Caroline Chisholm Centre for Health Ethics BULLETIN

Vol 3 No 3 AUTUMN 1998

Transplantation – Where do the Organs and Tissues Come From?

This article will explore the sources of transplant organs. These 'donors' as they are called in most literature, still invoke much discussion among health care personnel, ethicists, scientists, governments, the legal profession and the general public.

Transplantation involves removing a healthy organ or body part from a donor and surgically implanting it into a person whose own same body part has failed, is damaged or diseased. The donor may be a living relative, friend or unrelated other, or more commonly they may be an unrelated deceased person – a cadaver. Organs and tissues for transplantation are in short supply. In countries such as Australia, there seem to be fewer cadaver donors (using current guidelines) than in the past. Transplantation is a minefield of ethical issues which include identification of potential donors; determination of the most equitable way of allocating these scarce organs; definition of potential recipients; the prospect of routinely using modified animal organs in humans; the commercialisation of transplantation through the buying and selling of human organs and tissues; questioning the expense of such interventions aimed at only the few; and the recognition of death. Transplantation also highlights notions of giving and receiving in the human community. The me
dia's representation of transplantation and the flow on consequences also raise many ethical questions.

"Mercy Private Hospital. Respecting the dignity and value of each person, and their loved ones."

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In most scenarios transplantation is a treatment not a cure. Those who receive another person's organ (such as a kidney, heart or liver) must remain on a drug regime to prevent rejection which would mean a possible loss of the organ. Yet, for those people lucky enough to have their own diseased body part *successfully* replaced with a healthy one, a transplant can be life saving (in the case of hearts, lungs, livers and bone marrow), life prolonging and life enhancing (in the case of kidney transplants where quality of life is seen to be improved from that experienced on maintenance dialysis).

The Dead Human Donor

In the majority of cases for someone to

FEATURING

ISSN 1324-602X

receive a transplant it means that someone else has died. Currently, potential cadaver donors are those who have been pronounced brain dead in an intensive care unit where they are connected to a ventilator (without which they would stop breathing) and where they may also be receiving other technological and pharmacological support. There is no causal relationship between whether a person is diagnosed as brain dead and their becoming an organ donor. The person is diagnosed as brain dead *independent* of any potential that they may have to become an organ donor. Whether a brain dead person with healthy organs becomes an organ donor is usually dependent on the consent of the next of kin. Hopefully, the next of kin will either comply with the wishes of their recently deceased loved one, if their wishes are known, or otherwise make an informed decision with which they feel comfortable. Current legislation in Victoria, *The Human Tissue Act 1982,* uses the concept of *opting in* whereby consent must be given for the use of tissue for transplantation. Prior to death the person can take the opportunity to discuss their wishes with their next of kin or register with the Organ Donor Registry so that what they desire to be done with their body after death will be known. According to Jeffrey Prottas "The donation of organs is a community-building action of great emotional and symbolic potency. The gift is to a stranger; it binds the stranger to the givers in powerful ways. The stranger's gain mitigates the family's loss; a service is rendered in both directions, between people who will never meet. The givers assert their membership in a community in a tangible and symbolic way. Though the recipients benefit directly and critically from their membership in this community, all members benefit indirectly."

Brain Death

Brain death is the complete and irreversible cessation of whole brain function. Brain death means that there is no blood supply to the brain. Therefore, the brain is starved of oxygen and basically dies. The individual loses the capacity for consciousness, the capacity to breathe and cough, as well as losing such functions as gagging, pupillary responses, and reflex eye movements. Brain death is a state beyond which there is no evidence of the recovery of any ongoing organisation and integration.

'it would be entirely reasonable to stop artificial life support because it is futile"

A diagnosis of 'brain death', rather than simply 'death' became necessary when medical advances meant that the physical body could be kept functioning artificially, albeit only at the sub-personal level of cells, individual organs and isolated physiological systems. Because of technological developments people were being kept alive for prolonged periods in a state which traditionally would have been certified as dead. The diagnosis of brain death was formulated by a committee at Harvard University in America in 1968 so that there could be a fixed point at which it would be entirely reasonable to stop artificial life support because it is futile. The development of neurological criteria for death also meant that there would be less controversy in obtaining organs for transplantation.

According to the NHMRC discussion paper *Certifying death: the brain function criteria* "The clinical criteria employed to determine death using the brain function criterion are designed to provide 'practical' or 'moral' certainty (that is, certainly beyond any reasonable doubt) that the person has died." These criteria

"brain death is a very difficult concept to understand"

have to be met on two occasions within 24 hours of each other and the diagnosis has to be made by two experienced doctors who are totally unconnected with organ transplantation. There are also prerequisites that have to be met to indicate that the brain injury is severe enough to have caused the resultant loss in brain function.

Brain death is a very difficult concept to understand, especially for those who are not particularly educated about the workings of the body. The suddenness of death, often in a young, previously healthy loved one, is a tragic shock and one which must take a while to comprehend. To enter an intensive care unit and touch the body of a loved one who for all intents and purposes looks asleep, feels warm, is pink and whose heart rhythm is very obvious on the overhead monitor, and then to have to reconcile that they are dead and without the machinery would be cold and still, is difficult and distressing. It is the responsibility of staff in the intensive care unit to explain brain death and give the family time to accept the diagnosis before the prospect of organ donation is broached.

The Live Unpaid Human Donor

The tissues and organs which can be transplanted from *live* donors include kidneys (which are non-regenerative but still accounted for 23% of kidney transplants performed in 1994), blood, bone marrow, liver segments, bone, ova and sperm. In the case of kidneys and liver segments, the recipients of these live donor transplants are usually related, either genetically or by being a family member such as a spouse. Other tissues which can be transplanted from a live donor (such as blood, bone marrow, ova or sperm) are usually transplanted into an unknown person in the community who is in need. People who give their blood can do so regularly as blood is easily regenerated. Bone marrow donation is on a needs basis as it is imperative to have a good match. Only potential donors who have registered on a

centrally located list can be called upon to donate.

The live donation of a kidney or the lobe of a liver is usually dependent on a deep, meaningful relationship between the sick person in need and the person whose tissue donation could potentially save, or at least enhance, the life of that person.

"the decision to donate must be an autonomous one"

Those who do not support the live donation of tissue consider that the removal of a kidney or a segment of liver from a healthy person may constitute a harm and therefore may contradict one of the traditional ethical values known as non-maleficence. However, the donation must also be viewed in terms of the significant physical benefit that it will hopefully bring to the recipient, as well as the psychological benefit that it will bring to the donor, knowing that they have saved (or at least endeavoured to save) or enhanced the life of another. The decision to donate must be an autonomous one. It can only be autonomous if it is undertaken with a full understanding of the ramifications and the side effects. The decision must be voluntary in that it must be free from coercion and any controlling influences such as family pressure. It must be representative of a truly authentic choice made by the potential donor.

The Paid Human Donor?

Payment for human organs or tissues is not current practice in Australia. It *is* however an issue for consideration as it does happen in some developing countries and the recipients of these transplants (who could also be called the buyers) often come from countries such as Australia where such practices are illegal. Payment may entail a financial transaction to a living person for a kidney or cornea, or it could mean settling funeral expenses or some other remuneration to the estate of a cadaveric donor. According to Professor Napier Thomson the major reasons that paid living organ donation is condemned in most countries include: "concern about exploitation of the poor, potential and actual unethical behaviour, potential and actual criminal behaviour, excessive profit by brokers, failure of disclosure of disease in the donor and performance of donation in less than optimal conditions."

"organ and tissue donation is promoted for its altruistic character"

Payment for cadaveric donation is not generally condoned. In Australia at least, organ and tissue donation is promoted for its altruistic character in that it is a gift whether by a living person or by a deceased person and their next of kin to another or others in need. Paid cadaveric donation has been criticised because it is thought that it may discourage free donation; it may favour the rich as they could afford to pay more for the transplant and presumably the vendor would sell to the highest bidder; it may encourage an atmosphere of mistrust for health care personnel (however uninformed, as brain death is a static state caused by an irreversible brain insult) and it would reduce the environment to that of a market place where anything can be bought for a price.

The Animal Donor?

Xenotransplantation is the transplantation of tissue from one species to another – in this instance from an animal to a human. To some, xenotransplantation offers the promise of a reliable, long term solution to bridging the gap between supply and demand in transplantation. It would seem that if animal organs were freely available and safe and had few side effects, xenotransplantation may stop all the currently difficult allocation decisions which arise when supply does not meet demand.

The species of animal most likely to be used as a source for organs is the pig. As they are already bred for food, their use as 'spare parts' may be more acceptable to the general public than an animal species which is endangered or which is raised as a pet. Pigs reproduce fast, they are available in large numbers and they are surgically user friendly. They are also not riddled with disease like many other animals. Pigs have been used to make insulin for diabetics for many years and pig heart valves have been used to treat human heart disease.

Perhaps the biggest apprehension in xenotransplantation is the fear that

"fear that viruses from an animal species may become endemic in humans"

viruses from an animal species may become endemic in humans. The immune system in a transplanted person is suppressed to prevent rejection of the transplanted tissue so animal viruses would have a very hospitable environment in which to spread. Therefore, the burden of proof that this will not happen should lie with those developing the technology to demonstrate that it will not cause serious harm.

If xenotransplantation became routine, its use (apart from economic restrictions) could potentially be limitless. We are currently restricted with the number of transplants performed because of supply and this means transplanting those who have a reasonable chance of 'success'. If transplanting genetically modified animal organs were to become commonplace we would have to be careful that intervention was aimed at the patient's best interests and not utilised just because it was technically possible.

Conclusion

Defining the morally acceptable pool of sources for transplantable tissue is indeed a difficult and contentious issue. Currently in Australia, cadaveric donation using the diagnosis of brain death is the most

common and acceptable way to procure organs for transplantation. Obviously demand exceeds supply and with developments in medical technology it is entirely feasible to predict that there will be more and more people reaching a stage where their organs have failed and 'need' replacing. If we accept that transplantation is reasonable then we have to make sure that we are using all available resources to increase the supply of cadaveric organs. This may involve a bigger commitment to educate the public about the process of transplantation and the demystification of 'brain death'.

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Deirdre Fetherstonhaugh

From the Director

I am sure readers will be pleased to hear that we have been advised that the Department of Health and Family Services has approved our Centre as an *Approved Research Institute* (ARI) for the purposes of section 73A of the Income Tax Assessment Act. This recognition was given after thorough scrutiny of the Centre's staff and our Research Committee by the National Health and Medical Research Council.

The Australian Taxation Office has informed us that "gifts (not being testamentary gifts) of the value of $2 and upwards of money, or of property other than money which was purchased by the taxpayer within 12 months immediately preceding the making of the gift, made by taxpayers to the ARI *for the purposes of scientific research* will qualify as allowable income tax deductions under subsection 78(4) of the Act." We will have to open a special account for donations given to the Centre for the purposes of scientific research since such moneys must be used to fund research and not to defray general costs of the Centre. In order for donors to obtain the tax concession gifts must be given explicitly for the purposes of scientific research, and not simply be general donations to the Centre. Needless to say, donations to the Centre for the purposes of scientific research can be sent to the Centre from now on and would be most welcome. Of course the same applies to general donations to the Centre.

The general theme of our annual one day Conference for 1998 will centre on the topic of *Aboriginal Health: The Ethical Challenges*. It will be held at St Vincent's Hospital on Thursday 6 August 1998. We already have two eminent key note speakers who are passionately interested in this topic: the Hon. Dr Michael Wooldridge, Federal Minister for Health and Family Services and Sir Gustav Nossal AC. It is an important theme for us to consider as we complete the first 100 Years of the Commonwealth of Australia and prepare to embark on a new era of reconciliation with indigenous Australians and collaboration with all Australians. The program and other details will be available in the next issue of the **Bulletin**.

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Norman Ford SDB

A note for your diary...

The Centre is organising a one day conference on

Aboriginal Health: The Ethical Challenges

to be held on
6th August, 1998
at St Vincent's Hospital
41 Victoria Parade, Fitzroy.

The Randomised Clinical Trial (RCT)

Clinical trials pose several interesting ethical questions. This article will briefly look at some of these including: the role of doctors as investigators, the use of placebos and the responsibilities of institutional ethics committees (IECs) who approve and monitor clinical trials.

The Birth of Clinical Trials

Modern medical research follows a method established in the 1920s by Ronald Fisher. Fisher was testing an hypothesis about how to improve corn crops. He divided the field into two groups and made the groups as similar as possible for all variables, expect the one factor he was interested in – fertiliser. One group of corn was fertilised and the other was left untreated. Fisher concluded that any difference in the two crops was due to the fertiliser because nearly every other variable was the same in both groups. Since the 1940s Fisher and others have refined these principles into the clinical-trial methods scientific investigators use today.

Clinical Research

Clinical research in medicine involves studying various aspects of new treatments or procedures. The different stages of research are often referred to as phases. Phase I investigations look at drug delivery and treatment toxicity in human volunteers. The volunteers for Phase I trials are often normal healthy subjects. These investigations do not involve a comparison between a treatment group and a control group, just the observation of one group of people who are receiving treatment. They are known as uncontrolled trials. Phase II studies, which are also uncontrolled trials, involve monitoring the efficacy of the treatment under investigation in a predetermined set of patients with a specific disease. Phase III clinical trials are usually focussed on comparing two or more alternative treatments; often the standard or usual treatment, a new (potentially better, more effective, cheaper) treatment, and sometimes a group which receives a placebo. A placebo is a medicine which performs no physiological function but may benefit the patient because it has a psychological effect. A trial which involves a control group that receives the standard treatment is known as an active-control clinical trial and a trial in which the control group receives a placebo is known as a placebo-controlled trial.

"Phase III trials raise complexethical concerns"

The use of clinical controlled trials on large sample populations is the most scientific way of determining the effectiveness of a new treatment or therapy. However, these Phase III trials raise some of the more complex ethical concerns surrounding medical experimentation

The Doctor-Patient Relationship

The doctor-patient relationship has shifted from the strong paternalistic model, focussed on beneficence, to one that places greater value on patient autonomy. Two other important principles, non-maleficence and justice, still play an important role in the doctor-patient relationship. This important relationship can alter when the treating physician becomes the investigator. It is generally understood that a doctor should act in accordance with a patient's wishes (respecting autonomy) as well as in the patient's best interests (beneficence). The role of the physician is to practise medicine, to act in a way that benefits the well-being of their patients. Physicians provide a variety of services specifically for their patients including: diagnosis, preventative treatments and therapies. The role of scientific investigator or researcher is quite different. It includes activities which aim to develop and contribute to knowledge. Research seeks to develop theories, principles and relationships that can be corroborated by scientific observation and inference.

"he has an obligation to the welfare of his patient"

If a doctor is interested in the outcome of a particular treatment on a patient for research purposes, are the clinician's responsibilities to his patient jeopardised? The doctor has conflicting obligations. He has an obligation to the research or clinical trial and another obligation to the welfare of his patient. If a doctor was to take on this role he would certainly be ethically required to gain a patient's informed consent before admitting them into any trial.

Patient as Subject

The conflict between the roles of patient and subject reflect the dilemma posed by physicians acting as researchers. Patients receive treatment in order to become better. They are treated in the hope that they will have their health restored. A subject on the other hand undergoes treatment or investigation primarily in the hope that it will benefit others. Clinical trials do not always offer benefits to the research subjects. Clinical trials are aimed at helping the general community or others in the future who might find themselves in a similar position as the subject. Any potential subjects need to understand these different priorities in order to properly consent to participate in a trial.

Consent

The notion of informed consent is a complex and involved one. (It has

been discussed in detail in previous issues of The Bulletin.) Put simply, informed consent requires that a patient gives their consent voluntarily and on the basis of adequate information. Informed consent should be obtained in the daily practice of medicine. There should be no fundamental difference between this

"informed consent should ensure that the patient/subject receives all the relevant details"

consent and that which is required for participation in a clinical trial.
Informed consent requires that patients receive information regarding both what is known and what is unknown about potential treatments. In many cases the uncertainties surrounding a treatment may be more important than what is known about it. Ideally, informed consent should ensure that the patient/subject receives all the relevant details of the trial including: the purpose of the trial, the potential benefits to the patient and to the community, any potential risks associated with the treatment, the availability of alternative treatments, the right to refuse or withdraw from the trial at any time without prejudicing further treatment in doing so, and, the implications of randomisation.

There is some evidence that patients who have been informed of all possible risks of treatment display increased side-effects and decreased treatment efficacy, thus consent itself could be held responsible for influencing a therapeutic response. There are at least two possible explanations for this result. One is that patients who are aware of possible side-effects may be more alert to the effects of a treatment, and so report them more frequently, or they might be influenced by the knowledge of a possible side-effect and report experiencing the effect as a result. How a patient is informed of possible side-effects, their probabilities and the expected effectiveness of the treatment could also impact on the trial results. To avoid informed consent interfering with clinical trial outcomes in these ways the information provided to patients before they enter a trial should be as balanced and as honest as possible. A patient should not be exposed to either false hope or unnecessary anxiety about unwanted side-effects.

Randomisation and Placebos

Phase III trials require separate treatment groups to be as similar as possible except for the variable under investigation. All other features which may impact on the outcome should be distributed equally amongst the treatment groups. To ensure that this happens, investigators should randomly assign subjects to different treatment groups. Randomisation involves non-human choice, the random assignment of numbers is often used. Those given even numbers are assigned to one group while odds form another. The importance and implications of randomisation should be explained to potential subjects, especially when there is a possibility that they will be assigned to the placebo arm of a trial. Patients should be aware that they may receive no active treatment at all and before entering the trial

"randomisation involves non-human choice"

must consent to this possibility.
Trials of some treatments require either blind or double-blind trials. A blind trial is one in which the patient is unaware of which treatment group they have been randomly assigned to. In a double blind experiment neither the patient nor the investigator know which treatment was randomly allocated to a particular patient. This experiment design allows a treatment to be evaluated without the subjectiveness of the investigator interfering with the reporting of results. If an investigator believes that a treatment is effective they may unconsciously report results more favourably than if they were unaware of whether the patient was receiving an active treatment or a placebo.

Double blind randomised placebo-controlled trials are often used to determine the effectiveness of psychoactive drugs such as anti-depressants. The effectiveness of any anti-depressant is a somewhat subjective measure. If the doctors who rate the improvement in their patients' moods in a double blind trial are unaware of which treatment group their patients are assigned to, the reported effects of the anti-depressant drug cannot be biased. In this way any improvement patients receiving the anti-depressants experience, can be attributed to the drug's active agents rather than to the fact they are simply receiving treatment.

Problems with RCTs Involving Placebos

The use of placebos in clinical trials is often brought into question especially when a standard treatment for a condition already exists. It does appear unethical to deprive patients of an established treatment so that a new treatment can be compared with a placebo-control. It is, however, sometimes necessary to determine how effective a treatment is, when compared with no treatment, especially if the treatment is expensive or uses other scarce resources. Expensive, relatively ineffective treatments should not continue to be used and sometimes placebo-controlled trials are the only way of proving such a waste.

Trials involving placebo controls need to be closely monitored in case the treatment group shows dramatic signs of improvement. Patients should not remain in a placebo group once a treatment is scientifically shown to be effective. There is a fine line between continuing a trial long enough to establish statistical significance of a treatment's effectiveness, and depriving a placebo control group of an effective treatment.

IECs' Responsibilities and RCTs

IECs need to consider clinical trial protocols in a special way to ensure that they fulfil their role as trusted 'protectors' especially when one person is to assume the role of both physician and researcher. In reaching a decision about the ethics of a research protocol that requires the physician to also be the researcher, IECs need to focus particular attention on the following three points. Firstly, IECs should, in all research protocols, question whether or not there is any impairment to the capacity of prospective subjects to give their consent. Are there any serious risks to patient autonomy? Does the patient have the capacity to comprehend their situation? Are the prospective subjects legally competent?

"IECs need to fulfil their role as trusted 'protectors'"

The second point IECs need to consider is that of risk. The risk that should be of interest to the IEC is not only that associated with therapeutic or diagnostic procedures, performed for the benefit of the patient but, rather the risks associated with procedures performed in the interest of enhancing knowledge. Individual patients should not be exposed to unnecessary increases in risk for the benefit of the community. The IEC should ensure that all relevant information regarding potential risks to the patient is clearly stated in the plain English statement that all potential trial subjects should receive before they are asked for their consent.

"informing patients and gaining their consent is essential"

The final area that IECs need to consider when the physician is the researcher is the patient's ability to understand and consent to a procedure. Informing patients and gaining their consent is essential in all clinical trials and part of this is being made aware that their physician may have a conflict of roles. It is then up to the patient to decide how they feel about the situation and the consequences of accepting the dual role of patient and subject.

Why we Need RCTs

It is essential that any new therapy, and perhaps many currently accepted therapies, be subjected to proper scientific evaluation in the form of randomised controlled clinical trials. Science today uses clinical trials for evaluating nearly every aspect of patient care including: treatments, disease prevention programmes, diagnostic techniques, health delivery systems and the benefits of alternative treatments such as music, pets and humour. Without scientific evaluation via clinical trials many worthless treatments might be accepted as standard practice. What a tragedy it would be to see thousands of patients a year receive ineffective treatments, possibly for long periods of time because the evidence of effectiveness was never obtained.

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The Human Genome Project: Issues and Problems

The Human Genome Project has attracted considerable media attention over the last few years. In this second of three articles we look at some of the ethical and moral implications, both of the Project itself, and of the use of the information that the Project is expected to generate.

Introduction

In the previous article on the Human Genome Project (HGP) we looked at what the Project is, who is implementing it and what its aims are. In particular, we looked at what the HGP hopes to achieve – in the short term, to "map" the human genome and in the long term to determine the function of these mapped genes. Eventually, it is hoped, by determining the function of genes, we will be able to infer and thus correct their *mal*function. Thus, it could be argued that a long term goal of the HGP is to eventually find cures for all genetic diseases.

According to Elizabeth Hepburn, leaders of some of the more fundamental Christian traditions have argued that such DNA technology is a form of interference with God's plan for creation. However, says Elizabeth Hepburn, the views of others, including the US Catholic Bishops, is that as "co-creators" we must find

solutions to the problems that confront us, and take responsibility for our actions. So long as a particular form of genetic engineering is therapeutic, and is not contrary to the personal dignity of the human being, then it can be seen as morally licit. As such, the "application of these techniques is an outcome of our growing understanding of the world about us which we are called to care for and develop" (Hepburn). Justice Michael Kirby, of the Australian High Court, puts it another way: "The genome is knowledge that has come as part of the gift of humanity's own intelligence. In that sense, it is knowledge which was already with us in our capacity to think these extraordinary things through.... It should not be thought of as something alien to humanity, but as part of humanity discovered by humanity."

"we must ensure that the issues that arise are discussed by our society"

Of course the HGP still has many ethical and moral problems. Our role now is to be aware of what these problems are, and what legal and ethical issues can arise in the future from the HGP, just as we need to be aware of the legal and ethical issues that may arise in any area of health, or indeed of society as a whole. The challenge of the HGP is that we must ensure that it does not lead us down paths that will damage either individuals, or our own humanity, and that the issues that arise are discussed by our society.

Ethical Issues of the Project Itself

I concluded in the previous article that there are two areas of contention regarding the HGP. As pointed out by Timothy Murphy, it is frequently suggested that the HGP does not raise any ethical dilemmas in itself, and that the real issues that are of concern are related to what will be done with the resultant information. However, as Murphy argues, the Project does raise issues in itself, and it is these that we will discuss first.

The Modern Holy Grail

It has been suggested before that the DNA molecule has become the secular equivalent to the human soul and that, in the mind of the general public, genetics will eventually solve all ills. It is partly for this reason that the HGP has become known as the scientific Holy Grail. Therefore, it is important that we maintain a healthy scepticism, both about the importance of genes, and about the future achievements of the Project.

"the HGP will not change the incidence of other types of disease"

In particular, we must remember that genetic predisposition is only one of the elements that influences people's health and that environmental, and even cultural, factors must be taken into account, even for incidences of genetic disease: more often than not, disease is multifactorial. In addition, the HGP will not change the incidence of other types of disease – particularly communicable ones – that can be every bit as debilitating as genetic diseases. As Murphy points out, the use of genetic characterisations may actually prove useful only in a very small number of cases: it is unlikely to significantly alter the incidence of other – nongenetic – types of diseases, nor the costs associated with such diseases.

Cost: Social and Financial

This leads to another criticism of the HGP: that in pursuing this modern Holy Grail we may be evading our contemporary social and medical problems in favour of spending a vast amount of money on something of no appreciable benefit to those currently suffering. "To what extent, after all, should a society undertake a project whose beneficiaries, in the main, exist in the future?" asks Murphy. Of course, to a certain extent this is a criticism that could be made about any medical research, but in this case it is the size of the project that has prompted the critique. Many critics believe that such huge amounts of mapping and sequencing should have low priority in a time of limited funds for research on current communicable diseases. In addition the "big science" versus "little science" argument maintains that funding such large-scale projects takes scarce resources from other researchers who may study certain areas of particular interest more efficiently.

The argument against this contention maintains that coordination of the HGP is a more efficient way to conduct research into human genetics that, despite all criticism, would be conducted in any case. Thus, by coordinating research efforts, duplication of research is minimised and costs are saved. In addition, a compromise has been reached, whereby mapping of the genome is the primary goal, with complete sequencing to follow only if the cost becomes reasonable. Because of the exponential growth in technology in the last few years, it is possible that future costs will be cut dramatically. Meanwhile, a few pilot sequencing projects are focusing on certain coding regions that are most likely to contain information valuable to the medical and biological communities. Nonetheless, the priority being attached to the HGP remains a concern to many, particularly for those in developing communities.

Use of Resultant Information

Of greater concern, however, than the Project itself, is the ethical and legal effect of the use of the resultant information. It has been suggested that having the ability to diagnose a

"several mutations have been discovered without any treatment having been developed"

genetic disorder before any treatment is available does more harm than good because it creates anxiety and

frustration. Several disease or disorder-causing gene mutations have been discovered and studied in great detail without any treatment having been developed. We must be careful that, given the widespread use of prenatal testing, our society does not develop the attitude that couples who choose to give birth to a disabled child are "careless" or "selfish". We must ensure that such parents, and their children are not subsequently penalised by health or social welfare providers.

Confidentiality and Discrimination

Of particular concern for the future is the widespread availability of genetic screening, and who may have access to the information. If it is possible to test for a variety of genetic diseases or disorders for which there is no treatment, how far should we go in suggesting that people be genetically tested? This has specifically become an issue in the areas of health and life insurance. The argument put forward by insurance companies is that they have always used risk classification in order to determine how expensive a policy should

"under no circumstances should they be obliged to undergo genetic tests that they would not otherwise take"

be for an individual person: a twenty year old woman, for example, with no family history of heart disease or breast cancer, will not pay as much as a sixty year old who has a family history of both. Without such a system, insurance companies would either go bankrupt, or policies would be so expensive that very few would be able to afford them. Access to genetic screening for potential policy-holders, it is claimed, is simply the fairest method of ensuring that all holders pay the most appropriate levels of insurance. Those who argue against the use of genetic testing in this situation point to it as being one of the worst forms of discrimination: why should someone be further punished for having "bad genes" – something over which they have no control – by being refused insurance on the basis that they are a bad risk? While potential policy-holders should disclose their medical records, under no circumstances should they be obliged to undergo genetic tests that they would not otherwise take.

Similarly, should an employer be able to discriminate against a potential or current employee on the basis of their genes? Dawson and Singer use the example of an employment environment with a high level of air pollution which is very costly to eliminate. Should an employer, they ask, be able to screen their employees in order to dismiss those at risk of damaging their health? While it may be beneficial to employees, by reducing the health risks they will run, it could also be used as an excuse by the employer not to spend the money to provide a clean and healthy working environment. And what if a genetically susceptible employee wished to keep their job, despite the increased risk to their health? Should they, their employer, or society, bear the added costs of their possible illness in the future?

The Meaning of Difference

Is it possible that we are at risk of creating a new underclass in the future, made up of the genetically undesirable? What will this do to our attitude to *difference* in our society? Are we thereby suggesting that all people must conform to being a particular *type* of human? Says Murphy, "It seems to me ... that if there is a central moral issue at stake in the genome project, it is whether its characterisations will permit the erosion of difference in favour of genetic uniformity, whether its characterisations will offer yet another standard of "normalcy" to be used as a justification for the extermination of difference." In stating this, Murphy is not suggesting that people must be condemned to disease or disorder, simply for the sake of maintaining difference. Rather, we must carefully examine our definition of what it takes to be a "normal" human.

"yet another standard of 'normalcy' to be used as a justification for the extermination of difference"

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Anna Stokes

Making Morally Responsible Decisions

We are all required to make difficult moral decisions, as individuals and as believers. This article discusses some of the issues involved in moral decision making.

Some people are reluctant to make their own moral decisions. They depend on others for advice. This is prudent if one is unsure of what to do. However, this could hardly be recommended as a routine practice. A healthy use of one's sense of moral responsibility and personal freedom is a mark of a mature person.

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Our concept of moral goodness cannot be divorced from the nature of the human person. The moral good is conceived as that which is good for ourselves and/or others. We are morally bound to avoid doing evil precisely because we know that it is not good for us as persons. The same holds for leaving undone those deeds whose omission would not be good for us or others. We are morally free to choose to do good. Under no circumstances may we choose directly to do what we know is not good. Freedom itself is abused unless it is used in accord with the truth of the good.

Moral Formation

Feelings, intuitions and guess-work are not reliable criteria to discover the true good in difficult cases. We cannot dodge the hard work of improving our self-understanding and of reasoning things out accordingly. We must assess the impact that an act (or its omission) has on the total well-being of ourselves and others. A careful analysis is needed of all that is involved in relation to the truth of our personalised human nature *and* its requirements. Whatever is opposed to the nature of the human person and human acts cannot be truly good. A superficial grasp of human nature is no adequate foundation to determine what is truly good for a person as an individual and as a member of society.

It is not good enough to be highly educated in some disciplines without achieving comparable levels in moral formation. If, for example, one is convinced there are no objective truths, one is unlikely to accept that there are objective moral truths about what is right and wrong, good and evil. The absolute character of the moral imperative is derived from our need to seek true happiness in accord with our dignity as persons.

"particular religious beliefs influence our moral outlook"

The concept of the human person one employs is influenced by one's broader basic beliefs. Theists and atheists have very different views on the definition of a person and what makes a person moral. Particular religious beliefs influence our moral outlook. Christians in many ways differ from Moslems and Buddhists. Christians also differ among themselves, even though they all believe that the Bible contains divine revelation: in particular they differ on the teaching role of the Church for moral principles. Here I am writing from a Catholic perspective.

Discerning Moral Norms

We readily discover that certain types of acts conflict with the true good of human persons and are to be avoided. Moral norms are formulated to express such prohibitions. The *Ten Commandments* are examples of moral norms. They are valid so long as they are correctly understood in the light of their presuppositions. They also have an important educational value in forming the consciences of the young. However, if some change occurs in the presupposed situation of some norm, it may no longer be applicable in a new situation and in its stead another moral norm may be required. This does not mean the original norm does not count where it is applicable. As a general rule, it is true to say that one should not take another person's food. But if a starving person is unreasonably refused food, this person would be entitled to take the food needed to save their life. The right to life takes precedence over the right to private property.
There are cases where it is necessary

"the Ten Commandments have an important educational value in forming the consciences of the young"

to discern which moral norm is binding here and now: avoid injuring one's neighbour or take precautions for legitimate self-defence; maintain professional confidentiality or reveal to the authorities information required to safeguard the common good; keep a secret or tell an entertaining, but embarrassing, joke about a neighbour; work overtime or keep one's promise to take one's spouse out to dinner for a wedding anniversary; tell the truth or help an innocent person escape unjust arrest by telling a white lie. In these cases the right course of action can only be known after a prudent evaluation to determine which moral norm is the right one to apply in the concrete situation.

However, the situation is quite different where the choice is between adultery or financial loss; denying one's faith in Christ or risking one's life; directly intending to kill an innocent person or running the risk of letting somebody kill 20 hostages. In these cases one of the alternatives clearly involves the choosing of a morally evil act, which is not a practical moral option. No good, however great can ever justify doing an evil act, no matter how worthy the motive. *The end*

does not justify the means.

Role of Conscience

In all these cases a person is bound to follow a certain conscience after sufficient efforts have been given to find out the truth. One should never act when one is in doubt about the morality of a particular act. One should always resolve the doubt if one is to act with a good conscience. Conscience is not something outside ourselves. It is not even something distinct from the self. Conscience represents the total person, the whole self. It is our reason at work on a moral proposal that is at hand here and now. It tells the truth as one sincerely sees it. Conscience does not make free decisions. But we freely decide whether or not to act in accord with the dictates of our conscience. We are morally bound by conscience precisely

"the dictates of conscience are a summons served on our freedom in a categorical and unconditioned way to do or omit a particular act"

because we believe it to be objectively true. The dictates of conscience are a summons served on our freedom in a categorical and unconditioned way to do or omit a particular act. This judgement is made if it is seen to be absolutely required to be true to ourselves as persons. By acting in accordance with our conscience we set ourselves on the path towards authentic personal self-realisation. Conscience can only judge for oneself, not for another.

A genuinely formed conscience must be sincere and honest. We are all capable, both consciously and subconsciously, of directing our attention away from lines of investigation that we foresee might disturb a complacent *status quo*. An ingrained unwillingness to change as a result of the perception of new truths could subtly influence our free decision to focus our attention on less disturbing proposals. It would be extremely difficult to attempt to draw the fine line that divides the conscience of those who err in good faith, and those who err as a result of prejudice or a reluctance to examine all the relevant factors in a given case. Selfish interests of every type – greed, ambition, self-indulgence and pride – may blind us to the truth. The sincerity of a certain conscience needs to be verified.

There is no denying that not all agree in judgements of conscience on important issues that affect public life. We all need to admit that our personal, conscientious convictions are not all infallible. This realisation should inspire us to pool our resources on all the relevant factors to help the objective truth emerge and bring about a convergence of conscientious convictions. It would greatly enhance living together in community if more people were respectfully and sincerely engaged in genuine dialogue in search of the truth in controversial moral issues. The personal nature of conscience does not exempt one from the duty to seek objective moral truths to guide judgements of conscience in making the more difficult moral decisions.
In the last analysis we are left to ourselves to make the final judgement of

"a moral consensus that arises as a result of compromising one's conscience is blameworthy"

conscience in all sincerity. A consensus that emerges from a shared vision of the truth is a great ideal and a moral value to be cherished by all who wish to promote the public interest. But a moral consensus that arises as a result of compromising one's conscience is blameworthy. One should never renounce a conscientious conviction just to go along with the majority. By the same token, one should not induce another to act against their conscience by force or ridicule. Helping one to perceive the truth is the only honourable way to enable a person to change a conscientious conviction without detriment to personal dignity and integrity.

Conscience and Church Teaching

Catholics look to the Word of God and to the Teaching of the Church to form their conscience. The Church's *Declaration on Religious Liberty* put the position quite clearly: "... in forming their conscience, the faithful must pay careful attention to the sacred and certain teaching of the Church. For the Catholic Church is by the will of Christ the teacher of truth. It is her duty to proclaim and teach with authority the truth which is Christ and, at the same time, to declare and confirm by her authority the principles of the moral order which spring from human nature itself."(n.14). The same *Declaration* also taught: "It is through his conscience that man sees and recognises the demands of the divine law. He is bound to follow this conscience faithfully in all his activity so that he may come to God, who is his last end."(n.3).

The *Pastoral Constitution of the Church in the Modern World* also teaches the following: "Through loyalty to conscience Christians are joined to other men in the search for truth and for the right solutions to so many other moral problems which arise both in the life of individuals and from social relationships. Hence, the more a correct conscience prevails, the more so persons and groups turn aside from blind choice and try to be guided by objective standards of moral conduct. Yet it often happens that conscience goes astray through ignorance which it is unable to avoid, without thereby losing its dignity. This cannot be said of the man who takes little trouble to find out what is true and good, or when conscience is by degrees almost blinded through the habit of committing sin."(n.16).

Catholics ought always follow their certain and well informed conscience. At the same time Catholics ought also accept the Church's teaching on moral issues. Some Catholics are unable to assent to a particular moral teaching of the Church. We

should not judge our neighbour because it is difficult to measure the subconscious impact of culture, education, stress or fears on one's conscience. Such a person must still follow their conscience when making moral decisions. An open mind, however, should be kept while prayerfully continuing the search for the truth. It would still be necessary to show respect for the Church's teaching, avoid scandal and not disturb the conscience of other believers. Care must be taken to make sure the right to follow one's conscience is not taken to mean a right to dissent from Church Teaching, and much less a right to teach one's private convictions in the place of Church Teaching. Citizens' rights of dissent, protest and civil disobedience in the political life of a democratic state have no part in the life of the Church as the People of God and the Mystery of Christ.

Referring to the responsibilities of lay people, the *Pastoral Constitution of the Church in the Modern World* says: "It is their task to cultivate a properly informed conscience and to impress the divine law on the affairs of the earthly city. For guidance and spiritual strength let them turn to the clergy; but let them realise that their

"their pastors will not always be so expert as to have a ready and concrete answer to every new problem ... this is not the role of the clergy"

pastors will not always be so expert as to have a ready and concrete answer to every new problem (even a grave one) that arises; this is not the role of the clergy; it is rather up to the laymen to shoulder their responsibilities under the guidance of Christian wisdom and with eager attention to the teaching authority of the Church."(n.43).

Obviously every effort should be made to arrive at a well-informed and certain conscience. Doubts should be resolved before proceeding to take action. Responsible persons need to know the right moral principles and apply them in concrete situations where they themselves are expert. It must be admitted that in the case of people who have not received an adequate education in general moral principles and who do not feel competent to apply moral norms to particular situations, advice will have to be sought from competent persons.

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The Centre's Bulletin is a quarterly publication. Subscription fees; $25.00 US$25.00 Overseas

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