be tested if:

1. There is a family history of one specific disease
2. They show symptoms of a genetic disorder
3. They are concerned about passing on a genetic problem to their children.

Also, genetic profiles, or "DNA fingerprints" are compiled from the results of DNA testing to identify unique characteristics of an individual. No two individuals (save identical twins) are alike. This information has significant application in the forensic field and in cases involving paternity, and in the identification of victims of disasters and wars.

Moreover, the issue of genetic susceptibility to disease may have implications for employment and insurance. On a fundamental rights level, prenatal diagnosis and screening, if abused, can pose a serious threat to the right to life at inception.

Critical issues, which require legal regulation, include:

- **Privacy** - the rights of the individuals to maintain privacy.
- **Informed consent** - obtaining permission to carry out genetic testing. One must have knowledge of the risks, benefits, effectiveness and alternatives to testing in order to better understand the implications of genetic testing and exercise a choice.
- **Confidentiality** - this concerns the recognition that genetic information is sensitive and should be restricted to those authorised to receive it. Future access to a person's genetic information should also be limited.

The Convention on Bioethics

Existing national laws may regulate these issues relatively to conventional medicine. However, the implications of the new technologies not only on the individual but also on the human species necessitate specific rules.

The Convention on Bioethics and Medicine, 1997, adopted by the Council of Europe, has provisions affecting gene therapy, biotechnological research and cloning. This Convention makes it clear as a basic principle, that the individual is entitled to protection against unlawful interference with the human body, and prohibits the use of all or part of the body for financial gain.

In terms of *Article 1*, States Parties to the Convention are obliged to *protect the dignity and identity of all human beings and guarantee everyone, without discrimination, respect for their integrity and other rights and fundamental freedoms with regard to the application of biology and medicine.* In enunciating this principle, the Convention is entirely in consonance with previously existing Human rights treaties. The Convention covers all medical and biological applications

concerning human beings, including preventive, diagnostic, therapeutic and research applications.

The Convention does, however, also address its concern for the protection, not only of the individual, but also of present and future generations. The individual is thus placed in a social context as constituting part of society and of the human race. Nevertheless, the interests are not equal but are graded to reflect the priority attached to the interests of the individual as opposed to those of science and society alone. With reference to the benefits of biology and medicine to future generations, the Convention makes provisions for the necessary legal guarantees to protect the identity of the human being.

The primacy of the human being is expressed in article 2 of the Convention7. This is subject to certain restrictions, which largely echo *Article 8(2)* of the European Convention on Human Rights. These restrictions are such as are prescribed by law and are *necessary in a democratic society in the interest of public safety, for the prevention of disorder or crime, for the protection of public health or for the protection of the rights and freedoms of others.*

Thus the restriction based on the prevention of disorder would make it possible for the respect of privacy to be restricted by permitting a judicial authority to order a test to be carried out to identify the perpetrator of a crime.

Protection of the rights of others may, for example, justify an order by a judicial authority for a test to be carried out to establish parentage.

The Right To Privacy.

The right to privacy is a fundamental human right enshrined in international human rights Treaties. Each individual shall

be protected from the unlawful invasion by the State of this basic right and from any State act or authority which would undermine his dignity as a human being.

In consonance with the principle of primacy of the individual and the need to protect him from the improper use of scientific developments, the Bioethics Convention provides protection against the unlawful interference with the human body, and prohibits the use of all or part of the body for financial gain. It furthermore restricts the use of genetic testing.

The Convention in *Article 5* provides quite clearly that no intervention may be carried out in the health field without the free and informed consent of the person undergoing it.

Interventions in the field of research or application aimed at modifying the human genome are allowed on two conditions:

a) That the intervention must be undertaken for preventive, therapeutic or diagnostic purposes. Consequently interventions aimed at modifying genetic characteristics not related to disease are prohibited.
b) The aim of the intervention must not be to interfere with the human reproductive cells of a person who has already been born or of that of an unborn child. However it does not rule out interventions which may have unforeseen side effects on the human reproductive cells.

These restrictions are justified in view of the problems related to predictive testing as shall be illustrated further. Predictive testing here is strictly limited to its applicability to the health purposes of the individual. Commercial interests such as those of employers or insurance companies are excluded. Thus genetic testing as part of pre-employment medical examinations are excluded whenever they do not serve a health purpose. However, national law may allow such testing

for the reasons already stated justifying a limitation on the right to privacy of the individual.

With reference to tests which are predictive of genetic diseases, these tests could cover both the detection of the presence of genetic factors for a disease, or a predisposition to genetic disease. Sometimes the predisposition is certain to lead to a disease developing, and sometimes it can only indicate a possibility of the development of disease. In this latter case, early detection would allow for preventive measures such as adapting one's lifestyle or environmental conditions. This process may have advantages, therefore, for the future health of the individual as it would be expected to positively influence one's health. Tests that are predictive of genetic disease would also allow for informed decisions concerning one's offspring.

In this field, the right to know, as well as the right not to know are of particular importance. A complicating factor is that testing generates information not only on the individual concerned, but also on future offspring and on the biologically related family members. The right of privacy therefore involves more than one individual.

An example that can be given is in relation to the Tay-Sachs gene. If two persons carrying this gene marry, then statistically 25% of their children would receive two abnormal Tay-sachs genes which would produce a person afflicted with the disease (as opposed to being a carrier). The privacy of the individual leaves testing and decisions to the ambit of individual choice.

However, it is important to note that the Bioethics Convention prohibits predictive testing for reasons other than health or health-related even with the consent of the person concerned. Consequently, predictive testing in the field of employment or private insurance, for example, which does not have a health

purpose, would imply an infringement of the rights of the individual to privacy. An exception to this could justifiably arise from a work environment which may have deleterious consequences on the individual's health if he/she has a certain genetic predisposition. However, testing would be justified only if there are no reasonable possibilities of improving on working conditions and provided the tests clearly serve the health condition of the individual.

Informed Consent.

I have stated that the right to know as well as the right not to know is of particular importance in this field. Such problems can usually be addressed within the context of the patient-doctor relationship. In particular the patient's right not to know is discussed within the context of predictive testing for serious late-onset diseases for which at present, no treatment is available.

One could argue that what is of little therapeutic value is of no value to the patient either. Yet this paternalistic approach runs counter to recent advocacy of the patient's right to be informed of his/her medical condition.

Of course, there is no right to genetic testing per se. An individual has a right to health care but this would not necessarily imply a right to every diagnostic test not reasonably required for proper care.

It is true, however, that genetic tests are not the only source of information about a patient's condition and standard family medical histories can also shed light on an individual's susceptibility to disease.

Those who favour medical paternalism fear the effects of so-called *toxic knowledge.* For some people, the burden of the

discovery that they are at risk of suffering life-threatening diseases may so depress them that the quality and purpose of their lives would evaporate. However, it is also true to say that this reaction would vary from individual to individual.

There is an alternative to this attitude. The physician can ask patients before testing for one condition, whether they wish to have the information about another condition that will become available from the test. This places the decision within the ambit of the patient's control.

Confidentiality

The issue of the right to know is closely linked with that of confidentiality. Concerns about discrimination in employment or loss of insurance coverage are usually cited among persons refusing to take genetic tests.

Article 17 of the Bioethics Convention as we have seen, only allows genetic testing for health care purposes. The use of genetic testing outside health care, for example, pre-employment medicals, does not fall within this parameter. It is therefore important to distinguish between health-care purposes for the benefit of the individual on the one hand, and third parties' interests, which may be commercial, on the other hand.

As we have also seen, the consent of the individual would not make such tests permissible. Consequently, it would seem that an insurance company is not entitled to subject the conclusion or modification of an insurance policy to the holding of a predictive genetic test. Nor will the company be able to refuse issuing a policy on the basis that the individual applicant has not submitted to a test. Within this context, the insistence of the insurance company would imply a disproportionate infringement on the right of the individual to privacy.

Two cases exist which can be associated to this issue:

In *Katskee v Blue Cross/Blue Shield of Nebraska* the patient was found to have a 50% likelihood of developing breast or ovarian cancer because of her genetic make-up. She had surgery performed to prevent the disease and the insurance carrier denied payment because no cancer was currently present. The Court found that the insurer was responsible for the costs. The decision was based on the probability that the defective gene would cause a problem and in this sense was considered to be an illness.

In another case an insured was denied coverage for medical bills associated with retinal detachment. The insurer based the decision on the fact that the medical problems leading to the detachment constituted a pre-existing condition. In this case the carrier was found responsible because the condition was unknown to all parties at the time the policy was entered into.

It is this concern that knowing of one's susceptibility as a result of predictive testing would automatically void medical insurance policies that is often cited as a basis for refusing to submit to testing. Every genetic abnormality constitutes a pre-existing condition. From an insurer's point of view, a potential insured who tests positive for a particular condition is being insured at a rate not representative of the risk that person holds. Again, standard medical tests and family history generally places insurers in a position to make well-informed decisions about a potential insured person's suitability for coverage.

A case study may illustrate the pitfalls for the individual. An individual, let's call him Frank, a 35-year-old truck driver, fell and hurt his arm and was taken to a local hospital for treatment. He signed routine forms to conduct tests and treatment. As the hospital was also affiliated to the University, the forms

provided for consent for the medical information to be used in ongoing research. Consequently, blood tests included a DNA test. Frank's employer informed the company's insurer of the accident and the latter requested copies of Frank's medical results relating to the accident.

On his release, Frank instructed the hospital clerk to forward all documentation to the insurer. Unknown to him, the genetic screening showed that he was at significantly high risk of developing heart disease.

The upshot of this was that the insurance company, on receiving his medical records, decided that he was too high a risk for the company to continue to insure, thus placing the employer in a position of being unable to provide group coverage. Frank ultimately lost his job.

An interesting sideline to this study was that Frank had also applied for a loan to buy a new house and willingly supplied his medical records to the loan officer. The loan was refused.

In this study, the hospital records did not have a special system to separate the results of the genetic tests from the other medical results. In a sense there was no breach of confidentiality because the patient himself had authorised the transmission of the records to the insurance company. Yet was Frank fully informed of the tests to be carried out on him? Was his consent to testing sufficient to be deemed to cover also genetic testing? Would the hospital be responsible in this case?
Although this case is cited with respect of assessing insurance issues, it does raise difficulties attendant on the matter of informed consent and on confidentiality. An insurer would require full disclosure of any medical knowledge, which would affect the policy at the time of application. Consequently, if genetic testing has been done, the potential insured will have

to disclose the information. Otherwise the policy is void. Thus whilst no company can require genetic testing in order to insure, the applicant is required to disclose a result of a test already performed.

Yet should this matter be left to individual contracting parties? In the Netherlands, for example, federal legislation disallows insurers from requesting or using genetic information for life insurance policies which do not exceed a stipulated value. A number of states in the USA whilst not prohibiting the use of DNA data for underwriting purposes, strictly limit it. By New Jersey statute, for example, health insurers other than life and disability insurers are banned from using the information at all.

In a 1992 report on *Genetic Testing and privacy* the Privacy Commissioner of Canada asserted that Canadians should have *"a reasonable expectation of genetic privacy"*. Access to such private information as a person's genetic make-up makes many uncomfortable, and the use of such data can have far-reaching effects.

The disastrous effects of indiscriminate release of information on the individual's life have been illustrated above. The Bioethics Convention strictly prohibits the communication of test results outside the health field save for the reasons stated in the proviso to article 2 (e.g.for the prevention of disorder or crimes etc). This rationale of this is obvious. It would be more harmful for the individual to refuse to submit to a test about his health for fear of the consequences.

One of the effects that the release of genetic information may cause is discrimination against individuals with less than ideal genetic make up. Certain States have already legislated to preclude discrimination on this basis. In 1992, for example, a New Jersey statute was amended to include "familial status" as a basis for protection from discrimination at the place of work.

The Universal Declaration on the Human Genome and Human Rights

In 1997, the UN approved the Universal Declaration on the Human Genome and Human Rights. Article 6 of the Convention clearly states that "No one shall be subjected to discrimination based on genetic characteristics that is intended to infringe or has the effect of infringing human rights, fundamental freedoms and human dignity."

Discrimination on this basis is unlawful and violates the basic protection and freedoms to which an individual is entitled.

The **Maltese Constitution** in *Article 45* prohibits discrimination on the basis of race, place of origin, political opinions, colour, creed or sex. This definition would not include discrimination based on "genetic characteristics".

These are some of the legal problems encountered in the field of genetic testing. Problems do exist and call for immediate regulation. As in other areas, the law is seriously lacking. Issues of privacy, confidentiality, information, sanctions and compensation cannot be left to analogy but must be specifically addressed.

6.
Ethics, genetic screening, and pharmacogenetics

Ruth Chadwick

Pharmacogenetics

The publication of the human genome project results has increased predictions of a paradigm shift in medicine (Schmidt, 1998), and genetic screening and testing are at the heart of the debate . Over the past few years much work has been done on developing criteria for the implementation of population genetic screening, including the seriousness of the condition screened for; the reliability and predictive power of the test; and the possibilities for effective intervention, or scope for action in the light of a positive result. It has been argued, however, e.g. by John Bell in the *British Medical Journal*, that the "development of drugs along genetic guidelines will be a major force driving the implementation of screening by healthcare providers" (Bell, 1998). The term used to describe the use of genetics to show how variations in patients' DNA may diminish or increase the effects of a drug, or render it harmless, is 'pharmacogenetics'.

There are predictions that pharmacogenetics might lead to a new understanding of disease (Bell, 1998). Whereas common diseases are currently defined by their clinical appearance, it will become possible to subdivide heterogeneous diseases into discrete conditions, in other words, change our perception of what the condition is for which the treatment is sought (Roses, 2000a). As genetic variants are identified that are associated with drug response there is likely to be a move towards widespread testing before prescribing - in fact it may come to be considered unethical not to carry out such tests (Wolf et al, 2000). The type of testing involved, however, is

different from testing for single gene disorders: it will involve testing for single nucleotide polymorphisms (SNPs) and thus the transferability of guidelines developed for other kinds of testing cannot be assumed (Roses, 2000b).

The first criterion frequently referred to in discussions of genetic screening, e.g in the Euroscreen project, is whether the condition sought is an important health problem, or whether it is 'serious' (e.g., Nuffield Council on Bioethics, 1993) . There has been considerable discussion over what counts as serious, but despite the difficulties over a precise definition there is a widespread consensus on particular examples of conditions that are life-threatening, including some of the cancers and the haemoglobinopathies such as thalassaemia.

In the case of screening related to pharmacogenetics, however, the condition sought is susceptibility to drug toxicity - in other words, a manufactured or iatrogenic condition. Does this count as an 'important health problem' or 'serious' condition? It is estimated that adverse drug reactions account for more than 2 million hospitalisations and 100,000 deaths per annum in the United States (quoted in Schmidt, 1998; Stix, 1998). We cannot use these figures, however, to justify any given screening programme, unless what is sought is a predisposition to find all the drugs implicated in these figures toxic. What is envisaged is screening for risk factors for toxicity for particular drugs e.g., women who would be likely to suffer from blood clots from birth control pills; or who would be at risk of adverse side effects from the drug tamoxifen in breast cancer provision or treatment.

The second criterion to be discussed concerns what can be done in the light of a positive result. Where what is sought is a genetic diagnosis of an existing or pre-symptomatic condition, or a prediction of a late onset condition or predisposition, what might be at issue is the availability of

treatment. In the case of pharmacogenomics, however, this criterion again has problematic applicability. What is being tested for is the potential toxicity of the treatment itself, so it is difficult to use availability of treatment as a criterion of screening since the screening is being carried out to establish the extent to which this treatment is an 'available' treatment.

What may be envisaged however is not population wide screening but individual testing. Pharmacogenetics has been said to have the potential to individualise prescribing. This potential for predicting individual susceptibility to responsiveness to drugs has major implications not only for therapy but also for participation in clinical trials and research. As regards **therapy**, one of the principal benefits, it is suggested, is that more genetically informed prescribing will reduce the rates of morbidity and mortality due to iatrogenic disease. It has been estimated that about 1 in 15 hospital admissions is due to adverse drug reactions (cf. Schmidt, 1998; Stix, 1998; Wolf et al,. 2000). Pharmacogenetics could affect a prescribing decision for a given patient in at least three different ways: (1) adjustment of dosage of drug A; (2) a choice between prescribing drug A or drug B; (3) drug A or nothing (where there is no alternative treatment available).

Clinical trials in this area may have features that distinguish them from traditional clinical trials: (1) they are likely to involve storage of DNA samples as responses to drugs are tracked over time; (2) the nature of the risks and benefits to which the participants may be liable are of a different kind, such as the possible (mis)use of genetic information on the one hand; genetically informed prescribing on the other. The potential impact on research, however, has other aspects, including the extent to which it will be possible for clinical trials to become more targeted towards specific groups. These potential developments in therapy and research give rise to questions in bioethics of two kinds: (1) substantive ethical issues (2)

professional ethics (3) challenges to existing ethical frameworks.

Substantive ethical issues

As already indicated, some of the literature on this topic has described developments in pharmacogenetics as facilitating 'personal pills' (Persidis, 1998), the suggestion being that awareness of genetic variation between individuals will facilitate prescribing in accordance with the specific needs of the individual, thus arguably in accordance with a principle that heath care resources should be allocated according to need at the point of delivery. The possibilities of this with regard to monitoring of appropriate dosage as compared with choice of medication need to be considered. The situation where the choice is between drug A and *no* medication gives rise to the ethical problem of (perceived) abandonment. How pharmacogenetics will affect patient perception is important.

A major feature of the debate about the introduction of other genetic screening and testing programmes has been the right to know versus the right not to know question, supported by competing interpretations of concepts such as autonomy and solidarity (cf. Chadwick, Levitt and Shickle, 1997). It has been argued that there might be a right not to know genetic information about, for example, one's future health status. But it might appear that the same considerations would not apply in relation to susceptibility to drug toxicity - surely it could only be beneficial to have information enabling one to avoid the side effects of drugs? A right to know one's genetic status vis-à-vis susceptibility to drug toxicity might be supported by an autonomy-based argument where autonomy is interpreted in terms of self-determination - facilitating the choice of the individual in relation to treatment. In the event of multiplex testing, however, it might be possible to test at the same time for predisposition to a disease and for susceptibility to toxicity

for the standard treatment. Then the question arises as to whether having this information is a benefit or a burden, because this is analogous to the situation where there is no treatment available. In such a case the argument for a right not to know comes into play.

What other reasons might ground a right not to know about susceptibility to drug toxicity? One possibility is a quasi-placebo effect. The knowledge that one has a higher risk of toxicity might in itself increase that risk. Further genetic susceptibility to drug toxicity may have insurance implications in the way that genetic predisposition to health problems might - people who because of their genotype are slow to clear drugs from their bodies, or to convert them to nontoxic form, may be identified as belonging to a higher insurance risk category (Schmidt, 1998).

Connected with this problem is the issue of quality control in a situation where hundreds of thousands of tests are carried out annually. External quality assessment schemes (EQAs) of genetic tests in Europe have demonstrated a low but significant error rate in cystic fibrosis testing (Dequeker et al, 2001) and the number of laboratory tests carried out annually as pharmacogenetic testing comes on stream is set to increase dramatically. Mistakes may arise not only through technical error but also out of clerical error or sample mix-up (Dequeker et al., 2001).

Apart from the possibility of error, there are problems with uncritically accepting that an identification of genetic risk factors will determine or assist in determining the appropriate treatment for a particular patient. Other factors such as food intake, general state of health and age may account for someone's response to a drug (Haseltine, quoted in Stix, 1998; Chadwick and Levitt, 1995); drug efficacy and toxicity may be considered as multifactorial traits that involve some genetic

component(s) in much the same way as complex diseases do. Apart from the issues for individuals, there is the possibility of 'patient stratification', whereby patients could be classified according to genetic risk factors, as they are presently classified by other risk factors such as high blood pressure (Chadwick, 1999; Wolf et al., 2000). The possible implications for particular population groups should be considered, in the light of possible differences between ethnic groups as regards, for example, slow or rapid rate of metabolising a drug.

Thus patient stratification could have discriminatory implications. The Council on Ethical and Judicial Affairs of the American Medical Association in an article on 'Multiplex genetic testing' in the *Hastings Center Report* (1998) argued that "ethnic heritage may contribute to particular concerns, it is clinically relevant and should be considered. Offering multiplex tests that are bundled according to race or ethnicity, however, serves to categorise patients rather than to address their distinct needs...The profession can ill afford the perception that science is being used to bring attention to the genetic flaws present in lines of inheritance" (Council for Ethical and Judicial Affairs, 1998). One possibility is that genetic susceptibility might be correlated with some other characteristic such as ethnicity, leading in effect to a presumption of effective treatment for that condition for that particular group although there might be considerable variation within the group. Indeed, there is some support for the view that the significance of ethnic variation in drug response might have been overstated (Hodgson and Marshall, 1998).

In clinical trials, the extent to which research in pharmacogenetics raises ethical questions that are distinctive needs to be addressed, e.g. the implications for informed consent, feedback of information, privacy issues. Allen Roses, addressing the annual Human Genome Meeting in 2001, argued that there is a lesser privacy issue in pharmacogenetics

than in testing for predispositions to disease . What interests need to be protected for research participants in this field, and how, needs to be examined.

Professional ethics

Questions for professional ethics arise when considering how pharmacogenetics will affect health care delivery. Different modes of delivery will raise different ethical questions, and countries may differ in how they integrate pharmacogenetics into health care. If genetic testing becomes a standard accompaniment of prescribing, there are questions about how this will be carried out. If doctors carry out pharmacogenetic testing at the time of prescription then this will affect the doctor-patient relationship. On the other hand, what may be envisaged is that there will be a central database, containing patient genotype information, which will be accessed at the time of prescription. If the latter is the case then quality control issues, mentioned above, become particularly important to prevent errors being perpetuated over time. The person who accesses this database, however, need not be the doctor - it may be, for example, the pharmacist. There may be an expanding role here for pharmacists, if for example doctors *prescribe* generically and pharmacists *dispense* according to genotype. There is a need however to think through the ethical implications for doctors and pharmacists arising out of these possible changes to their roles. The last scenario may be more appropriate in certain applications of pharmacogenetics e.g., when the choice is between drug A and drug B. There will also be a need for education and training in the ethical implications. What form this training should take will depend on how the ethical issues should be addressed.

Challenges to existing ethical frameworks

In addition to the implications for practice it is important to consider ethical frameworks themselves. Developments in technology have the potential to change the way we look at things and to challenge the boundaries of our concepts. In the case of pharmacogenetics, the implications for concepts of disease have already been mentioned, but the impact is wider than that: the ethical frameworks we use sometimes need to be revised. It cannot be assumed that principles of bioethics are immune to revision. Developments in genetics have led to rethinking, for example, of the meaning of autonomy, the extent and limits of the duty of confidentiality, the right to know and the right not to know. There is a growing body of opinion that it is not sufficient to continue with the traditional principles of biomedical ethics and simply seek to apply them in the new context and there is specific concern about the transferability of existing guidelines to pharmacogenetics: "It is ...incumbent that medical guidelines for mendelian- or susceptibility-gene testing do not extend automatically to discussions of other types of genetically based profiles in pharmacogenetics. Clear language and differentiation of respective ethical, legal and societal issues are required..." (Roses, 2000b).

Discussions of historical precedents in medicine, genetic screening and counselling may nevertheless be instructive: it has been recognised that ever larger amounts of information may be a burden rather than autonomy-enhancing. In her address to the American Association for Bioethics and Humanities in 1999, Onora O'Neill made a similar point: that in the context of the vast amount of information and storage issues, we need to think again about what it means to respect people and protect them, and that bioethics needs to become more political, with individualistic conceptions of informed consent, taken by themselves, perhaps becoming obsolete (cf also Chadwick, 2001). If this were the case, then there

would be clear implications not only for ethical thinking but also practice, and for the medical ethics curricula that are being developed in European countries. To date the philosophical, ethical and legal implications have not been assessed in detail and there is a large agenda to address in terms of the potential paradigm shifts and policy implications.

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7.
When Care does not Cure
Ethical issues in Neonatology & Paediatrics

S.P. Attard Montalto

Introduction

Fortunately, most childhood illness is curable without any lasting sequelae. Indeed, death in childhood is an unlikely event in 2001. Although approximately 10% of all newborns in Malta and Gozo require intensive care, less than 10% of these will succumb. About 8% of these early deaths are due to extreme prematurity (i.e. before 28 completed weeks of gestation), with a smaller percentage due to congenital anomalies and infection. Less than 1% of older children do not survive and most of these deaths are due to childhood cancer and accidental injury. In children, death is usually not a totally unexpected event but can be anticipated after a short or long term illness. For these, a point is reached when cure is no longer possible and cure is replaced by palliative care.

The transition from cure to care can be difficult and ethical dilemmas are not uncommon at this stage. Indeed, many of the decisions that need to be addressed are complex, and many issues relating to the dying child rarely provide a simple answer. These invariably have a significant impact on the child as an individual, his/her family and friends, as well as society at large. If this transition is to be appropriate and acceptable, a code of practice based on sound ethical values is essential.

When does care not cure?

Palliative care replaces curative care in children with different underlying conditions. In the newborn period, these often include infants where viability is not an option e.g. extreme prematurity (below 24 weeks gestation), and those with severe genetic or congenital anomalies. In older children, cure may not be possible due to the severity of their illness (e.g. overwhelming sepsis), in those where there has been a failure to respond to potentially curative therapy (e.g. relapsed cancer), and in situations where no effective therapy is yet available (e.g. certain inborn errors of metabolism). Hopefully, as medical and surgical intervention improves, many of these conditions will become 'salvageable' in the future but, until such time, every effort should be made to provide comprehensive care and effective on-going support for these children.

When to opt for care and not cure?

This difficult milestone requires a multidisciplinary decision involving the patient, whenever possible, the family, relatives, friends and the entire team of carers. Stopping curative therapy will depend on medical considerations such as patient viability, futility of further aggressive therapy, and the exhaustion of all reasonable, potentially curative options. The patient must be 'ready' for the transition (with appropriate, sensitive discussion in the older child). The importance of family preparedness and, especially, acceptance of palliation versus cure cannot be stressed enough and requires frank discussion, often over several hours. Finally, but equally important, the acceptance of carers must never be overlooked and the personal view of each individual should be actively explored. Ultimately, a unified team decision by all involved will avoid painful conflict which can only add to the distress of the child and his/her family.

Medical ethics which apply to palliative care in children

The transition to care but not cure in critically ill children does not involve a special set of medical ethics. Indeed, the appropriate application of basic principles provides the platform on which difficult issues can be discussed and ethically-acceptable decisions taken. Hence, carers should strive toward beneficience (essentially 'do good', or in this context, what is in the patient's best interest) whilst respecting the patient's autonomy within the confines of his/her competence. They should respect confidentiality, avoid being paternalistic, anticipate and avert conflict. All issues should be aired realistically, honestly and sympathetically, with due consideration for the patient's/family's views, beliefs and wishes. If medical decisions are to be ethically acceptable, they should be based on the following simple criteria:

omniscience	- *decisions based on all the facts*
omnipercipience	- *decisions based on all points of view*
disinterest	- *decisions taken without any bias*
dispassion	- *decisions with no emotional overtones*
consistency	- *decisions reproducible from one patient to another*

Other considerations

Although the foregoing ethical guidelines would constitute the ideal, in practice, the decision making process is rarely straightforward. Often an accurate prediction of outcome (and time-scales) may be difficult in critically ill children, especially in the light of unexpected 'cures', albeit anecdotal. Prolongation of life through palliative care raises the issue of quality of life, invariably an extremely subjective issue dependent on a plethora of factors including personality, inherent expectations (realistic or otherwise), cultural background, religious beliefs and pressure from third parties.

The caring team have a primary duty to maintain the quality of life of, firstly, the child and, secondly, that of his/her family. In addition, they must portray an honest assessment of the medical condition with realistic goals and argue toward the reasonableness, or otherwise, of continuing support. In the real world with monetary/resource constraints, this cannot be done without taking account of healthcare resources. Clearly the concept of healthcare 'rationing', although ethically acceptable, is a very difficult issue in the context of the terminally ill child.

Indeed, all these decisions are made doubly difficult in children, most of whom are too young to grasp the complex issues involved. Many cannot participate in the decision process and depend on third parties, usually their immediate family members. In the vast majority of cases, the family correctly decides what is right for their child and for them as a family. At this stage the role of the caring team is essentially to support and facilitate their decisions. Rarely family members may, knowingly or unwittingly, hold strong views which may be biased by their own fears/beliefs and may not be in their child's interest. At this point the caring professionals may be required to gently redress any misguided views to ensure that the child is not put through any unnecessary suffering. Once a decision for palliative and not curative care is taken, the unified focus should be toward support, quality and not quantity of life and, ultimately, the child's right to die with dignity.

Children and dying

Toward the later stages of palliative care respect must be shown for the wishes of the patient, the family and carers in the light of their background, culture and creed. Throughout the dying process, great attention must be paid to the child and his family's needs, both physical and emotional. Whenever possible, decisions relating to "Where to die?", "With

whom?" and "How?" should be discussed and planned with the family. What may be the ideal for one child/family may be abhorrent for another. Every effort should be made to enroll all support services (e.g. Hospice movement, social workers, friends, etc) in order to fulfill the child's and the family's wishes. Certainly in the majority of expected deaths (e.g. cancer relapse) this is eminently feasible, but it is extremely difficult with sudden, unexpected death (e.g. post-accidental).

The fact that each child will die only once and that this is invariably a major event for loved ones should form the basis for a *modus operandi* which strives to ensure that death is as 'acceptable' as possible. A concerted drive to respect the patient's and family's wishes, to ensure 'quality time', and 'humanise' the dying process can help enormously in allowing loved ones to 'let go with resigned acceptance'. In this regard, the spiritual needs of the family must be taken into consideration, whatever their creed, and a conscious effort made to ask the family if they would like the appropriate religious counsellor to attend. Finally, it is entirely appropriate to decide, together with the family, against active resuscitation and the initiation of further extraordinary (but futile) measures. Indeed, there is little to compare death after a frantic resuscitative attempt without family or friends, with the peaceful death of a child in his/her mother's arms quietly surrounded by loved ones.

Conclusion

For critically ill children, cure should not be pursued at all costs and there may come a time when cure is impossible and palliative care is in the child's best interest. Certainly, appropriate supportive care should continue at all times and must include the child's family and friends. Acceptance of death is very important, particularly for the child's family, and can only be achieved after sympathetic, often prolonged and

repeated discussion, with loved ones. Palliation should provide 'quality time' for both family and their dying child and, ultimately, strive for one overriding goal: namely, to ensure death with dignity.

8.
Fear of Death: Patients' perceptions of spiritual care during the acute phase of myocardial infarction.

Donia Baldacchino

Abstract

The recovery time from myocardial infarction (MI) to the return to normal life is one of uncertainty and emotional turmoil for the patient and the relatives. Thus, patients facing acute MI, a sudden onset of life-threatening illness, tend to experience anxiety and depression due to fear of sudden death. This sudden onset may serve as a spiritual encounter to the patients whereby patients may reflect on their life, evaluating their rank of priorities in life. Additionally the patients may turn to spirituality as a coping mechanism.

Levels of anxiety and depression can be reduced by effective coping skills such as positiveness towards life, including the use of spiritual coping strategies. The essence of spiritual care is *being* as opposed to *doing* (Piles 1990, Ross 1997, Turner 1996, Widerquist 1991). Thus the role of the nurse and the multidisciplinary team is to help the patient find meaning and purpose in life and have a positive outlook to life.

The aim of this paper is to describe the experience of fear of death of a sample of 53 patients with first acute MI, together with their perceptions of the role of the nurse in the delivery of spiritual care. Recommendations to the nursing practice, hospital management, education and further research are included.

Aims

The aim of this paper is twofold,:

a) to present the findings on patients' perceptions of spiritual care after experiencing the acute phase of their first myocardial infarction, a life threatening illness.
b) to identify any differences in patients' perceptions on spiritual care in terms of their characteristics and levels of anxiety.

Rationale for this research study

My interest in spiritual care was promoted by my clinical experience, as a staff nurse working in ITU in St. Luke's Hospital in 1980's and in several hospitals in UK. While I used to consider the patients' future to be distorted because of his/her chronic illness following the sudden onset of an acute illness such as myocardial infarction or neurological disorder, I was often impressed by the patients' strong will to live, accompanied by a positive outlook to their future.

Very often patients used to transcend their difficulties and reach a higher power, such as having faith in the medical profession or in God, hoping that things will get better. On reflection, I must admit that at times, I was not in tune with the patients' perceptions of their recovery from their illness. Hence, my nursing care might have overlooked the outcome of the spiritual dimension of the patients' coping mechanism.

Consequently, following a personal consultation with two foreign nurse researchers, Prof. Philip Burnard and Dr. Linda Ross in 1998, I decided to explore the spiritual dimension in nursing care. Thus, I took Dr. Linda Ross research question, generated from her study, to explore patients' perceptions of spiritual care as part of a longitudinal research study.

Anxiety and Fear of Death During the Acute Phase of MI

Research suggests that anxiety tends to be common among survivors of myocardial infarction (Conn et al 1991, Thompson et al 1995). This is because patients may perceive their MI as a source of stress beyond their control due to the possibility of another attack and impending death (Webb and Riggin 1994, Lidell et al 1997, Rose et al 1994).

An example is given by a 44 year old male patient with MI, stating,

Waqt l-uġiegħ, ma kontx naf li hu attakk tal-qalb, għax jien, fl-eta' żgħira ta' 44 sena, żgur li qatt m'għaddhieli minn moħħi li kellu jtini attakk tal-qalb. Dak il-ħin bżajt ħafna, għax qas stajt nifhem x'kien dak l-uġiegħ. Ħsibtni se mmut bl-uġiegħ, għax dak tagħfis ġo sidri..... u uġiegħ f'idejja, u sirt għarqan xraba. Dak il-ħin, ħsibtni se mmut u bdejt naħseb fit-tfal li nħalli warajja u l-mara li tant inħobb u hi tirrispettani ħafna. Ha ngħidlek ta', imurlek il-qżież kollu li jkollok u malajr tisserja, issib il-mewt ma' wiċċek! (M21)

Moreover, the question of meaning arises in acute sudden illness, when the individual may go through a period of reappraisal and re-evaluation of one's life (McSherry 1996, Burnard 1988). Thus myocardial infarction could force the individual to undertake life review, find meaning and make sense of one's illness and hoping for the future.

Furthermore, in times of crisis such as illness, individuals tend to turn to spirituality (Belcher et al 1989, O'Brien 1982, Reed 1986, 1987). This is supported by the statement from a 57 year old male patient who came to retire in Malta following 40 years abroad.

X'ħin wasalt l-isptar, tatni rasi.... Il-kamra imtliet bit-tobba u n-nurses.... Qalbi għamlet tikk.... Tgħidx kemm bżajt,..... Se mmut, se mmut! Għidt bejni u bejn ruħi! F'ħakka t'għajn, ħajti ġiet quddiem għajnejja....Ħeq, jiena kont fil-business... kien għad kelli unfinished business.....

U, ara kemm għamlu miegħi n-nurses! Imma jien, dak il-ħin l-aktar li kelli bżonn kien li nqerr..... xtaqt inserraħ qalbi.... Lanqas fis-CCU ma stajt nagħmel dan, għax kont f'kamra ta' bi tnejn. Imbagħad kif qomt fuq saqajja stajt inqerr, u għidt għall-erwieħ! It's a pity li m'hawnx fejn titkellem naqra b'mod personali ġo dan l-isptar! (M14-57 years)

Consequently, literature proposes that illness and hospitalisation may be a source of spiritual encounter to the patient. Thus, since nurses are present day and night with the patients, they are in a position to safeguard the wholeness and integrity of the patient (Forbis 1988, Granstrom 1985, Ross 1997).

Defintion of Spirituality

Spirituality is derived from the Latin word spiritus, spirit, the essential part of the person (Piles 1990) which "controls the mind and the mind controls the body" (Neuman 1995:48). Therefore it infers that spirituality is the vital life force which unifies all aspects of the human being (Reed 1992, Burkhardt 1989, Golberg 1998). Thus it denotes that spirituality encompasses the physical, psychological and social components (Neuman 1995, Colburn 1990, Henderson 1967)

Stoll(1989) summarises the definition of spirituality as 'my being, my inner person. It is one expressed through my body, my thinking, my feelings, my judgements and creativity. Through my spirituality, I give and receive love, I respond to and appreciate God, other people, a sunset, a symphony and spring' (p:6).

Literature suggests that a person who is in tune with this vital unifying force of the spiritual dimension, a more balanced state of physical, mental and social well-being will result. This is because spirituality helps the person to strive for meaning and purpose in life (Orley 1994, Brooke 1987, O'Brien 1982).

Unfortunately, literature has misinterpreted spirituality as being synonymous with religiosity. However, spirituality is broader than religion (Cawley 1997, Nagai-Jacobson and Burkhardt 1989, Burnard 1988). Therefore Narayanasamy (1991) argues that spirituality goes beyond religious affiliation as it strives for inspirations, meaning and purpose in life, even in those who do not believe in any god. Hence, Baldacchino and Draper (2001) assert that spirituality applies to both believers and non-believers, including the presence of different cultural and religious beliefs.

Definition Of Spiritual Care

Spiritual care is defined in the literature, as recognising, respecting, meeting patients' spiritual needs, facilitating participation in religious ritual, communicating by listening and talking with clients, being with the patient by caring, supporting, showing empathy, promoting a sense of well-being and referring to others and clergy (Ross 1997, Piles 1991,Taylor et al 1994) .

Therefore, the essence of spiritual care is *being* as opposed to *doing* (Piles 1990, Ross 1997, Turner 1996, Widerquist 1991). Therefore, the nurse's availability and actual presence to the patient, may help him/her to find meaning and purpose in life situations, by religious and/or non-religious means. Thus, Govier (2000) proposes that nursing care should address the human spirit, both within and outside the context of religion.

Furthermore literature argues that it is not merely the delivery of care which matters, but it includes the heart and the spirit by which holistic care is given (Piles 1990, Younger 1995, Bradshaw 1994, McSherry 2000).

Consequently, the nurse's role in the delivery of spiritual care is prescribed by the International Council of Nurses (ICN-1973) reinforcing the responsibility of the nurse to promote "an environment in which the values, customs and spiritual beliefs of the individual are respected". This is supported by the Maltese code of Ethics for nurses and midwives (1997:3) stating that the nurse is to "recognise and respect the uniqueness of every patient/client's biological, psychological, social and spiritual status and needs".

Research Design And Methodology

This research is part of a longitudinal study conducted in the main local general hospital between January and March 2000. A systematic sample of 70 patients was recruited on alternate basis, aged 40 years and over, capable of participating in an interview and self-administered questionnaires. 53 patients participated, thus having a response rate of 76%.

The three instruments used are as follows,

1. *The Hospital Anxiety and Depression (HAD) Scale*, an established tool developed in U.K. by (Zigmond and Snaith 1983).
   Test retest on a cohort group of student nurses, revealed a Cronbach alpha coefficient of 0.89, thus showing a high internal consistency of the translated tool.

2. *The Nurse's role in spiritual care (N.R.S.C.) questionnaire*
   The N.R.S.C. questionnaire was developed for this study, based on the nursing and social sciences literature and

validated by a panel of ten experts consisting of 5 foreign nurse researchers on spirituality; two English hospital chaplains and two Maltese hospital chaplains and a Theologian.

3. *The Likert form N.R.S.C. questionnaire* consists of 25 statements with 5 categories ranging from *strongly agree* to *strongly disagree.* Test retest statistical analysis of the bilingual version, on a cohort group of nursing students, revealed a Cronbach alpha coefficient of 0.82 which shows an acceptable internal consistency of the tool.

Factor analysis of the N.R.S.C. questionnaire revealed three factors:

Factor 1 : Facilitation of spiritual coping methods.
e.g. Enable patient to find meaning and purpose in illness.
Facilitate private/group prayers on the ward.

Factor 2 : Promotion of interpersonal relationships, self-transcendence and achievement of life goals.
e.g. Assess patient's relationship with relatives and friends.
Evaluate the effect of illness on the patient relationship with God/others during hospitalisation.

Factor 3 : Enhancing nurse-patient communication and relief of spiritual distress.
e.g. Spend quality time with the patient to give support and instil hope in illness.
Allow time for the patient to discuss his/her concerns and worries.

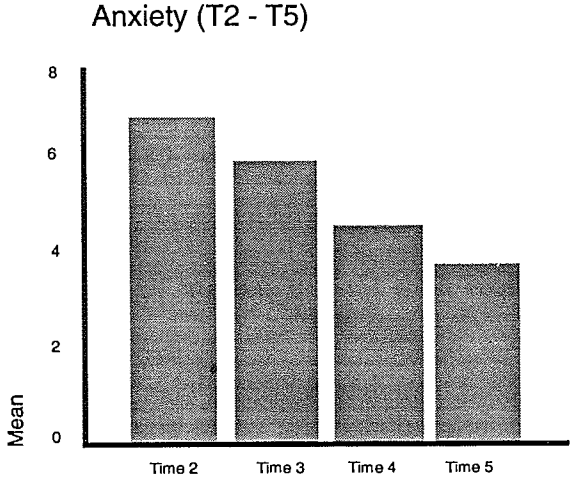
A semi-structured interview schedule was used to elicit the patients' experience during the acute stage of myocardial infarction.

Ethical Considerations

Permissions were granted by the Director of the Institute of Health Care to include the groups of students for test-retest statistical analysis of the instruments. The Chairperson of the Medical Services approved the recruitment of a sample of patients. A written informed consent was obtained from the sample of patients. Since this study is part of a longitudinal study, where data collection was done five times, confidentiality was ensured by the use of coding system to decrease the possibility of identification of patients. Finally, every precaution was attempted to maintain participants' privacy and protect the patients from any physical or psychological harm or discomfort.

Findings

The findings are presented in total, that is how the patients responded to the overall statements, in each of the three individual factors and in specific statements which were found significantly different.



This bar chart shows the highest level of anxiety on transfer to the medical ward (Time 2). However, had this been measured on admission to hospital, the anxiety levels could have been higher as indicated by the quotes which hinted at their frightening experience of impending death.

All patients agreed with the statement, helping patient to see the positive side of his/her life. However, although not significant, it is worth noting that patients with normal level of anxiety scored higher (X=4.74, SD=.45) than those with moderate anxiety level (X=4.30, SD=.48). It appears that the patients may have felt the need for help from other members of the health care team such as the psychologist, clergy or other members of the health care team.
Furthermore, there was agreement by all patients in their overall perceptions of the three factors of spiritual care. Only the variable past history of angina produced a significant difference.

All the three factors were rated lower by those with a past history of angina. This may indicate that the patients with past history of angina, were scared to death by this bitter experience of MI. Since the majority of patients used to smoke, and some had not been compliant with treatment, such as antihypertensive treatment, the patients' guilt feelings may have interfered with the ability of the nurse to help them come to terms with the situation and encourage them to look positively to their future. Additionally, some ethical problems, such as lack of privacy in interactions between patients and nurses or other members of the health care team, may have inhibited a positive response. This is clearly seen by a 54 year old male patient stating,

Jiena ħadt pjaċir ħafna, ngħid għalija li qaluli li se ninżel mis-CCU għal hawn, ġos-sala tal-mediċina. Fejn kont qabel, kien hemm lack of privacy tremenda. Dan minhabba ċ-ċokon ta' l-ambjent! Jiena

ħassejtu jumiljani wisq il-professur, meta quddiem żewġ pazjenti oħra, li kienu fl-istess unit miegħi, ċanfarni, jgħajjat miegħi kemm jiflaħ, għaliex erġajt qbadt inpejjep 20 kuljum. Veru li t-tort tiegħi, imma.....(crying) (M62).

One is to note that this patient died the day after the interview, due to a severe complication of MI.

No significant differences were detected between the responses of different age-groups, which ranged from 40 years to 89 years, although the literature suggests that younger patients tend to be less spiritual.This supports the literature stating that during times of distress, the person may turn to spirituality as a means of coping.

Moreover, all patients agreed with statement Facilitate attendance to the hospital chapel/quiet reflection room. However, the females' scores were higher than the males, implying that the females, more than males, may find refuge in reflection time. According to the literature, this may be because the females tend to be more religious in their everyday life. It appears that reflection may help the patient to connect with the inner self, acknowledging one' potentials to overcome the obstacles of illness. Additionally, this quiet time may help them transcend to God, their resource of help and security in life. However problems arise, as described by a 67 year old female patient stating,

Kemm domt l-isptar ma kienx possibbli li mmur il-kappella għax kienet naqra 'l bogħod. Ara kieku kien hawn naqra ta' quiet room biex forsi, wieħed ikun irid jinġabar ftit fit-talb, kieku kont nistaħja. Kieku dil-kamra tkun tista' sservi bħala kamra fejn bniedem ikun irid iqerrr, jew ikellem il-patri. Għax kun af, x'jaf min ma ġarrabx! Tara l-mewt ma wiċċek, mhux ċajta, binti. Għal dawn l-affarijiet m'hawn xejn privatezza, ħlief għal dawk il-pazjenti li jinzertaw f' single room. (PF6)

Consequently this finding reinforces the need for privacy in hospital and the need for a quiet room to be introduced in each floor of the new hospital as is being currently introduced in foreign hospitals, such as Leeds State General Hospital in the United Kingdom.

Finally, the response to "Who do you think should be responsible for providing spiritual care? It was found that the majority of patients pointed out that spiritual care is not only the nurse's role but the role of all the members of the multidisciplinary team, that is nurses, multidisciplinary team, chaplains, patient, patient's family, friends and personal spiritual/religious leader.

Therefore, further research is suggested to explore the role of the health care team to explore their perceptions about spiritual care and to compare their responses with those of the patients. This finding suggests the importance of the caregiver to build therapeutic relationships with the patient through their availability, sensitive handling skills, understanding patients by listening and respecting them and accepting them as they are in their vulnerability during their distress of illness.

Conclusion And Recommendations

1. Since the essence of spiritual care is *being as* opposed to doing (Piles 1990, Carson 1989), it is suggested that nurses commit themselves to reflect on their care as well as increasing their self-awareness to be able to meet patients' spiritual/holistic needs.

2. While considering the complexity of the spiritual dimension in patient's care, the provision of quality time of the nurses and the multidisciplinary team, including the clergy, is recommended. This will help the patient to relieve the

current and future stress of illness enabling him/her to find meaning and purpose in life.

3. The nurse's role is to work in a team to meet patients' spiritual/holistic needs and not simply referring them to the hospital chaplain. To enable optimum holistic care, the curriculum of the nurses and the multidisciplinary team is to include education on spiritual care.

4. Patients' perceptions of the nurse's role in the delivery of spiritual care appears to incorporate the other members of the multidisciplinary team. Thus further research is suggested, amalgamating the quantitative and qualitative research designs, to explore the perceptions of the nurses and the different members of the health care team and compare these findings with those of the patients. This may provide an insight into the nurse's role and the patients' preference for specific interventions of spiritual care.

5. The Management of the new hospital is recommended to reserve a ounselling room in each ward where the patient can confide in privacy. Additionally, a quiet reflection room in each floor by the wards is to be introduced, to provide the patient with an appropriate place for reflection and prayers.

Hopefully, after seeing what the patient had to say, through their experience of such a life-threatening illness of MI, the responsibility now falls on us. As members of the multidisciplinary team, we are to listen to the voice of the patients and try to implement spiritual care in order to help the patient to find meaning and purpose in their life.

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9.
'A gentle, peaceful and easy death' .....Euthanasia or Palliative Care?

Moira Camilleri

On July 29th 1826, Dr. Karl Marx delivered an address on the occasion of his installation as Associate Professor of Medicine at the University of Goettingen. In this address, published later as De Euthanasia Medica, Dr. Karl Marx speaks of euthanasia as that science '*which checks oppressing features of illness, relieves pain, and renders the supreme and inescapable hour a most peaceful one.*'

Dr. Marx's treatise on medical euthanasia is in fact an early nineteenth-century treatise on palliative medicine, capturing in its essentials the dominant contemporary consensus to date about how Palliative Medicine should be practiced. Aside from the advances in palliative medicine available today, as compared with the palliative medical knowledge of a 170 years ago, the major difference between Marx's palliative medicine and Palliative Medicine today centres on the meaning and use of the term euthanasia. Today, euthanasia means exactly what Marx *excluded* from his use of the term, namely, the administration of death to the dying - the hastening or advancing of death.

With every generation since then and before that, people have been thinking, writing and proposing legislation about euthanasia. Arguments from either side have been weighted with moral, religious, ethical, social, human and scientific issues. We too debate euthanasia, propose laws which seek to protect that which is sacred to us; life itself, dignity, control, faith, religion, pulling the favours towards and against its use.

A gentle peaceful easy death.....this is the way Solzhenitsyn describes the dying of older folk in "The Cancer Ward". People did not fight against death. They did not pretend they were not going to die. They prepared themselves quietly and departed easily as if it were just moving into a new house.

The euthanasia we are now debating in the media, in the courts, and in countless publications is linked to the fact that so many people today do not die "as if they were just moving into a new home". People fear they will not be able to die in this gentle easy way. They fear they will have little or no control over their dying. They fear ' a twilight life tethered to feeding tubes or respirators. As they have been doing for over twenty years, people are now still, and with increasing intensity, echoing Montaigne' statement, "*It is dying, not death, that I fear*"

Patients fear the uprooting of their lives by the disease and the dying process. It is the uprooting of one's family life, work, friends and routine, interests, hobbies, mobility, independence. It is the uprooting of the environment in which they have grown up, which they have built, in which they have nurtured a life: the environment in which the photos, 'urniture, objects, bring to life the person's past. It is the environment from which the patient must frequently leave to undergo treatment, investigations, and finally, to die, often tethered to life-prolonging technology.

Patients fear the enslavement within relentless pain and distressing symptoms. They fear what they think Palliative Care has to offer, a release from pain at the cost of their being plunged into a lingering state of semi-consciousness, of being doped with stupor, while all around sit and awa.t one's death. Some find the prospect of this particular type of loss of control to be quite unbearable. Pain may be relieved but the suffering not.

Suffering cannot be predicted, so that those who care for the dying must look for it and learn to recognise it, because patients never complain of it. It may be manifest as anger, depression, sadness, grief, unhappiness, melancholy, rage, withdrawal, yearning. Its other name is anguish. If suffering is to be relieved, one needs an ear to listen a mind to understand and a heart to stand firm. There are no medicines for suffering, there are only people who will support and try to understand.

When the objectives of Palliative Care can be realised, the patient will end his days in comfort, he and his family will be enabled to cope with dying, they will feel secure rather than anxious, they will be assured of competent care which will not be withdrawn, they will be encouraged and enabled to be open with each other, and the family will later be offered support, if need, in their bereavement.

The actual achievement will not always reach those heights, of course, and it will be dishonest and useless to pretend that dying will always be, or could be, made dignified and comfortable.

To minimise, suffering, it is necessary for palliative services to be adequately funded, and for the effectiveness of treatments to be evaluated. However, palliative care will never eliminate all suffering. When a person is socially isolated and alienated, it would be foolish to expect palliative care to work miracles, and so sometimes, the outcome is meagre indeed.

Terminally ill patients experience an array of distressing symptoms despite the provision of palliative care. Patients commonly experience progressive weakness, which causes loss of function, diminished quality of life, and dependence, and there is no effective treatment to increase their strength. We witness people suffering disfigurement, nausea, suffocation, incontinence, pain, psychological distress,

confusion and more. Dying is always sad, often difficult and occasionally overwhelming.

But what do we do when we cannot find a language within which we can suffer these uncertainties together? Patients become depressed from time to time and may ask for release from life, to flee into autonomy, into an act of seemingly ultimate control: the act of ending one's life, of destroying that consciousness within which one senses one's own essential isolation, as well as one's profound dependency. What are we to do? Apart from continuing to provide excellent care, there are no agreed human answers to their problem, as indeed there are no answers to many of life's most difficult challenges.

The demands for rapid, painless death, and the debates these demands provoke, are a signal that we all, at the beginning of this century have entered a very deep crisis about how we understand, experience, and should bear the human condition.

It is not enough just to oppose euthanasia: we have to be able to put forwards better strategies of care, realistic of attainment and respectful of human life. It has been suggested that if doctors communicated well with patients and families, respected patient choice of treatment, knew when not to continue treatment which served no good purpose and was unwanted, and were familiar with the principles of palliative care, there would be little need to discuss euthanasia at all. But would that be the complete answer?

Would universal, good palliative care be enough to meet the call for euthanasia?

Acknowledging that there is a distinction between euthanasia and palliative care is central to the controversy on euthanasia. It may be that this distinction is clinically, ethically, and legally

essential and logically defensible. The defense of this distinctions and their meaning rest upon three points:

1. **the goals and mandates of palliative medicine:**

- to help those, who need not die now, to live as fully as they possibly can;

- to help those who can no longer live, to die on time, not too early not too late.

- To help those who must now die, and who are dying, to die in peace and with dignity.

2. **Doctors do not possess unlimited authority to intervene in the bodies and lives of sick people.**

- Each intervention must be justified through the clinical goals that come to predominate as a disease progresses. When treatments, including chemotherapy and life-sustaining treatments, have been start, as justified by an earlier governing clinical goal, and are now doing more harm than good, the ethically critical question is not, 'are doctors justified in discontinuing the treatment?' but rather, "is there any justification for continuing these treatments?'

- Treatments designed to restore health, function or consciousness become futile as the disease progresses irreversibly and may even be harmful. In these situations, it is correct to speak of allowing a person to die. This differs from euthanasia in intent, in act, and in professional mandate. Even when the doctor is motivated by compassion, the intent of euthanasia is to *cause death immediately*. The intent of discontinuing life-prolonging treatment is to *cease hindering an inevitable process from reaching its timely end.*

- With the act of euthanasia the doctor assumes, however temporarily, a mandate of *total dominion over a human life in extremis.* The act of discontinuing life-sustaining treatments from patients who are in the advanced stages of disease implies that the mandate of doctors over human life is *limited to accompanying and serving a dying patient* with all the scientific and compassionate skills of comforting a life that cannot be saved. *Acceptance or rejection of this limit marks the difference between palliative medicine and euthanasia.*

3. **One of the essential elements of dying with dignity is freedom from pain, and the various kinds of bodily and mental fatigue and distress, that can dominate consciousness and leave free no psychic space for the personally important things people want to think, say and do before they die.**

- Pain separates the dying persons from themselves and from their loved ones: it can drive the dying from coping, control and integration to chaos and hopelessness.

- Patients have a right to request and doctors an obligation of fidelity to the dying to employ, every proportionate means available to relieve suffering and agony provoked by pain and symptom distress. Administering medications in combinations, dosages and frequencies needed to relieve effectively the suffering of the dying is logically, clinically and ethically totally different from the act of administering death. These two acts differ both as to end and as to means. The goal of palliative medicine is emancipation, the freeing of the dying person's consciousness from the domination of pain. The goal of euthanasia is death.

- The distinction between the administration of death, which is what euthanasia is, and the administration of relief from suffering, which is what palliative medicine is, should serve as a directive for law, ethics, medical education and healthcare planning. Doctors must not be barred by any law of the state or by any dictate of morality from freeing the dying, as best their knowledge and skills allow from the agonies of advanced and terminal stages of disease. Patients should never have to beg for relief because doctors' unenlightened fears. It is indeed foolish to deny patients relief from suffering because of unfounded fears and concerns that effective relief of pain will shorten life.

Where competent palliative medicine and care are not available, health care planners should set the organisation and equitable delivery of such care as a top priority of a civilised health care system. To substitute this with pro-euthanasia arguments is, if anything apathetic, ignorant and short-sighted: can we afford these to become premises in an argument favouring the legalisation of the administration of death?

The clinical goal of palliative medicine underlying the discussion of ethical issues encompasses the co-ordination of knowledge, skills, reflection, and compassion to allow us, at the end of our days, to die as Philip Aries outlines:

Death must simply become the discreet but dignified exit of a peaceful person from a helpful society. A death without pain or suffering, and ultimately, without fear.

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10.
The Elderly Patient and Quality of Life Judgements

Anthony Fiorini

Quality of life and the elderly.

How does one define quality of life in the elderly age group? Is it their health status; their functional status; whether they are still living in their own homes; their financial means, whether their favourite football team is winning? Since I have been asked to discuss patients, I'll stick to health.

Health-related quality of life - definitions.

There are definitions on health-related quality of life in the elderly. The ideal, or preferred definition, must reflect the multiple and inter-related dimensions that are characteristic features in health of the elderly. Functional, mental and social aspects commonly complicate the physical problems and all have to, and can, be objectively assessed and measured. At the same time, subjective parameters such as "morale", "self-esteem", "life-satisfaction", "dignity" "autonomy" also need to be addressed. Therefore, the formulation of a definition is not an easy task and threatens to be incomplete.

Also, once health is influenced by health care, quality of life is controlled by the quality of care given. Therefore, any measure of an individual's quality of life must take into consideration that individual's surroundings, i.e. whether the elderly person is living at home, or is in a hospital ward, or resides in a long-stay institution. For example, in a very recent article in the British Medical Journal, it was stated that the dignity and autonomy of older persons were being undermined in health care settings in the United Kingdom (1).

Health-related quality of life - a goal to aim for?

Health care professionals and learned societies agree, and recommend, that health-related quality of life is a goal to aim for.

For example, in 1994, and then in 1996, Roberts et al (2) (3) asked health care workers and managers to rank 14 separate measures in order of importance to reflect their goals and priorities, and hence their performance indicators, in providing care for the elderly. The results obtained indicated that geriatricians, general practitioners, nurse managers, physiotherapy and occupational therapy managers and even general managers all put "improving quality of life" in the number one slot.

Similarly, in 1992, the Royal College of Physicians of London together with the British Geriatrics Society (4), recommended that the assessment of all elderly patients should be standardised and, besides their medical problems, information should be routinely obtained, and documented, on such aspects as functional abilities, cognitive function, the presence of depression and their quality of life.

The Royal College of Physicians of London together with the British Geriatrics Society, also published in 1992 (5), and then again in 1998 (6), documents to "enhance the quality of health care of older people in long-term care that have an obvious link to quality of life". In these documents the College recommended the routine assessment and measurement of twelve key factors amongst which were included such headings as "preserving autonomy", "optimising the environment", "overcoming disability".

Health-related quality of life - assessment instruments.

A good number of assessment instruments now exist to gauge health-related quality of life in the elderly. The publications of the Royal College of Physicians and the British Geriatrics Society have already been mentioned. Besides these there are others and include:

The Comprehensive Assessment and Referral Evaluation (CARE); The Older Americans Research and Service Center Instrument (OARS); The Nottingham Health Profile; The Sickness Impact Profile; The Southampton Self-esteem Scale; The Life Satisfaction Index; The Philadelphia Geriatric Centre Morale Scale; The Bradburn Affect Balance scale; The Rosser Index of Disability and Distress (7); The Medical Outcomes Study SF 36 (8) and so on. All measure a range of parameters. For example the Medical Outcomes Study looks at physical functioning, role functioning, social functioning, mental health, general health perception and bodily pain.

Quality of life measures for specific diseases are also available, for example the Parkinson's Disease Quality of Life Questionnaire (9), which looks at symptoms, social and emotional functioning.

Health-related quality of life - positive attitudes.

Therefore tools are available to judge quality of life. Most are used for research purposes whilst others are recommended for routine everyday use. These quality of life assessments should be viewed as positive tools. They emphasise the fact that being elderly, although associated with the 'twilight years' does not mean 'end of life'. They also emphasis the fact that a lot can be done to improve problems that may effect the elderly. A sample of elderly people attending a Day Hospital in the United Kingdom were asked what they expected from

health care (1). In their replies they gave greatest importance to improving their quality of life and reducing disability.

And it is also relevant at this stage to remember that not treating on the basis of old age alone should be considered unacceptable, dare I say unethical, even as a mechanism to ration resources. For example, in 1992, it was noted that one fifth of coronary care units in the United Kingdom operated an age-related admission policy whilst two fifths operated an age-related thrombolysis policy (10). In other words, older age groups were being denied medical management known, and shown, to be of benefit to them, even life-saving. Such policies are worrying and have to be discarded.

Health-related quality of life - end of life decisions.

There are situations when a decision to withhold or withdraw treatment is the right one and there are guidelines to help reach such decisions.

The statement that "all patients who are competent to consent to life prolonging treatment are also competent to refuse it " (11) is also relevant to the elderly. Their wishes have to be listened to. The statement that "all clinicians must act to enable incompetent patients to flourish as persons to the degree to which they are capable " (11) is also without argument.

On the other hand there are situations where stopping or withholding treatment in incompetent elderly patients is acceptable and justified. Such situations include (11):

1. Imminent and irreversible closeness to death.
2. Extensive neurological damage leading to the permanent destruction of both self-awareness and intentional action.
3. Little self-awareness and severe motor disability.
4. Destruction of both long-term and short-term memory such that the person who used to exist, no longer exists.

5. Distressing and marginally effective life-saving treatment that leads to a demonstrably awful life.

These are guidelines and clinicians have to make decisions according to a range of personal beliefs. Decisions have to be made in consultation with relatives and with other members of the multidisciplinary health care team looking after the patient.

Health-related quality of life - the wish to die.

In general elderly people do not express a wish to die. For example in a study carried out in Australia (12), it was noted that only 2% of the elderly interviewed wished to die. In this study, depression, poor self-rated health, disability and living in residential care were considered to be important risk factors towards expressing a wish to die. It is important to remember that depression, which can lead to death wishes and suicidal thoughts, can respond to treatment even in elderly people.

Also, in a study published on "Active Euthanasia and Physician Assisted Suicide in Dutch Nursing Homes" (13), it was noted that the characteristics of the patients (86 cases) who were helped to die were different from the average elderly resident. The majority (65%) were male (whereas normal deaths showed a ratio of 37% males and 63% females). Their average age was 70 years (whereas the average age for residents was 80 years), 53% suffered from malignant disorders, and 21% suffered from either motor neurone disease or multiple sclerosis.

Therefore elderly people do not usually express a wish to die just because they are old.

Health-related quality of life - the situation in Malta.

As far as I am aware, there are no published studies on health-related quality of life research carried out on the elderly in Malta. However, a number of thesis, some at Masters level, are available to read and digest and contain information relevant to this talk.

For example, a study carried out on self-perceived health and health practising behaviour on a sample of Maltese older people found that community dwellers had positive attitudes about their health and were health conscious and associated health-related quality of life with self-care abilities in activities of daily living (14).

A recent study on long-stay residents at St. Vincent de Paule Complex has indicated that their quality of life, especially their dignity and autonomy, is being undermined and the reasons given for this situation included negative and abusive practices as well as staffing oriented issues (15).

The issue of inadequate staffing levels and their ramifications at St. Vincent de Paule Complex were also tackled by another author. In this thesis the author also asked staff members, which consisted primarily of nurses, about end of life decisions. A higher percentage were against the acceleration of the dying process by limiting or stopping medical intervention indicating that health care professionals in Malta remain reticent to withdraw or withhold treatment (16).

Conclusion

Tools to measure health-related quality of life, as well as guidelines on the withdrawal and withholding of treatment in end of life situations are available to guide decisions on the elderly. They should be used in Malta either as everyday

instruments or as research tools or both. The majority of elderly people have positive attitudes and want to improve, and expect us as health care professionals, to improve their health-related quality of life, not end it.

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11.
End of life issues: xenotransplantation

Ruth Chadwick

In thinking about end of life issues the perspective of palliative care contrasts sharply with the discussion of developing new technologies to prolong life. I want to use the example of xenotransplantation to discuss this, with reference to the European project on this topic co-ordinated from Lueneburg, Germany, and in which I was responsible for the ethical part. In providing an overview of the ethical results of the project it was decided by the project team to use a framework for analysis based on the ethical matrix developed by Ben Mepham (Mepham, 1995). This approach proceeds by identifying the main interested parties affected by a certain development, in this case xenotransplantation, and applying certain principles to them. The principles used by Ben Mepham are themselves based on the four principles of biomedical ethics advocated by Tom Beauchamp and James Childress - beneficence, nonmaleficence, autonomy and justice (Beauchamp and Childress, 1994). In Mepham's version the three principles are well-being, autonomy and justice.

The groups whose interests may be affected by xenotransplantation include at least the following: animals, organ recipients, the contacts of recipients, scientists, health care professionals, industry and members of the public. The result of setting these out in the form of a matrix is shown in Table 1:

Well-Being

Under the heading of well-being we have to consider the effects of xenotransplantation on the well-being of all the

interested parties. As far as animals are concerned, there are clearly questions about the extent to which suffering is imposed upon them, for example through the process of genetic modification or on account of the conditions under which they are kept.

While it is difficult to articulate any benefits involved in the well-being implications for animals, for the organ recipients the well-being issues include both potential benefits and potential harms. On the one hand, it is said to be the argument from need of potential recipients (the argument from shortage) that provides the justification of efforts to introduce xenotransplantation, although there are reasons to think that while this demand may be the 'pull', the 'push' comes from recent developments in medicine. In any case whereas the greatest demand exists for kidneys and livers, these are not the organs where research effort is concentrated. On the other hand, they are exposed to further risks, such as new viruses, in addition to the experience of undergoing the medical interventions themselves. There are also psychological harms to be considered. These include personal identity issues resulting from having received an organ from a different species and the ways in which this might be perceived. It is known that in human transplantation recipients of organs have experienced identity problems: xenotransplantation may exacerbate this.

The potential implications for recipient contacts introduce a new interest group in the debate about transplantation: in the case of xenotransplantation the possibilities of virus transfer from species to recipient exposes the contacts of the latter also to such viruses. This is an issue for the wider population as well, in the case of the introduction of new diseases into the human population. Health care professionals may have threats to their well-being in so far as new technologies bring with them a redefinition of the scope of medicine, along with new expectations of success and cure including, possibly, false hopes.

	WELL-BEING	AUTONOMY	JUSTICE
ANIMALS	Suffering (e.g. from genetic modification; conditions in which they are kept)	Freedom to fulfil natural *telos* Integrity of creatures	Speciesism
ORGAN RECIPIENTS	Medical need Exposure to viruses Personal identity issues	Choice Surveillance Informed consent Dignity	Issues of access/distribution Stigmatisation Shortage
RECIPIENT CONTACTS	Risks of infection	Surveillance Informed consent	Stigmatisation
HEALTH CARE PROFESSIONALS	Definition of scope of medicine	Regulation Consent	Shortage of organs
SCIENTISTS		Freedom to research	
INDUSTRY	Investment	Freedom to pursue commercial interests	
PUBLIC	Safety Environment	Participation in decision-making Concerns/trust	

Autonomy

Autonomy is traditionally a principle that is applicable only to rational agents. However in the ethical matrix it may be interpreted slightly differently to have application to animals in the sense of being free to fulfil their natural telos. Xenotransplantation clearly does not allow an animal to fulfil its natural telos, where the telos is defined in relation to what is natural to its kind rather than to the individual member of a species. Thus it would be no defence to argue that this particular animal would not have been brought into existence had it not been intended as an organ source. It is arguably genetic modification, however, that is particularly problematic here. There may be issues over what the natural kind is where species boundaries are crossed.

The application of autonomy is clearer in the case of the human interests at stake. Under this heading the concept of human dignity is also important. From a Kantian point of view autonomy is the ground of human dignity, and this concept is important in Germany, for example. There will be a question as to whether it is regarded as contrary to human dignity to introduce organs from another species. Under the umbrella of autonomy and rights we may also consider the issue of privacy and surveillance, which would almost certainly be put in place both for organ recipients and their contacts as continual monitoring would be required of the health status of the patients and their families, certainly in the initial stages when the procedures would still be experimental.

A key issue relating to autonomy will be informed consent. This will apply both at the research stage and at the medical practice stage. There is a problem as to the extent to which a consent in this area can be genuinely 'informed', as with all fields in which there is not only innovation but also rapid change. There are also concerns about the 'consent' aspect

of informed consent, in so far as it may be the case that individuals may be unhappy about consenting to be transplanted with an animal organ but feel that there may be no alternative. This concern leads to the suggestion that it is important to continue to pursue alternative forms of treatment to xenotransplantation.

Where xenotransplantation is available, potential organ recipients have from one point of view an enlarged range of options. (This does not by itself, of course, settle the question of whether their choices are autonomous ones.) From another point of view the consequences of agreeing to receive an organ from another species may be the acceptance of a large degree of future restrictions on one's freedom.

Health care professionals may be subject to increased constraints on their practice - there is an issue over the monitoring and regulation of this area, for example. This may also affect the interests of scientists' freedom to research and the freedom of commercial interests in this area. This leads naturally to the question appropriate to another box on the matrix, namely the extent to which there has been wider public consultation on this issue and support for such medical developments, particularly in a context where there is evidence of increasing mistrust of science, of which there is some evidence in the UK,

Justice

It may be queried whether animals can be incorporated within the sphere of justice as such, even if there are ethical questions that are raised with regard to their treatment. For present purposes, however, this theoretical question will be put on one side - arguably what is at stake here is speciesism, the systematic discrimination in favour of our own species, to the detriment of others, and this may be construed as a justice

issue. Clearly this is not a new thing and the context of xenotransplantation has not of itself given rise to this, but there is a question as to whether the possibility of xenotransplantation introduces something different in kind or only in degree from what has been found in the past with reference to e.g. meat eating and animal experiments.

Moving on to organ recipients, issues of justice arise with regard to access and distribution. If xenotransplantation becomes sufficiently successful to be regarded as a standard form of treatment rather than as an experimental procedure, then there will be problems about allocation of resources. The problem of 'shortage' is unlikely to disappear but to be reinterpreted. While the main driving force towards the introduction of xenotransplantation is said to be the desperate shortage of organs and the impossibility of meeting the demand from human sources, this argument should be subjected to critique as to how, if at all, the shortage is 'constructed', what commercial interests are driving developments, how the present shortage manifests itself in different population groups. It is important to consider how shortage can be made worse if not created by the appearance of new specialisms in medicine, for example, and new target groups for transplantation. For example, one possibility that has been canvassed is that the ready availability of animal organs for transplant may affect the age range considered suitable for transplantation. Whether or not it is constructed, however, shortage is also an issue for health care professionals who have to 'deal' face to face with patients who need help but whom they cannot help.

Justice issues arise, however, not only in relation to possible discrimination in access and distribution but in the subsequent attitudes to those who are involved. Thus there may be possibilities of stigmatisation of those who have received organs and indeed of their contacts, especially if part of the

deal is that they agree to extend their life in quantity but at the same time to restrictions on its quality (e.g. by agreeing not to beget a child). This particular provision may be held to be in conflict with other human rights considerations.

The European dimension

In looking at how the different European countries approached the issues identified above a number of considerations need to be borne in mind:
(1) while the matrix identifies the issues in the application of three principles, using it as a comparative tool can show up the dominance, where it exists, of one particular principle in the approach of an individual or group. For example, the Greek report to the project suggests that in Greece the dominant approach is the concept of human dignity.

(2) similarly, on the horizontal axis, it can show the priority given to particular sets of interests when compared with others.

Animals

All countries saw the interests of animals as being a key if not the key ethical issue in considering xenotransplantation. While it may seem obvious, however, it is important to note that of 7 rows in the matrix only 1 concerns animal interests while the other 6 are related to human interests. The Spanish report specifically comments that the approach to ethics is an anthropocentric one. This is important to note at a time when non-anthropocentric ethics is growing in influence, and while the matrix does have the ability to demonstrate whether an anthropocentric approach is being taken, it may not always be explicit.

While the first horizontal line of the matrix deals with the interests of 'animals' there is also an issue, however, about

the specification of the membership of that class - in other words, which are the animals whose interests are at stake? This is discussed in several of the ethical country reports. There is concern about the use of primates for transplantation purposes because of the closeness of humans and primates in evolutionary terms (cf. Nuffield Council on Bioethics, 1996) Pigs are the source animals of choice, although there are ongoing concerns about the justification of this (cf. the German report). It is important to the ethical discussion also that xenotransplantation can include the use of cells rather than whole organs. This may affect the personal identity issues, for example, but not eliminate them, because the possibility of transplanting animal cells into e.g., the brain may still give rise to personal identity concerns.

From a theoretical ethical point of view there are different approaches to the question of animal interests and these broadly correspond to the columns in the matrix. Thus the well-being column broadly corresponds with a consequentialist approach; the autonomy and rights column with a deontological one. This is another advantage of the matrix, that it enables us to see what ethical stances are being adopted, and their implications. Historically utilitarian approaches have focused on the relevance of the fact that animals, like people, suffer, whereas a Kantian approach has concentrated on what it is about humans that sets them apart, e.g. rationality and personhood. For Kant it was the differences between humans and animals that were important, rather than the similarities. Contemporary deontologists, such as Tom Regan (1983) have argued that what qualifies human beings for personhood is also present, to some degree, in other species. Every being that satisfies Tom Regan's 'subject of a life'-criterion has an inherent value and should not be used merely as a means to certain ends. Regan widens the scope of Kantian thinking to include non-human animals. A present-day consequentialist approach such as we find in

Peter Singer (1975), suggests that the equal consideration of interests requires us to use humans with a similar intellectual capacity to animals we might wish to use for xenotransplantation, too, or to use neither of these. The reasoning consequentialist ethicists employ is that there is no morally relevant difference between some humans and higher mammals (cf. Chadwick and Schüklenk, 2001).

Well-being considerations were paramount in several countries - in the UK for example, the Kennedy report (1997) proceeded by weighing up benefits and harms, but as in that report the well-being approach to animal interests is not considered to be overriding:

> While the pig may be exposed to harm we do not regard it as so unjustifiable as to make the use of the pig unacceptable in principle. Instead, as regards the pig, the issue is one of balancing the rights of the pig to be free from harm, as we understand them, against the rights of the human who, as we have seen, could benefit from xenotransplantation.

The weighing up approach, as here, typically concludes that, subject to certain provisos, human interests can take priority. The Netherlands however takes a 'no, unless' approach, meaning that animals are not purely of instrumental value but they may be used for valid reasons. Another possibility is the introduction of a notion of proportionality. For example the Spanish report quotes the Pontifical Academy of Life to the effect that it is not acceptable to cause suffering without a reason proportional to social utility.

Where autonomy and rights are concerned, the Greek report says that although there has been increasing concern about animal suffering over the last twenty years, the debate about animal rights is virtually non-existent in Greece. However elsewhere there is not inconsiderable support, e.g. in

Switzerland, for an argument based on the integrity of creatures and the concept of a 'good animal life'. This seems not unrelated to the idea identified in the matrix of freedom of the animal to pursue its natural telos.

Consideration of this horizontal row of the matrix in the country reports therefore does not tend to lead to the conclusion that xenotransplantation should be ruled out on the grounds of animal interests.

Human interests: organ recipients

It is by no means the case, however, that the interests of organ recipients in having an organ are regarded as the overriding issue in all countries, despite widespread acceptance of the argument from shortage. The Greek report mentions a right to health giving rise to duty on the part of the state to pursue those means necessary to make this possible, while the Swiss report makes the point that there is no right to receive a transplant. There is, on the other hand, considerable concern about the negative effects on well-being of introducing this technology, in terms of both personal identity issues and risks to health.

Personal identity issues are mentioned in several of the reports (e.g., Italy), including the possibility that individual human beings may be regarded as 'genetically modified organisms' (see, e.g. the Swiss report). From a symbolic point of view, as acknowledged in the French report, certain organs or tissues may be more important than others (Chadwick, 1993) and this is likely to vary between societies (Welsh and Evans, 1999). Recent controversies in the UK over the removal of organs from children without the informed consent of their parents have demonstrated the importance that organs can have for conceptions of personal identity. In this case parents who have discovered that their children have been buried

without their organs have spoken in terms of burying only the 'shell' of their child. This gives rise to questions about where, if anywhere, the essence of the person is perceived to lie. From another point of view, the 'essence' of the person may be regarded as located in the genes and so it may be the receipt of genetic material from another species that may be regarded as problematic.

In addition, the risks to the health of recipients, it is argued, may be great not only because of new viruses but also because of the need for higher levels of immunosuppression, although the use of transgenic animals may reduce the need for this. On the other hand awareness of the potential developments in xenotransplantation may lead to unrealistic expectations which will have a detrimental effect on well-being.

There is considerable discussion of the autonomy implications for organ recipients, particularly with regard to privacy, surveillance (which figures prominently in the UK report) and informed consent. While there is a view that the normal standard of consent should be adhered to there are concerns about who should explain about safety and worries about potential disadvantages to those unwilling to participate (Nuffield Council on Bioethics, 1996). There are also specific concerns about minors and incompetent adults (e.g., Switzerland).

Where recipient interests are concerned, the well-being and autonomy issues figure far more prominently than the justice and distribution issues, perhaps reflecting the fact that at the present time the debate is focusing on the desirability of the procedure as a whole rather than issues of access and selection, although there is some discussion over the choice of the first candidates, and the German report recommends that in the event of the implementation of xenotransplantation, it ought to be available to all on the basis of need.

Human interests: recipient contacts

In the UK there is explicit discussion of the issues relating to recipient contacts, including the question of how these are to be defined. The potentially serious nature and extent of the implications for surveillance of contacts constitute an area in which arguably the ethical issues surrounding xenotransplantation are genuinely new.

Human interests: science

The scientific imperative is acknowledged in the reports of Switzerland and Italy. In the latter our attention is drawn to the importance of research as an ethical imperative. The Swiss report points out that science cannot be expected to be neutral and the "primary goal remains the development, confirmation and broadening of generalizable knowledge". From an ethical point of view this is a striking statement, given the influence of the dominant rhetoric of shortage, and draws our attention to the fact that breaking down the rejection reaction between species is an exciting scientific challenge which has to be taken into account in considering the forces driving the development of xenotransplantation.

The public interest is discussed under all three principles, well-being, autonomy and justice, the latter aspect being less well developed than the other two. First, it is widely acknowledged that health risks may be imposed not only on recipients and their contacts but also on the general population.

Where issues of justice are concerned these are said to include the urgency of not overlooking plurality and minority opinion e.g. of particular religions or ethnic groups. Another important issue concerns the opportunity costs of putting public health care funds into high-tech care (see e.g. Netherlands). Whatever its health care system, every country has problems to face about allocation of its health care budget.

Comment

Although the matrix is very useful in identifying issues and providing a basis for comparison, there are certain limitations also which become apparent. There is always an issue about the way in which ethical questions are framed and the danger of any framework at all is that it might privilege certain approaches at the expense of others. Given that the principles are derived from the four -principles approach of Beauchamp and Childress, which derive from a cultural setting where individualism is prominent, there may be concern that certain ethical approaches may fit less well into it - for example, feminist ethical approaches. While arguably these could be accommodated in the justice column, in so far as feminist ethics will be concerned with how new technologies will impact upon women (e.g. recipients will be debarred from childbearing and breastfeeding), and with issues of power and control over their development and implementation.

Similarly the principle of solidarity may appear not to fit well into the scheme, although this principle is mentioned in some of the ethical country reports, in different ways, some of which at least are seen as necessary means to well-being. For example, in the Italian report Battaglia is quoted in support of the view that human solidarity must be obtained for the furtherance of human donations to one another, but Berlinguer's argument for 'interspecies solidarity' is also mentioned.

It may also be regarded as problematic to accommodate the concept of the natural although this is a consideration for some countries e.g. Germany, where the idea of natural barriers is something to be considered. The extent to which ideas of the 'natural' can be compatible with the matrix is an interesting question. In so far as what is at stake is a preference for what is perceived as 'natural' in different countries it could be

considered in the box of the matrix at the intersection between 'autonomy' and 'public'. On the other hand it may be associated with well-being. On yet another interpretation there may be a concern for a 'justice in nature' as we find in Heraclitus' saying that even the sun must not overstep his measures - otherwise the Furies, ministers of justice, will seek him out (see Chadwick, 1989). On the other hand, an argument that xenotransplantation just is unnatural and should be rejected in principle on that ground, without any association with preference, well-being, or ideas of justice, may be advanced. It would, however, face problems both of defining 'natural' and of ruling out too much. The point is that in some senses arguments based on the natural can be accommodated in the matrix.

It is worthy of note that although there is considerable consensus about the centrality of animal interests in the ethical analysis of xenotransplantation, the discussion of the part played by genetic modification in this process is not dominant, although this was included in the well-being column of the matrix. In contrast, in the discussion by Welsh and Evans xenotransplantation is presented as an aspect of the 'new genetics' (Welsh and Evans, 1999). The relative unimportance

of this aspect in the country reports may seem surprising in the light of the prominence of the gm food debate over the last few years, and suggests that there may be a need for more work in this area.

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12.
WITHHOLDING AND WITHDRAWING TREATMENTS: ETHICS AT THE BEDSIDE

Emmanuel Agius

In his treatise The Art Hippocrates defined the purpose of medicine this way:

> *... to do away with the suffering of the sick, to lesson the violence of their disease, and to refuse to treat those who are over-mastered by their diseases realising in such cases that medicine is powerless.*[1]

Further on in the same treatise he adds:

> *Whenever therefore a man suffers an illness, which is too strong for the means at the disposal of medicine, he surely must not expect that it can be overcome by medicine.*[2]

In these words the Father of Medicine recognised the limits of medicine and gave moral sanction to decisions to refrain from treatment when it becomes futile. For many centuries in the history of medicine, health professionals followed this Hippocratic dictum. Only in the modern era, when medicine's capabilities expanded enormously, did the tendency arise to treat against all odds.

But in the last few decades it has become clear that treatment should not be prolonged indefinitely, when it has ceased to provide a benefit for the patient. Mechanical respirators, artificial hearts, dialysis machines, and resuscitation techniques can prolong the act of dying and at great financial, social, and emotional costs to individuals and society. Now the central ethical question is: When is it morally permissible or even mandatory to withhold or withdraw life-sustaining treatments? How is Hippocrates' moral dictum to be implemented amid the technical complexities of contemporary medicine?

This is the most frequent ethical dilemma in clinical medicine today. It is one which most of us will be forced to face not only in the care and treatment of patients, but in our own lives and in the lives of those for whom we act as surrogates.

In the last few decades moral sanctions for withholding and withdrawing life-sustaining treatments have come from a wide variety of sources. As a result a consensus is emerging on a moral perspective to guide these decisions. What are these moral guidelines and how are they to be applied at the bedside? Clinicians have the unique task of translating moral principles and rules into concrete decisions despite the uncertainties and uniqueness of each patient's experience of illness. This is what makes clinical ethics a more strenuous exercise than its classroom analogue.

Healthcare professionals must be able to make both technical and moral decisions to fulfil the obligation of trust inherent in the healing relationship. For this reason every clinician must understand and know how to answer the following two questions which are crucial to a sound practical decision: i) Who should decide? ii) By what criteria should decisions be taken?

The Moral Issue

The moral issue gaining acceptance today runs as follows: Is the patient competent? If so, the patient has the moral and legal right to make his or her own decisions about acceptance or rejection of treatment of all kinds. These decisions take precedence over the wishes of the doctor or family. If the patient was once competent but is now incompetent, then healthcare professionals must seek some way to come as close as possible to what the patient would have wanted were he or she able to make the decisions. The source of this judgement can be some advance directive. In the absence of

these, the decision of a valid surrogate must be sought. If the patient has never been competent, e.g. infants, the retarded or insane, a valid surrogate makes the decision.

The criteria to be used by the decision-maker are not as easily decided upon as who makes the decision. Several criteria are in common upon use: diagnosis, prognosis, benefit and effectiveness of treatment, futility or burdensomeness of treatment, brain death or permanent brain dysfunction, costs of care, quality of life, and age.

1. Who shall decide?

The question of competence

The patient's competence to make his or her own decisions is the first and perhaps the most crucial decision in the whole issue. What constitutes competence? Usually, it is defined as a capacity to make a reasoned judgement about a particular clinical choice. This involves the capacity to receive information, recognise its relevance, understand the gravity of each option, make a choice consistent with one's own value system, and communicate it. Competence is a limited capacity. It does not entail the capacity to make all decisions or handle all of one's affairs. Competence does not require that the choices be agreeable to the doctor, family or society. A person may be retarded, depressed or psychotic in other spheres and still have the capacity to choose according to personal values. Nor is competence age-linked.

The competent patient

The majority of bioethicicts today argue for the autonomy of the competent patient. I think that there are few greater violations of beneficence than to over-ride the patient's moral right to decide what is in his or her own best interest. To respect autonomy is to act beneficently; to violate it is malificent.

In actual fact the strong paternalists do not treat the patient by the use of force. More usually they violate autonomy indirectly - by manipulating consent through the selective presentation or withholding of information. Even though the intent is the good of the patient, deception and coercion of this kind are morally inadmissible. Particularly reprehensive is the boast of some physicians: "I can get any decision I want by the way I present facts".

In very acute situations, there may be some justification for a weaker form of paternalism. When competence is doubtful because of reversible disturbances of the brain resulting from shock or fever, the physician has first the obligation to treat these reversible causes and restore competence. As soon as this is accomplished, the wishes of the patient should be ascertained and followed. When the patient losses competence, the last competent decision should prevail. The physician ought not to speculate that the patient may have changed his or her mind. On the other hand, competent patients should be permitted to change their minds whenever they wish and are competent mentally to do so.

The incompetent patient

If the patient is incompetent, then the decision is made through some surrogate mechanism. The moral requirement here is to come as close as possible to what the patient would wish were he or she able to decide, not what the physician or surrogate would wish if he or she were the patient. When an advance directive is at hand, it "substitutes" for the patient's will. In the absence of advance directives, the autonomy of the patient is transferred, first to his or her chosen surrogate and then to others if the patient has not made a choice.

Surrogates must meet several tests of moral validity whether they are family members, friends, or court-appointed guardians: first, they must meet the same tests of competence

already discussed for the patient's decisions; second, they must be free of conflict of interests, financial or emotional; and third, they must know the patient's values well enough to make a so-called "substitute judgement" for the patient, i.e., they should provide evidence that their decisions reflects the patient's values.

The physician has a special obligation to be the advocate for the patient's best interests. Healthcare professionals must therefore make some effort to ascertain the moral validity of surrogate decisions. The surrogate decision must be in the best interests of the patient.

In emergency situations, when there is doubt about what the patient would wish, the patient should be treated. The moral onus rests on anyone who chooses to shorten life. The supposition is that most patients would wish to live. Healthcare professionals must be especially careful to avoid decisions not to treat that are based on their own value systems or in their evaluation of the quality or burden of the patient's life or the value of the patient to society. If the treatment is medically indicated it should be instituted, at least until valid surrogates are available or the patient recovers sufficiently to act in his or her own behalf.

2. By what criteria?

Whoever makes the decision, that decision itself must be grounded in morally valid criteria. Here the clinician has grave obligations because ethical decisions depend on the judgements and clinical knowledge of the technical expert. The physician's irreplaceable expertise is in his or her knowledge of the technical facts. If they are shaky, the whole process of ethical decision-making will be distorted.

Diagnosis and prognosis

In every case diagnosis and prognosis are the first and indispensable criteria. They are essential to deciding whether a medical treatment is futile or, to use Hippocrates' phrase, "beyond the means at the disposal of medicine". It is the clinician's responsibility to make as accurate an assessment as possible of the chances for recovery. In some cases it is not easy to determine the prognostic criterion as a terminal or preterminal state. A conscientious doctor will not consider withdrawal of treatment unless he or she is morally certain that the patient is in a "terminal state".

But how is this state defined? At the one extreme, we may all be "preterminal" in that we shall all die. Some ethicists find it safer to consider a patient terminal when death, to the best of our limited prognostic abilities, is foreseeable within hours, days or weeks. This is admittedly arbitrary but some practical limit must be set if decisions are to be made.

Brain "death" criteria

From an ethical point of view one can ask: which criterion is indicative of the patient's death? This question is essential in establishing a moral foundation for terminating life-support systems, artificial feeding and hydration, removing organs for transplantation, or writing do not resuscitate orders.

Some neurologists equate death of the person with death of the brainstem. Others define the "point of no return" as death of the neocortex, in which the brainstem is spared but patients remain in a persistent vegetative state. Others disagree strongly and require "total" brain death to consider the person dead.

Effectiveness and benefit

Two criteria are the effectiveness and benefit of proposed treatments. The two are not synonymous. Effective treatments

are those which demonstrably alter the natural history of an illness or alleviate an important symptom. Beneficial treatments are those which bring some good for the patient, not simply medical benefit, but benefit in terms of his or her value system. Antibiotic treatment of pneumonia in a patient dying of metastatic malignancy is effective, but not beneficial if it merely postpones the moment of dying when neither patient nor surrogate wish to prolong the dying process. Another example is in the use of analgesics. They are effective for pain relief in terminal cancer and therefore beneficial, but not effective so far as the natural history of the disease is concerned.

Ordinary treatments ought to be both effective and beneficial to warrant their use. This applies to life-support measures like respirator, artificial hearts, dialysis or cardiopulmonary resuscitation (CPR) as well. Artificial feeding and hydration are in a special category. There is substantial debate about whether they should be classified like any other medical treatment or regarded as care which would always be continued even when other life-sustaining measures can validly be withdrawn.

Futile and burdensome treatment

Most bioethists agree that a treatment that is futile or excessively burdensome ought to be discontinued. But again the problem is how to define the terms "futile" and "burden".

Ordinarily a treatment with little chance of altering the natural history of the primary disease can be considered futile. But how poor should those chances be? Allowances must be made for differences in values among physicians, families, or patients. The same ambiguities accompany assessment of burdensomeness. No clear-cut definition is possible. What is a burden to one is to another a challenge to be overcome.

Competent patients can make these determinations for themselves. But it is difficult to tell what is burdensome for a comatose or otherwise incompetent patient.

Opinions vary about whether patients in coma or with other manifestations of brain dysfunction suffer when food and fluids are withdrawn. Often the burden is more on the family and the medical care team who must carry out the nursing care, pass the nasogastric tube repeatedly, do the feeding, dress the bed sores, and come in day-by-day to see no palpable result to their efforts.

Quality of life

Should quality-of-life be a factor into the decision? There is no question that many clinicians, families and even courts take "quality of life" as a valid criterion for withholding or withdrawing treatment, especially in the aged or in disabled and handicapped infants. Quality-of-life is more a defensible criterion only for the competent patient. Only the competent patient can judge what quality-of-life means in terms of personal values, religious beliefs, or life plans within the limitations on autonomy. Only the patient can decide when life is so burdensome that it is not worth living.

With the incompetent patient - and especially with the never competent (the retarded, the infant, or the chronically insane) - we have no idea what constitutes a quality-of-life from the patient's point of view. It is impossible to decide what is a quality of life for anyone else. The opportunities for abuse, by imposing one's own values or by devaluating certain categories of persons are genuine.

Age as criterion

There is a growing tendency among bioethicists to suggest, either through voluntary or public policy, that limits ought to be placed on the amount and kinds of care given to the elderly.

Some suggest that when competition for some scarce resource occurs, preferences should automatically go to the young. This perspective raises serious questions. Does each human life have the same intrinsic value? Are the aged less worthy of care simply because they are aged?

Age alone is a poor indicator for moral decisions. The morally defensible way to use age as a criterion is to weigh it along with other clinical factors in deciding whether the treatment will be effective and/or beneficial.

Concluding remarks

There are still unresolved fundamental philosophical problems in the current decision-making process. We should continue to examine and clarify them even though they may seem abstract to practical people. Is there a real difference between withholding and withdrawing treatment? Is there a distinction of kind or any of degree between killing and letting die, between active and passive euthanasia? Is personal death synonymous with total, neocortical, or brainstem death? Is passive euthanasia the same as assisted suicide or homicide? Is there a difference between withholding treatments because they are burdensome and futile and doing so because of quality-of-life considerations? Is not the intent the same - hastening the death of the patient?

These questions still occur in discussions of withholding or withdrawing of life-sustaining measures? They reflect differences in our concept of the purpose, destiny and meaning of human life. While the moral perspectives emerging from the various groups are providing some answers, the deeper questions still remain for many people because of differences in deeply held religious and philosophical beliefs. These fundamental questions demand a continuing dialogue among ethicists, theologians, clinicians and policy-makers.

We can agree with Hippocrates that there should be limits to medicine. But deciding when to withhold and withdraw treatment is far more complex for us than for him. He did not face the immense power of today's medicine and the difficulty of balancing their benefits and harms.

Yet, paradoxically, we have the same tool for making our decisions that he had: the discipline of ethics, a discipline born in his era. The more technologically advanced we become, the more healthcare professionals must temper technical proficiency with ethical sensibility. "Doing" ethics has become as crucial as "doing" science for anyone who aspires to be a competent health care professional.

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1 Hippocrates, *"The Art"*, in Hippocrates, vol. II, W.H.S. Jones (trans.) Loeb Classical Library, Harvard University Press, Cambridge, 1967, 14, p. 193

2 *Ibid.*, p. 203-205

Appendix 1

THE ADVANCE DIRECTIVE

Pierre Mallia,

Patient autonomy is one of the guiding ethical principles of modern medicine, and is encountered daily in negotiations with patients about diagnostic tests to which they are willing to submit and medications they are willing to take, and through the process of informed consent, which is intended to assure that the patient is aware of the risks and benefits of potentially harmful interventions. These expressions of autonomy are based on a patient's ability to understand and to make reason judgements as a partner in their health care. There may come a time whem the patient is incapable of decision making, and, under these circumstances, there are two ways in which the patient's autonomy may be expressed: a living will and a durable power of attorney.

Rakel, R.E.
Textbook of Family Practice

An Advance Directive is a written or oral directive given by a competent person in order to govern and to control medical decision making for future situations of incapacity (Sass, 1998). It is also called a 'Living Will' because in effect it is a will, which the person writes for himself for actions to be taken on his or her behalf when he or she is still alive (Welie 2001). One has to distinguish therefore between wills which indicate what the person wishes after his or her death, for example organ donation, or the use of his or her body for research, and what that same person wishes to be carried out on his or her behalf when not in a position to take decisions any longer. A living will, however, is more specific. By definition it is itself an advance directive refusing or requesting specific types of medical intervention in the event of future incapacity (Sass, *op.cit.*).

Advance directives are an indispensable and essential part of medical practice today. They give the power to a patient to make an informed choice, within the law of the country, about him or her when mentally incapacitated, dying or in palliative care. A patient may designate a trusted person or family doctor to be his or her health care representative and take decisions on his or her behalf. In this case the advance directive is a written statement addressing who this 'power of attorney for health care' is. The power of attorney, that is, the person acting on the patient's behalf, obviates the problem that living wills are not legally binding and therefore may be challenged by relatives and the medical team. The word of the person designated by the patient to act on his or her behalf is almost as binding as the word of the patient.

Naturally there comes a time in many people's lives where difficult decisions need to be taken. Should we strive to keep the person alive at all costs, even compromising what many would feel is the dignity of the person? Or should the person be allowed to die quietly? Doctors, facing patients without explicit directives, are obliged to resuscitate people and to try to keep them alive as long as is reasonably justified. Whilst in the past it was the medical team to decide a DNR order, nowadays this decision is taken with the family (Welie, 2001: 170). The family is in the best position to know what the patient would have wished. An advance directive makes things easier. A person may thus express a wish that he wants to live as long as possible and that all the powers of modern medicine should be used to keep him alive. Another may express a wish not to be resuscitated if terminally ill but to be kept comfortable at all times, or not to be given any form of extraordinary treatment. However the qualifier 'within the law of the country' is important in this respect - no one is obliged to carry out a directive which is morally questionable or illegal, such as assisted suicide.

There are problems however both with the directive itself and with implementing it. Consider a person suffering from dementia. There is a bioethical debate of whether a previous written old directive should take precedence over the present wishes of the person (Vollman, 2001). The person may be having gaps when memory functions rather well stating he wishes all to be done to keep him alive, forgetting the advance directive he had written a couple of years earlier should he be demented. Naturally the family and the particular situation come into place in upholding or not the directive. But it is not all that easy. Clinicians may be aware that when confronted with death or with a severe disease, the wishes expressed by the person previously may change. As long as patients are competent there is no problem in changing the directive. The issue arises when competence, which may be compromised by the pain someone has, is doubtful. The second problem, that of advance directives not being available, can be tackled by educating people on these issues and having them discuss with their doctor what can be done.

The local scenario

Advance directives are by necessity subject to cultural and legal restrictrictions. In a country where euthanasia is not legal, an advance directive indicating that the person would wish to be put to death in case of dementia or severe pain would be invalid. But the culture of a country can dictate where these written directives can be extremely useful. Advance directives need not be restricted to medical decisions only but to decisions taken beforehand for a time when the person is no longer competent because of medical conditions or old age. In Malta, advance directives are still unpopular. Usually the medical team converses with the family to find out the wishes of the ill person. More frequently, decisions are taken on their behalf without the ill having made any explicit requests.

Whilst the family doctor can play an important role in keeping written advance directive for patients (Christie, 1986: 172), the problem is that people are not registered with specific doctors. Hence if two doctors turn up holding divergent wishes of patients, this would be a confusing issue, unless one is simply to take the last wish written assuming that the previous one is void. The law would have no way of knowing which doctor is the 'legal' attorney for health care of the patient. But this problem aside, responsible people can abide by a family doctor and have written documents, which can take the form of a questionnaire, kept in their files (Daly 1995: 128). Of course the system does not call in the family doctor should this patient be taken to hospital without the latter's knowledge and the hospital team would have no way of knowing about such directives. Such is the importance to have patient registration and to enhance the co-operation between secondary and tertiary with primary care (Mallia, 2001), and the role of the GP in hospital (Christie, 1986:161).

There may be sound reasons for people wishing their family doctors to keep advance directives. Old people in particular are afraid of decisions being taken on their behalf to which they are not consenting, such as being put in a home, hospitalization, or worse still being made to sign wills that go against their previous ones. Old people are often put in embarrassing and coercive positions to write testimonials to which they may have reservations. Naturally for fear of being abandoned they sign documents presented to them by notaries they have never seen before (usually brought in by the particular member of the family in whose interest it is that the will be signed) and consent to being examined by doctors who are not their family doctors. Of course it goes without saying that professional ethics would still dictate that notaries and family doctors do not cheat in this process. It is not the first time I was called to sign a document for a notary stating that the person was capable of making informed choice, only

to find that the person fails badly the mental examination test. The family may find another doctor, who was not the family doctor of the patient, but who can still legally issue documents, who is ready to express a different opinion.

Legislation requiring people to register with a family doctor will create the legal framework to avoid abuses, which unfortunately may be found in every profession. The family doctor is the ideal person to intervene on behalf of the patient who does not wish to give power of attorney to a relative or friend, and to entrusted with his or her wishes (Rakel, 1995: 151). The doctor would be in a position to help with DNR orders and other end-of-life decisions, even if no specific written document was available. Since advance directives can also be oral, physicians are culturally and objectively the ideal candidates to be trusted with advance health care directives.

However, the legal framework is useless unless people are instructed in the powerful potential of this tool. Whether written in legal or religious language, an advance directive that gives a clear indication of the person's wishes vis-à-vis health care choices, is a powerful tool. Yet the power of this tool must come at the expense of regulations in the National Health Care system which allows the hospital team to know who is truly the family doctor. In our system there may be more than one doctor involved in the family; moreover the 'usual' doctor may not have been found at the time of admission, and another doctor been used to refer the patient to hospital.

In a country where one still may wait up to three weeks to receive a discharge letter from hospital and where family doctors are not part of the national health services, it seems ambitious to be speaking about advance directives. Yet our patients deserve no less than the rest of European countries. An advance directive allows physicians to continue giving compassionate care whilst respecting the wishes of patients

even when they are no longer capable of communicating. Any guidelines for patient rights should include the right to give advance directive and the right to have them recognised.

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Appendix 2

THE RIGHTS OF THE DYING PATIENT

Emmanuel Agius

At no time in our history have we been so reluctant to face death and discuss it. Death, which is such an intrinsic part of life, has become a taboo for today's culture. In actual fact, it is not death itself that people dread, but the manner, time and even place of death. As a result of this fear to talk about death, today's culture is facing the danger of leaving the dying to approach their end unsupported not only by their relatives, but even by health carers.

In order to provide the best possible care and treatment for dying patients, nurses, doctors and other health care professionals who come in direct contact with terminally-ill patients need to be trained in those attitudes and dispositions which enable them to approach the dying patient with skills and confidence with which they treat other patients. Training in palliative care, or care of the dying, needs to feature more prominently in the curriculum of all health care professionals.

It is a fact that illness of any serious kind wounds our capacity to express fully our humanity. When we are ill, we lose our freedom to do things we are accustomed to do; we lack knowledge to heal ourselves; and we are in pain, suffering or disabled, anxious, fearful, and dependent. In that state of vulnerability, we seek out those who profess to be healers. Along with our bodies and our minds, illness wounds our very humanity. To be healed, as humans, we need therefore healing not only of minds, and bodies, but also of our whole humanity. When patients know that their illness is incurable and that death is inevitable, the usual wounds illness inflicts on their humanity become more and more painful. Vulnerability, dependence, and the need for compassion become overwhelming.

The relationship between the terminally ill patient and the healthcare professional who undertakes the obligations to treat and care for that person involves more than a medical dimension What obligations do health carers assume when they promise to help someone who is suffering, dying, and in pain? First and foremost, doctors, nurses and other healthcare professionals have the moral obligation to respect the dying patient as a person right up to death. Good quality terminal care must be patient-centred and accordingly must respect the patient as person. Health care professionals must remember that they are caring not for a dying patient, but for a person who is dying. Respecting the dying patient as a person means in practice respecting the patient as a subject of rights. This approach conforms with the spirit of Hippocrates.

It is a well-known fact that where there is staff shortage, it is the patient with a good chance of recovery who absorbs much of the staff's attention. There is the danger, that for convenience, the dying patient is moved to a corner or a side ward and is thereby isolated from other patients and neglected by health carers. Such an attitude is demeaning to the dignity of the dying patient who has the right to humane care and treatment. A dying patient will sometimes apologise for being such a trouble for health professionals, feeling embarrassed and guilty perhaps for taking time from others. The breathless speed of a busy ward is definitely ill-suited to the dying patient's need for tranquillity and peace.

Respecting the dying patient as a person means to offer holistic care for that patient. A holistic view of health care for patients comprises not only a physical aspect, but also emotional, spiritual and social dimensions. The healthcare team is expected to fulfil multiples roles, providing not only medical or nursing skills, but also psychological and emotional support. Moreover, patients may have the need for spiritual care. The dying person may wish to discuss personal, moral or spiritual problems. Dying patients are seen and treated as whole

individuals only when all these dimensions of care are provided for by healthcare professionals.

It is essential for health carers to master techniques to control pain and distressing symptoms. However, in addition to the technical skills required, health carers need to be able to develop a caring relationship with the dying patient. Since dying patients show a wide range of emotions and feelings, doctors and nurses must posses those qualities and dispositions which enable them to respond appropriately. In many cases their care tends to require more emotional involvement than technological skill.

Traditionally doctors have been taught to concentrate on the mechanisms of treatment. They have found it easier and safer for their emotional survival to distance themselves from the emotional issues surrounding the process of dying. While distancing oneself may be helpful for the health carer, it is not helpful for the patient or relatives. Dying patients want reassurance that their doctor is interested in them as individuals right up to death. Doctors and nurses should approach the dying patient with a deepened sense of conviction that they have a noble vocation of responding with sensitivity and feeling to patients' needs.

Many patients fear that their rights may be compromised at the end of life. Due to the widespread consciousness that under certain aspects, medicine can easily be dehumanising, various attempts have been made to construct a bill of rights for patients. Since those approaching the end of life are envisaged as being particularly vulnerable, such statements make specific references to dying patients. The language of rights presupposes that others have corresponding duties to see that rights are respected. In what follows I shall attempt to mention briefly some of the most fundamental rights of the dying patient:

1. Right to caring environment

In her famous book *On Death and Dying*, Elizabeth Kubler-Ross attributes modern man's flight from death to the fact that today, death takes place in an environment that is gruesome, lonelier and many ways mechanical. Kubler-Ross contrasts this modern way of dying with what she called the "old fashioned ways", where the dying person usually passed away at home, surrounded with his/her relatives. This contrast indicates the importance of a caring environment that makes a lot of difference to the dying patient.

Care of the dying must be founded on the same ethical principles as the treatment of all other patients. Health carers should be aware that their relationship with patients may change when there can be no longer any expectation of restoring the patient to health. As the patient moves into a terminal stage, the focus will shift to support, ensuring the best quality of life and coming to terms with the situation. When death becomes inevitable, the aim of treatment alters, but this does not affect adherence to fundamental ethical principles.

It is unacceptable for a health carer to make remarks, such as, "There is nothing more I can do". At no point in the patient's dying process can one say, "There is nothing more that I can do". It all depends on how you define 'doing'. It may be 'no further surgery, 'no further treatment', 'no new drug therapy", but that is still not the end of the line. There still remains relationship, caring, the comfort of the presence of a person whom the patient trusts. It is here that the roles of the doctor and the nurse are entirely interchangeable, but not mutually exclusive.

Caring for the dying patient requires separating out how much of the patient's distress is due to pain mechanisms, and how

much to suffering caused by other causes like anxiety and fear, guilt and the feeling of being punished and abandoned by the family, friends, or medical attendants. To deal adequately with these sources of suffering demands discernment of the causes of suffering, its effect on pain, and its meaning to this patient. It is obvious that the treatment for some of the varied sources of suffering is not analgesia. Rather, it is necessary to take the time needed to know the patient, to enable him/her through compassionate understanding, psychological or emotional assistance.

Health carers must extend themselves emotionally not only to the patient but also to his/her family who are in need of information, comfort and support.

2. Rights to autonomy and choice

The patient has the right to make decisions about his or her medical treatment. Respecting the autonomy of the dying patient means to acknowledge the patient's right to informed consent. There are three basic prerequisites for informed consent: the patient must have the capacity to reason and make judgements, the decision must be made voluntarily and without coercion, and the patient must have a clear understanding of the risks and benefits of the proposed treatment alternatives or non-treatment, along with a full understanding of the disease and the prognosis.

Fulfilment of the third condition requires that the physician takes the time to discuss the issues fully with the patient and outline the differences among alternatives, which are sometimes very difficult to estimate. In addition to being thoroughly informed, the patient must also understand clearly his or her right to make choices about the type of care to be received - a right many patients are not aware of. The pre-eminence of the patient's choice does not preclude the

physician's responsibility to make and to share with the patient a personal judgement about what the patient should do.

Dying patients have the right to exercise their autonomy and control to the fullest possible extent at the end of their lives. Doctors provide patients with information to enable them to do this but, particularly at the end of life, the doctor-patient relationship demands more than the simple provision by the doctor of a list of options. The physician has a special obligation to listen to the doubts and fears expressed by patients who are hopelessly or terminally ill. Advanced directives must be respected.

3. The right to information

Caring for the dying patients demands ongoing communication with the patient, his/her relatives and with other health care professionals. Doctors should seek to be as frank as possible with patients. In the past, information was withheld on the grounds that it would distress the patient. This argument is still valid in those circumstances in which the doctor feels that information would harm the dying patient. But this is the exception not the general rule. Respecting the autonomy of the patient requires truth-telling and keeping promises.

Doctors should avoid being paternalistic with dying patients by withholding all information. Doctors often find it easier to talk to those close to the patient rather than to the actual patient. For a long time, physicians held that knowledge of a fatal disease should be withheld from the patient or communicated to the family only. This is a further degradation of the person of the patient. The principle of patient's autonomy requires the empowering of patients through the provision of information.

The dying patient has also the right not to be informed, when this is his or her expressed wish.

4. The right to confidentiality and privacy

The patient has the right to have his sickness and information related to it in confidence. Illness intrudes into the person's privacy. This calls for confidentiality and modesty in any examination and treatment of the dying patient.

5. The right to a good death

Dying patients have a right to be looked after by caring, sensitive and experienced professionals who will attempt to understand their needs and support them facing the process of their own death. What is sought, however, by some who defend this right, is not simply a right of access to the best available terminal care, but also the acknowledgement that the patient has a right to choose to die by "voluntary euthanasia". Rather than helping the dying patient to terminate his/her life, dying patients need to be cared for to continue to live while dying. The Hippocratic tradition gives pre-eminence to the doctor's responsibility to benefit and not harm the patient.

6. The right to support

Dying should not be an event suffered in isolation. When the patient's symptoms have been adequately controlled and communication is a possibility, the crisis of dying, like the other crises of life, can become an opportunity for reconciliation and growth. Ideally, support for the dying patient should come from family members and other people close to the patient.

Notes on Contributors

Rev Professor Emmanuel Agius studied philosophy and theology at the University of Malta and at the Catholic University of Leuven, Belgium, where he obtained an M.A. in philosophy and S.Th.D. He pursued post-doctoral research in the field of bioethics at the University of Tübingen, Germany, as a fellow of the Alexander von Humbold Stiftung, at Georgetown University, Washington, D.C. as a Fulbright scholar and at the University of Notre Dame, Indiana. He is professor of Moral Theology and Philosophical Ethics at the University of Malta. He is a member of the National Bioethics Committee and co-ordinator of the Future Generations Programme which is supported by UNESO. Prof. Agius 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. Simon Attard Montalto, MB.ChB, MD (L'pool), FRCP, FRCPCH, DCH, graduated MB.ChB from Liverpool University in 1985, and was awarded a Doctorate in Medicine from the same University in 1998 following his research on nutritional and metabolic changes in children undergoing intensive therapy for malignant disease. Dr Attard Montalto trained in Paediatrics, initially at Alder Hey Children's Hospital, Liverpool and later, Great Ormond Street Hospital, Guy's Hospital and St. Bartholomew's Hospital, London. He has a particular interest in paediatric oncology, undergraduate/postgraduate teaching and critical care and is a UK Resuscitation Council PALS Instructor. He has published widely on various topics concerning child health and, in addition, has co-authored four books for postgraduate and undergraduate training in paediatrics. He is a Fellow of both the Royal College of Physicians, London, and the Royal College of Paediatrics and Child Health, London. Dr Attard Montalto is currently Chairman of the Department of Paediatrics, St. Luke's Hospital and Head, Academic Department of Paediatrics, The University of Malta.

Ms Donia Baldacchino is a lecturer in nursing at the Institute of Health Care, University of Malta She is in the final year of her Ph.D studies on Spiritual Coping Strategies of Patients with first heart attack. The study is being conducted under the supervision of the University of Hull, Yorkshire, UK.

Dr Moira Camilleri has qualified in Palliative Medicine from the University of Cardiff and is presently undergoing a Master's in Palliative Medicine with the same University. She works with the Malta Hospice Movement as medical officer, practicing mostly with people suffering with advanced cancer, both in their own homes and within the Oncology Department at Boffa Hospital where she holds a Palliative Care clinic. Dr Camilleri lectures on Palliative Medicine at the University of Malta.

Professor Maurice N. Cauchi, A.M., M.Q.R., M.D., M.Sc., Ph.D, F.R.C.RA., F.R.C.Path Professor Cauchi graduated M.D. (Malta, 1991) and furthered his education at the Universities of London, Monash and Melbourne. He is professor of Pathology, University of Malta, and Chairman, Gozo Health Council. 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 written several articles relating to bioethics in the local press. He is currently Chair, Bioethics Consultative Committee.

Prof. Ruth Chadwick is Professor of Bioethics and Director of the Institue for Environment, Philosophy and Public Policy, Lancaster University. Up until recently she was Director of the Centre for Professional Ethics, University of Central Lancaster where she headed various projects including the European funded EUroscreen Project, which studied genetic screening in various European countries, and other projects which focused on issues in prolonging life by organ/xeno transplantation.. She was also an official for the HUGO (Human Genome Project) committee and has written and edited a number of philosophical and bioethics books; and is

one of the key figures in European Bioethics. Her talk today is on : Ethical Issues and the Euroscreen project.

Professor Alfred Cuschieri is Professor of Anatomy and Genetics at the University of Malta and Consultant Geneticist in the Department of Health. He graduated Doctor of Medicine and Surgery from the University of Malta in 1967 and Doctor of Philosophy (Ph.D.) from the University of London in 1972 having performed postgraduate research at Guy's Hospital Medical School, London. He was Associate Professor in Anatomy at Kuwait University and consultant in Genetics at the Kuwait Medical Genetics Centre between 1979 and 1983. He established the first genetic counselling and cytogenetics clinic in Malta in 1983 and the Malta Congenital Anomalies Register, in 1984. He has been collaborating in the EUROCAT project, a collaborative European project on congenital anomalies since 1986. He was Director of the Institute of Gerontology, University of Malta between 1990 and 1996 and head of the Department of Anatomy from 1992 to 1996He was also a member of the Bioethics consultative Committee.. His current research is in the field of congenital anomalies, the fragile X syndrome and Huntington's disease in Malta.

Professor Alex. E. Felice is a graduate of the Medical School of the University of Malta (M.D., 1971, M.Phil, 1975) and the School of Graduate Studies of the Medical College of Georgia (MCG: Augusta GA, U.S.A.; Ph.D. 1981).. He was appointed on the Faculty at MCG (Assistant Professor 1981, Associate Professor 1986) and as Program Director in Hemoglobin Research.
In 1992 he was appointed Professor (Biomedical Sciences) in the University of Malta where he established the Thalassaemia and Molecular Genetics services and the development of a Molecular Biotechnology Program. He is the author of numerous research manuscripts on the molecular genetics of haemoglobin disorders including thalassaemia and sickle cell disease.

He is an elected member of the American Association for the Advancement of Science, the American and European Societies of Human Genetics, The Human Genome Organisation (HUGO), the American Society of Hematology, and Foundation President of the Malta Chamber of Scientists as well as member of the board of the Malta Council for Science and Technology. For a number of years he has been Editorial Reviewer of The American Journal of Hematology and of Hemoglobin. Professor Felice is Chairman of Atheneum Biotechnology Ltd and member of the board of directors of Optima Laboratories Ltd and Synergene Technologies Ltd.

Dr. Anthony Fiorini is a Consultant Geriatrician at Zammit Clapp Hospital and at St. Vincent de Paule Residence. He is also a lecturer in the Department of Medicine and the Institute of Gerontology at the University of Malta. He graduated MB ChB from Dundee University and Medical School, Scotland, in 1980. After completing his general training in hospital medicine, he obtained specialised experience in geriatric medicine in the United Kingdom. In 1989 he returned to Malta and took up his present post in the Department for the Care of the Elderly. He became a fellow of the Royal College of Physicians of London, FRCP, in 1998. His main fields of interest include services for the elderly, the frail elderly, and medical rehabilitation. He was recently conferred with an MD doctorate degree from Dundee University after submitting a thesis on the effectiveness of geriatric units.

Dr Pierre Maila graduated M.D. in 1993 and M.Phil. (Bioethics) in 1993. for which he obtained a distinction. He is currently secretary to the Bioethics Consultative Committee and lecturers part-time in Bioethics at the University of Malta whilst being a fulitime 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 (Kiuwer Academic Publishers). He is reading a PhD in Bioethics at the Catholic University of Nijmengen, Holland, under Prof. Henk ten Have with whom he also works on EU-related projects in Bioethics.

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 (1 982), and holds a Masters degree in European Law, as well as a Diploma to serve before the Ecclestiastical Tribunal. Her Doctorate thesis dealt with problems of carrier liability in container carriage whilst her Masters thesis dealt with "The Doctrine of Direct Effect' 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 (1 990-92), and Vice-Chairperson of the Commission for the Advancement of Women (1 989-1996). 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. (1 992-1996), 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 Oriand and has one son, Kevin. She is partner in the Law firm Farrugia Schembri Orland.

Dr Christian A. Scerri qualified M.D. in 1985 and then read for his Ph.D. at the University of Malta under the mentorship

of Prof. Alex E. Felice M.D., Ph.D. He was conferred his Ph.D. in 1998. His Ph.D. thesis was on the genotypical and phenotypical characterization of Thalassaemia in Malta. He is at present employed at St. Luke's Hospital as a Molecular Geneticist in the Molecular Genetics Clinic and is also an invited lecturer in physiology within the Institute of Health Care. He has attended and presented various papers in international genetic conferences.

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