

National Statement on Ethical Conduct in Research Involving Humans

This article will briefly outline the principles underlying the recently released National Statement on Ethical Conduct in Research Involving Humans.

The *National Statement on Ethical Conduct in Research Involving Humans* was issued by the National Health and Medical Research Council (NHMRC) in June 1999 after much public consultation¹. The release of this document is significant because no longer are these guidelines simply for those conducting health and medical research. For the first time outside Canada, the same ethical guidelines will apply to all research involving humans across all disciplines. The National Statement has been endorsed by the: Australian Vice-Chancellors' Committee (AVCC), Australian Research Council (ARC), Australian Academy of the Humanities, Australian Academy of Science and Academy of the Social Sciences in Australia.

The document begins by highlighting four principles on which the remainder of the document is based. These ethical principles are integrity, respect for persons, beneficence and justice. I will briefly outline these principles, before considering why integrity has been included, perhaps question why some other principles were excluded and finally review the remainder of the document in light of its impact on re-

"St Vincent's Institute of Medical Research is conducting ongoing research into heart disease, breast and prostate cancer and treatment of drug dependence."

Photo courtesy of St Vincent's Hospital, Melbourne.

search.

Respect for Persons

The first principle discussed is 'respect for persons'. In this document it is taken to mean that 'individuals should be treated as autonomous agents and that persons with diminished autonomy are entitled to protection.'² Later in

individuals are never to be treated as merely a means to an end

the same section 'respect for persons' is taken to ensure that respect is shown for the inherent dignity and rights of persons and that individuals are never to be treated as merely a means to an

FEATURING

<i>National Statement on Ethical Conduct in Research Involving Humans</i>	1
<i>Health Care from a Distance –Telemedicine/ telehealth!</i>	4
<i>Genetic Therapy and Genetic Enhancement</i>	7
<i>How to Find out What is Morally Right or Wrong</i>	10

end. This essential principle has been very well expanded and aptly covers the need to respect all potential research subjects, while placing a special emphasis on protecting subjects who are no longer or never have been autonomous agents. In other words, the principle implies the need not only to respect the autonomy of individuals but more importantly, to respect the individuals themselves.

Beneficence

Beneficence is a principle that has been widely used in ethical discourse, especially in the area of bioethics, and it can be interpreted in several different ways. Beneficence, as I think it is generally understood, 'refers to a moral obligation to act for the benefit of others.'³ However, the National Statement interprets beneficence as, 'the obligations to maximise possible benefits and minimise possible harms.'⁴ While not too dissimilar from other interpretations, in that it acknowledges the importance of maximising bene-

avoiding harm in research is so important that it warrants recognition as a separate principle

fits, another very important ethical principle, non-maleficence, is subsumed into it. Non-maleficence refers to the obligation to not intentionally inflict harm. While the statement acknowledges that risks of harm should be minimised I think that avoiding harm in research is so important that it warrants recognition as a separate principle. In trialling a new drug for example, it is essential that researchers prevent any harmful effects the drug may have before they concern themselves with whether or not the drug provides any benefit to the research subject. In my opinion a separate acknowledgment of the principle of non-maleficence would have improved the document.

Justice

The third principle considered in the document is justice. Justice is taken to address the issue of who ought to receive the benefits of research and bear its burdens. In other words the same people who bear the 'burden'

the principle of justice also extends more broadly to the funding of research

of participating in research should have the opportunity to receive the benefits. The principle of justice also extends more broadly to the funding of research and conducting research on all types of people within the community. Considerations of justice such as these are integral to all levels of health care and, as the document notes, should be of particular importance in research.

Integrity

The ethical principle of integrity is discussed first in the Statement. 'Among the essential values for research is that of the integrity of researchers.'⁵ I agree with the statement that the honour, honesty and reliability of researchers is of paramount importance, however, it is possibly not the most important ethical consideration regarding research. Even if, as the Statement demands, researchers have a commitment to the pursuit and protection of truth, a reliance on appropriate research methods and a commitment to research questions that are designed to contribute to knowledge, researchers can still exploit, harm, or risk harming research subjects. I agree that the integrity of researchers is important and acknowledge that it is only one of four ethical principles presented, however, I think that the other three principles discussed are far more important, as they aim to protect the subjects of research.

While I do not agree entirely with the four general principles the Statement presents, they do go a long way to helping researchers across a variety of disciplines focus on the ethi-

cal concerns that their research may generate. With these principles as a foundation the document addresses specific issues in research and provides, in the most part, clear and appropriate ethical guidelines.

Ethics and Law in Research

The preamble of the Statement also includes a section on ethics and the law in research. It should be remembered here that the organisations supporting the Statement are national bodies and, that it is State and Territory Governments that make most of the legislation in areas that would be affected by research. As a result of the different jurisdictions the Statement attempts to provide direction on whether the legal regulation or ethical guidelines takes precedence. The Statement offers this advice, 'In the event that both a legal requirement and an ethical guideline apply, the legal requirement will prevail (although they will normally be consistent).'⁶ This is sound advice, however, it may conflict with the statement that follows in the same paragraph, 'Where the guidelines prescribe a standard that

the higher standard, whether it is the ethical or legal one, should be the one adhered to

exceeds that required by the law, then researchers should apply this standard.' Perhaps the point being made is that the higher standard, whether it is the ethical or legal one, should be the one adhered to.

Guidelines Within the National Statement

Following the preamble the general overview of ethical principles is expanded upon to form Section 1. From there the report focuses on practical as well as ethical issues. Sections 2 and 3 detail the requirements of Human Research Ethics Committees (HRECs) and Multi-Centre Research respectively. These two sections are not particularly pre-

scriptive in nature. While the guidelines do prescribe the minimum composition of HRECs, record keeping of decisions and monitoring processes, they leave decisions regarding the appointment of members, meeting procedures as well as review of multi-centre research, up to the individual HRECs.

Section 4 concentrates on research involving children and young people

these measures are essential to ensure that those research subjects who are potentially most vulnerable are well protected

and Section 5 is dedicated exclusively to research involving persons with an intellectual disability or mental impairment. Both sections aim to ensure firstly, that when the subject of research is not capable of giving their own informed consent that someone else, who is responsible for their welfare, for example their parent or guardian, gives their consent. Secondly, the two sections require that HRECs must not approve research that is contrary to the best interests of the research subjects. Both these measures are essential to ensure that those research subjects who are potentially most vulnerable are well protected.

Sections 6, 7, 8 and 9 focus on protecting research subjects who belong to particular groups as well as those subjects who are in restrictive circumstances. These sections prohibit certain types of research involving people who are not in a position to give their voluntary and informed consent, for example invasive research on unconscious persons. Special mention is also made of other vulnerable groups including; persons in intensive care, emergency care, persons highly dependent on medical care, people in dependent or unequal relationships such as students and teachers and prisoners and prison authorities. Section 8 details the particular dilemmas that research involving collectivities can create. Collectivities are 'distinct human groups with their own social

structures that link members with a common identity, with common customs and with designated leaders...'⁷. Both this section and Section 9, which deals with Aborigines and Torres Strait Islanders, provide guidelines on how to conduct research involving these groups in an ethically appropriate manner as well as providing references for further guidelines in the particular case of Aborigines and Torres Strait Islanders.

Sections 10 and 11 refer readers to other documents firstly, *NHMRC Recommendations for Limiting Exposure to Ionising Radiation (1995)* and secondly to *NHMRC Ethical Guidelines on Assisted Reproductive Technology (1996)*. Section 12 is perhaps one of the most important sections contained in the National Statement and its focus is clinical trials. This section provides HRECs with specific criteria on which to assess all clinical trial protocols. Not only must all clinical trials adhere to international guidelines such as the Declaration of Helsinki but they must also be scientifically valid. That is the protocols must seek to answer specific questions and the methodology of research must be appropriate to the discipline. These requirements are made clearly and succinctly and would be very helpful in determining the ethical acceptability of research projects.

Reference is made again to the Helsinki Declaration in Section 13, which deals with innovative therapy or intervention. The section is forced to consider the fine line that exists in clinical practice between slight variations or extensions of existing techniques and completely novel technologies. While the ultimate decision about when introducing an innovative therapy should be considered clinical research rests with the responsible clinician, it should be remembered that it is definitely clinical research when subjects are recruited and/or the therapy undergoes systematic investigation to determine its efficacy and safety.

When the introduction of new therapies is deemed to be research then, like all clinical research, the protocol should be submitted to a HREC for consideration.

Epidemiological research is the subject of Section 14, which is one of the more detailed sections in the statement. This section accurately defines three categories of personal information that may be used in epidemiological research; identified, potentially identifiable (coded or re-identified) and de-identified or anonymous information. The guidelines require that different types of information be handled with particular care and that any research involving the use of such information must be approved by a HREC. This section also makes it clear that researchers dealing with personal information that is either identifiable or potentially identifiable must meet the standards detailed in the *Privacy Act 1988* and other national privacy standards.

Sections 15 and 16 focus on the use of human tissue samples and human genetic research. Both these areas

genetic information, unlike other information, has an impact not only on the individual but also on other family members

of research are rapidly expanding, which makes ethical guidance all the more valuable. Respect for persons and the social implications of these types of research are well documented. The critical area of privacy and confidentiality is dealt with clearly and effectively and these sections should be read in conjunction with Section 18, which comprehensively deals with privacy of information and legal regulation. The section on human genetic research sets out clearly the other sections in the national statement that also have an impact on genetic research. Issues regarding consent, collectivities, epidemiology as well as the effect of dependent relationships all become very important when dealing with genetics. Genetic informa-

tion, unlike other information, has an impact not only on the individual but also on other family members, that is information may relate to third parties' future health risks or those of their offspring. As a result guidelines regarding genetic research must protect not only the research subject but also their families. The statement goes a long way towards achieving this, however, stricter guidelines could be developed especially in the areas of research subject follow up and the ownership of information and samples.

It is generally accepted that research involving deception should be avoided, however, Section 17 deals with those few instances in which it may be the only effective way of conducting research projects such as the study of natural human behaviour. This section contains a list of criteria that must be satisfied before

a HREC approves research involving concealment or deception. It is particularly important that HRECs reflect carefully on this type of research because the research subjects themselves cannot consent or dissent to participate. This means that HRECs are the only ones able to ensure that the privacy of research subjects and the subjects themselves are respected. The final section in the document deals with intellectual property and refers readers to relevant documents produced by the NHMRC and AVCC.

Overall the document is a well-constructed guide for HREC members who are frequently presented with a wide variety of research proposals. It is essential however, that this document still be considered with reference to other NHMRC documents that deal with particular types of research in greater depth.

The National Statement should be considered a wonderful achievement. It is encouraging to have a comprehensive guide that aims to protect **all persons** that may be the subject of **any type of research**.

ENDNOTES

¹ *National Statement on Ethical Conduct in Research Involving Humans, Commonwealth of Australia* (1999). The Statement is available from AusInfo Government Info Bookshops.

² *National Statement 4*.

³ Tom L Beauchamp & James F Childress, *Principles of Biomedical Ethics* Fourth Edition, Oxford University Press, New York (1994) 260.

⁴ *National Statement 4*.

⁵ *National Statement 3*.

⁶ *National Statement 5*.

⁷ *National Statement 31*.



Tracey Phelan

Health Care from a Distance – Telemedicine/telehealth!

This article will discuss the delivery of health care over long distances using technology. Technology in health care is obviously not new but there are some potentially problematic issues that need to be confronted before 'hands off' health care becomes further entrenched in practice.

Telehealth/telemedicine – What is it?

Telemedicine is the clinical practice of medicine by remote means. This may include video consultation between doctor or other health professionals and the patient, surgery performed by doctors while being instructed by a distant specialist and the electronic transmission of information including X-rays and pathology images between different sites.

telehealth can involve a range of health professionals, patients and other recipients

Telehealth refers to the information services and technology that can be applied to health services more generally. Examples of telehealth include videoconferencing for clinical care, distance education and training,

and peer review; electronic transmission of diagnostic images for analysis; online health information services; telephone call centres for giving health information and advice; and electronic medical records.¹ Telephone triage, telephone counselling and personal alarm systems are other examples of telehealth services. Telehealth can involve a range of health professionals, patients and other recipients. It can be used in a variety of settings including community health, remote areas, regional and teaching hospitals, universities and other teaching centres, peoples' homes and prisons.

Examples of Telehealth

Teleconsultations can be carried out by either telephone or via videoconferencing. The telephone has long been used as a one on one tool in

health care but more recently it has been used in conferencing where several people can communicate together. Videoconferencing usually means being able to visualise people at both ends and it means that better rapport can be developed than if people are unable to see each other. With videoconferencing the taking of a history is enhanced for both patient and doctor and the signs and symptoms of the patient can be demonstrated and viewed. Pictures of Xrays or scans sent via a scanner, as well as pathology images through a microscope, can further supplement the consultation. The long distance health professional can therefore have access to all the data and information about the patient that will help them to determine the diagnosis and the best course of action. Such videoconferencing prevents the necessity for patients to travel long dis-

tances for a consultation.²

Home Telecare is where health care

it just shifts the cost from one program to another

can be delivered to a patient in their own home without the health professional necessarily being in physical attendance. The increasing cost of inpatient care has meant that in most developed countries patients are being increasingly managed at home, often being discharged from hospital much earlier than they would have been a decade ago. Visiting nurses and doctors either from the discharging hospital or a separate service currently provide the health care to those sent home. While this may appear to save money it could actually be argued that it just shifts the cost from one program to another. According to Steven Strode, the application of home telecare whereby low-cost televideo equipment runs over regular phonelines means that the patient has constant access to help and this would be cheaper than maintaining regular visits.³ Strode also discusses a variety of diagnostic devices such as an electronic stethoscope, respiratory flow data or blood glucose monitoring that would aid the doctor or nurse in being able to monitor and manage patients from a distance.

The Demand for Telehealth!

There are several challenges to the provision of quality health care not the least being the rising cost. In developed countries, especially those that have large landmasses such as Australia, the United States and Canada there are added problems. The large landmass means that there is often a widely distributed population with many living in rural and remote areas. This geographical distribution of people means that there is an uneven allocation of health care resources. Most of the more specialised health services are located in the larger cities. It could be argued that this is inequitable and

unjust. There is also inadequate access to health care for some segments of the community who by virtue of their age, disability or language spoken cannot have the same contact with the health care system as others. All these disadvantaged groups could potentially benefit from telehealth.

Benefits of Telehealth/telemedicine

It is hoped that the use of computers and telecommunications technology in health will improve the effectiveness and efficiency of health services, which also includes the cost of health care. However, it must be the demand for the services that different telehealth applications can provide rather than the availability of technology used for telehealth, that drives the development of telehealth. According to an Australian Telehealth Services Issue Paper telehealth services may enhance peoples' access to health care because of the following.⁴ It can improve the availability of health care, meaning that the services such as specialist health professionals, facilities, programs and others are adequate for the patient's needs. Secondly, telehealth may improve peoples' ac-

telehealth may improve peoples' acceptability of health services

ceptability of health services because they are able to have increased choice of health care providers. A third dimension of access is the actual geographical accessibility in that previously the remoteness of a patient's location meant that there was not the opportunity to use certain health services or, patients had to travel long distances for those services. Telehealth has changed this situation by improving equity of access and reducing travel costs. We must be careful however not to use telehealth as a means by which we solve the problem of acute shortages of doctors and nurses in rural and remote areas. A final dimension of how it is thought that telehealth

can address access is in its relative affordability because the indirect costs of health services can be reduced. This reduction in costs, however, has not been stringently proven as there doesn't seem to be agreement as to whether it is just the cost of the delivery of the health care services that should be measured or whether such parameters as outcomes and the advantages to the patient of not having to travel long distances, should also be included.

Potentially Contentious Issues in Telehealth/telemedicine

There are many issues with telemedicine and telehealth that pertain to the transfer of sensitive information and these need to be discussed. These include the standard of the technology, the privacy and confidentiality of personal information, informed consent and the costs. There is also the issue particularly pertinent to telemedicine regarding the relationship between the patient who is the recipient of the treatment, the primary doctor and the doctor from whom the specialist knowledge, guidance, and expertise is being sought.

The standard and reliability of the equipment used is a practical issue and one where the highest possible benchmarks should be maintained. Ownership of the different pieces of equipment needs to be well defined and understood by all so that if there is an equipment breakdown it is easily determined who is responsible for fixing it.

Privacy and confidentiality issues in telehealth certainly need to be ac-

the privacy and confidentiality of personal information

knowledge and addressed as information can potentially be sent all over the world. Even just within hospitals and doctors' surgeries more and more information about patients is being stored electronically so there needs to be some lo-

cally universal security precautions. Privacy is related to individuality and autonomy. What other people know about us depends on how much we wish to share about ourselves. To an extent our vulnerability can be protected when we decide how much, and to whom we wish to share information about ourselves. As telehealth services also involve the transmission of this information across long distances and across geographical barriers and may involve the public and private sector, the protection of patients' privacy must be guaranteed and the mechanisms by which this happens must be understood and maintained by all involved in accessing the information. Patients need to be able to trust a health care system to keep highly personal and sometimes sensitive information about them, confidential. Otherwise, trust, which is a crucial factor in the relationship between the patient and the professional providing the health care, is undermined.⁵ There also needs to be a guarantee of the integrity of the information. Written patient records can be authenticated using a signature and date. Electronic records would have to be authenticated as well and this may entail the use of passwords, digitally signing the document and electronically time stamping any changes or additions. The requirements of informed consent for telehealth or telemedicine

guarantee of the integrity of the information

should not be any different than for any health procedure. According to Bruce Swanson, 'in telehealth services the key point is that the patients understand the telehealth procedures and its limitations. Verbal consent is considered to be sufficient for the majority of video-consultations. Written consent is recommended where there is a surgical procedure involved, a permanent videotape is to be kept, the patient is part of a research study, or there is thought to be some significant risk attached to the telehealth service.'⁶ The patient

should have everything explained to them in language that they can understand and, in the case of video-conferencing, they should know exactly who is viewing at the other end.

The ethical and legal issues pertaining to the doctor/patient relationship and areas of responsibility in telemedicine are perhaps the most difficult ones to address. Does the distant doctor, who has no actual physical contact with the patient who is on the end of the telephone or involved in a video link up, have a doctor/patient relationship that is sufficient for them to assume a duty of care to that patient? According to Fitzsimon⁷ a 'doctor will owe a duty of care to a patient where it is reasonably foreseeable that the doctor's acts or omissions may cause harm to the patient. In a traditional doctor-patient relationship the duty arises as a matter of course through a request by the patient or an undertaking by the doctor to provide services to the patient.' It is the *status* of the relationship between the telemedicine doctor and the patient that has to be determined. Responsibility in individual consultations should be formalised and documented so that professionals at a distance know whether the person at another location is their patient, and local practitioners will know whether the distant specialist is independently treating the patient or providing an informal second opinion.⁸ By clarifying and being specific about responsibilities liability can hopefully be appropriately assigned.

Another important issue with telemedicine is the required standard of care of a practitioner. Should it be

required standard of care of a practitioner

the same as that for medicine delivered by more traditional means? The new legal issues that arise with telehealth and telemedicine will depend on the exact type of service being delivered and the extent to which the service is different from conven-

tional health care practice.

The recommendations made by Fitzsimon so that Australian doctors meet the standard of care required in telemedicine are that:

- national telemedicine technology standards be developed and equipment manufactured in accordance with such standards;
- practitioners use the technology in accordance with national protocols to ensure best practice;
- patients be informed verbally and in writing of any material risks in telemedicine, and specifically, that telemedicine may be less reliable than face to face consultations;
- risks in diagnosis, treatment or mode of delivery be specified in percentage or quantifiable terms where possible; and
- the formalisation of responsibility in telemedicine consultations includes the provision of information to patients and subsequent documentation in patient records.⁹

Health professionals have to be registered in order to practise. Registration is required so that there can be confidence that a registered per-

health professionals have to be registered in order to practise

son in a particular area of health has been appropriately trained and meets a minimum standard of competence. As states and territories may have varying definitions of what constitutes an accepted activity or behaviour for a given health care profession there may be difficulties when the activities of telehealth cross geographical boundaries. Telehealth (and related technologies) may give rise to new methods of service and treatment delivery and this may be problematic. A suggestion made by Bruce Swanson is that perhaps telehealth practitioners should be accredited and registered on a separate list¹⁰ along with their 'normal' registration so that it is known that they have specific expertise in telehealth and an accepted standard can be

achieved. According to the Report 'Health on Line'¹¹ the 'Australian Medical Association has urged a review of the present system and State governments are unanimous in calling for the development of a simple multi-State registration mechanism or mutual recognition in order to allow Telehealth to be practised across jurisdictions. The Committee has recommended that the Australian Medical Council negotiate with registration bodies in the various States and Territories to introduce a national framework of mutual recognition.' When looking at issues of negligence and the establishment of a standard of care do telehealth consultations entail a lower standard of care than face to face consultations? There may be justifications such as 'the videoconferencing may not be as effective in eliciting the patient history, the doctor may be unable to elicit the physical signs as accurately, the Xray will not have the same resolution, and hence the diagnosis and treatment advice may not be as accurate as for a face-to-face consultation.'¹² Alternatively, some doctors may be concerned that if telemedicine is considered to assist in the delivery of high quality care then if they do not use it they may be seen as negligent.

Conclusion

The use of telecommunications and information technology in health

care is increasing at an exponential rate. 'The technology transcends and is disrespectful of conventional, geographical, institutional and disciplinary borders. It redefines responsibilities and ignores traditional hierarchies. By democratising knowledge it allows new ways for consumers and health professionals to relate to each other.'¹³ Some of these changes may have many beneficial effects in improving access to health care as well as the effectiveness and efficiency of many interventions. There are, however, many issues that need to be addressed to protect the patient and health care professional. Telehealth or tele-

some of these changes may have many beneficial effects in improving access to health care

medicine changes the method or the means of delivering health care but what it delivers is really not any different from what the doctor or other health professional can provide the patient 'on site'.

ENDNOTES

¹ Dimitri Serghis, 'Time for telehealth' *Australian Nursing Journal*, 7/1 (July 1999) 16.

² B Swanson, 'Introduction to Telehealth' http://www.telehealth.org.au/discussion_papers/intro_tele.html

³ S Strode, 'Technical and Clinical Progress in Telemedicine.' *JAMA*, 281/12 (March 24 1999) 1068.

⁴ Australian National Telehealth Com-

mittee, Australian Telehealth Services Issues Paper. http://telehealth.org.au/issue_oct96/pap_cont.html

⁵ S A Alpert, 'Health care information: access, confidentiality, and good practice,' *Ethics, Computing, and Medicine*. Kenneth W Goodman, ed., (Cambridge: Cambridge University Press, 1998) 79.

⁶ B Swanson, 'Telehealth and the Law,' http://www.telehealth.org.au/discussion_papers/th&law.html

⁷ J Fitzsimon, 'Telemedicine: Negligence Revisited.' *The Australian Institute of Health Law & Ethics Issues Papers* 7 Autumn 1998, 2.

⁸ J Fitzsimon, 'Telemedicine.....', 3.

⁹ J Fitzsimon, 'Telemedicine.....', 5 - 6.

¹⁰ B Swanson, 'Telehealth and the Law,' http://www.telehealth.org.au/discussion_papers/th&law.html

¹¹ House of Representatives Standing Committee on Family and Community, *Health on Line - A Report on Health Information Management and Telemedicine*, Australian Government Publishing Service, October 1997, xiv.

¹² B Swanson, 'Telehealth and the Law,' http://www.telehealth.org.au/discussion_papers/th&law.html

¹³ <http://www-sph.health.latrobe.edu.au/telehealth/definit.htm>



Deirdre Fetherstonhaugh

Genetic Therapy and Genetic Enhancement

In this article I will consider the application of genetic manipulation techniques, which are currently available in agricultural science, as they may be applied to humans. If one day it becomes possible and we could change the genetic make-up of humans, when if ever would it be ethically permissible to do so?

Introduction

There has been a great deal of discussion surrounding genetic engineering, or manipulation, both at a practical level, such as what sort of genetic modification is possible, and at a philosophical level, when we consider what sort of genetic modi-

fications should be attempted. The practical discussions often focus on the genetic engineering that is already used frequently on both plants and animals.

Plants, including many food crops, have been genetically altered so that they are now more resistant to par-

ticular diseases, brighter in colour, larger than usual and the list of improved features goes on. Further genetic manipulation has created plants with resistance to some pesticides, insects and diseases as well as plants with improved nutritional qualities to enhance livestock productivity¹. This type of genetic ma-

nipulation, best known as germ line genetic manipulation or therapy, changes the plant and animal species permanently and the changes are passed on to future generations. I will briefly outline the basic genetic engineering techniques used on plants and animals before considering the moral acceptability of applying such techniques to humans at some time in the future. I will divide this second part of the discussion into two parts. Firstly, is it ethically acceptable to genetically manipulate a person to prevent or ameliorate disease or disability, and secondly, is it ethically permissible to use genetic technology to enhance a person's abilities?

experience with plants and animals should provide us with valuable lessons

Before continuing I wish to make it clear that in this article I am not going to discuss the ethical acceptability or otherwise of somatic-cell gene therapy, ie the treatment of just the 'body' cells. I am also not going to address the ethical evaluation of the use of in-vitro embryos that may undergo germ-line therapy. Both these concerns require articles in their own right. So the discussion here will only attempt to address the issues surrounding germ-line genetic manipulations.

Genetic Engineering in Plants and Animals

Genetic engineering involves taking genes from their normal location in one organism and either transferring them elsewhere or putting them back into the original organism in different combinations. Scientists can also take useful genes from plant and animal cells and transfer them to microorganisms, such as yeast and bacteria, which are easy to grow in large quantities. This means that products that were only available in small amounts from an animal or plant are now available in large quantities from rapidly growing microbes. One example of this technology, which

has a great benefit for medicine, is the use of genetically engineered bacteria to produce human insulin for treating diabetes.

Genetic engineering also holds particular promise for plant and animal breeders. Genetic engineering allows desirable genes from one plant, animal or microorganism to be incorporated into an unrelated species, thus avoiding the constraints of normal cross breeding. A wider range of traits is available to breeders and these traits can be incorporated more rapidly and reliably into target species than has been possible with conventional methods of breeding.

Genetic Engineering in Humans

Using the type of technology outlined above it may one day be possible to insert or alter certain genes within adults, children or embryos. While this technology is not currently available for humans it should be considered before the scientific reality races in front of adequate ethical evaluation. I will, as many writers have done, consider the possibilities raised by genetically engineering humans under two broad umbrellas. Firstly, genetic engineering as therapy and secondly, genetic engineering for enhancement.

The distinction being drawn between genetic therapy and genetic enhancement is perhaps best understood using Norman Daniels' idea of 'species-typical functioning'.² In an age of limited health care resources, species-typical functioning attempts to use a theoretical account of the design and function of an organism, in this case humans, to describe 'the natural functional organisation of a typical member of the species'. Using Daniels' idea, any actions or treatment aimed at bringing an organism to within species typical parameters is therapy or restoration, while improving on those norms is enhancement. While the distinction between therapy and enhancement based on an appreciation of normal

species functioning is not universally accepted, many writers including Glenn McGee strongly disagree with the idea³, I think it is a very useful distinction with which to begin an ethical evaluation.

Genetic Engineering

Science and medicine have long had the aim of providing cures and amelioration for disease and disability. Technology is now allowing science to turn its hand to the possibility of *preventing disease* and disability through genetic engineering. For example, one could locate the particular gene responsible for cystic fibrosis and either correct it or replace it with a 'healthy' gene. This would ensure that the person was prevented from experiencing a life with cystic fibrosis. It would also prevent future offspring of that particular individual suffering from cystic fibrosis because the gene responsible for cystic fibrosis and for passing it on to offspring would no longer exist in that individual. This kind of genetic engineering can be considered as therapeutic and is in most cases ethically acceptable because it would prevent pain and suffering. Of course, the technique used would have to ensure that no other genetic modifications occur as a result of the genetic manipulation.

Enhancements Can Sometimes be Ethically Acceptable

In general it could be argued that we as a community do not have any moral objections to adults choosing to undergo cosmetic surgery to change, for example, the shape of their larger-than-average noses. However, this might not be true if such surgery was being paid for out of a restricted public health budget. While we may think it is permissible for adults to make these decisions for themselves it is not so clear that we would willingly accept similar decisions made on the behalf of their children. One could imagine that a cosmetic surgeon might question the

appropriateness of performing nose-altering surgery on a child. While it appears that certain kinds of decisions regarding appearance, which can be considered as enhancements, can be made for children by parents such as orthodontic work (which arguably has associated health benefits), other decisions regarding cosmetic improvement raise reservations.

Genetic Manipulation as Therapy

An example may be useful to highlight the details relevant to drawing a distinction between therapy and enhancement. Let us imagine that at some time in the future it might be possible to alter or replace the gene or genes that determine a person's height. Such a breakthrough would certainly be a health benefit to people who suffer from growth hormone deficiency or similar conditions, which cause them to be short-statured adults who often have weak bones and insufficient muscle mass to live a normal healthy life. Altering the gene responsible for height or for growth hormone production would allow potentially affected people to be free from crippling and debilitating disorders.

The Same Manipulation as Enhancement

The same technique used to enable people destined to be short-statured to reach a normal height could be used to make those same people or people who would otherwise have reached an average height extremely tall. This use of genetic manipulation could produce numerous individuals with heights exceeding 2.1 or even 2.2 metres. People with these heights do exist in the population but creating individuals with such heights should not be considered as therapy and does not restore individuals to normal species functioning. While of no therapeutic value, the technique may seem appealing to parents who desire their future children to be AFL ruckmen or NBL basketball players.

Genetic manipulation used to enhance future people by altering their physical or mental capabilities raises several ethical questions. While it may seem that increased height would be an advantage this would only be the case if the child you had 'designed' to be tall actually enjoyed endeavours such as basketball. Creating people with physical capabilities that their parents value will not necessarily create happier or healthier children. Parental expectations placed on children created with specific biological advantages such as height or muscle bulk, are unfair and often limit their own choices of sporting activities, careers and life plans.

it is not the role of parents to determine children's talents and abilities genetically

Some writers have argued that using genetic technology to enhance members of the human species is no different from many other forms of enhancement that we attempt to undertake throughout our lives. However, I disagree with this idea when applied to either future offspring or to individuals themselves. Firstly, in the case of children it is not the role of parents, or anyone else, to determine children's talents and abilities genetically. While it is morally acceptable for parents to send their children to music lessons to enhance their musical ability, this should only be done so long as the child continues to demonstrate a talent and/or interest in music. (I am not considering here the need for parents to sometimes nag their children to practise their music). Most people see parents who force their children to study subjects or play sports that the child does not like as cruel and overbearing. The same would be true of parents who genetically enhance their children in ways the child does not care for, or worse still, detests. Children should be allowed to develop their own individual talents, some of which are often naturally genetically endowed, but children should not be designed with specific capabilities and then pres-

sured to perform to expectations.

Secondly, I do not think it is appropriate for genetic enhancements to be used on individuals even if they choose so themselves. It is true that we accept individuals endeavouring to better themselves in a variety of ways. We admire athletes who train rigorously to improve their performance or scholars who spend years studying in order to gain a better understanding of the universe. However, these improvements must be worked for, even though we sometimes employ tools such as caffeine supplements in order to study all night for a final exam. In other words, we must strive to achieve success and build on the talents nature has endowed us with. This is different from genetically enhancing ourselves in order to achieve better results.

Ideally we would all start out in life

genetic enhancement should not be used on individuals

on an equal playing field, with equal opportunities for improving ourselves. Unfortunately this is not the reality and some people receive a private education while others have access to specialised sport coaches or the like. The use of genetic manipulation could widen this gap. Just because we do not currently have equal opportunities for enhancement does not mean that we should create a further imbalance by allowing genetic enhancements that are potentially limitless. Genetically altering ourselves also raises questions about risks to our genetic composition, because improving one aspect of ourselves genetically could risk damaging another part of ourselves with disastrous results. This point should more so be kept in mind when considering genetically altering future generations. Genetic enhancement should not be used on individuals, even those who ask for it, because it may pose health risks that we cannot predict and also risks exacerbating the imbalance between the haves and have nots.

Conclusion

Ashley and O'Rourke reach this conclusion regarding the genetic manipulation of human beings, 'Genetic engineering and less radical transformations of the present normal human body would be permissible if they improve rather than mutilate the basic human functions, especially as they relate to supporting human intelligence and creativity.'⁴ While I agree, I remain committed to the distinction between therapy and enhancement. As a result, I think it would be inappropriate to allocate any portion of the

limited public funding available to medial research to the area of genetic enhancement research. Using genetic technology to try and improve ourselves beyond our current limits raises too many questions at this point in time to be considered ethically appropriate. However, if genetic manipulation is aimed at improving an individual so they can experience normal species functioning then it is one of the greatest benefits that medicine can provide and should be encouraged.

ENDNOTES

¹Australian Biotechnology Association, *What is genetic engineering? No. 2* (1996) <http://www.aba.asn.au>

²Norman Daniels, *Just Health Care* (New York: Cambridge University Press, 1986) 28.

³Glen McGee, *The Perfect Baby: A Pragmatic Approach to Genetics* (Lanham: Rowman & Littlefield, 1997).

⁴Benedict Ashley & Kevin O'Rourke, *Ethics of Health Care: An Introductory Textbook* Second Edition (Washington DC: Georgetown University Press, 1994) 172. †

Tracey Phelan

How to Find Out What is Morally Right or Wrong

When we try to solve moral problems we keep coming back to the question of what it is that makes an action moral or immoral. This article discusses the meaning of morality and the relevance of the notion of good to the person and to morality. We will then consider how to find out what is moral or immoral. Should we rely only on feelings or outcomes alone or should we use reason to solve our moral dilemmas?

Meaning of Morality and Ethics

Morality and ethics have had much the same meaning, the former having a Latin and the latter a Greek derivation. Of late the term ethics is used more for professional and public life whereas morality, while retaining a broader meaning, is used by some to refer more to private life. As rationally self-conscious and free beings we are moral agents in every sphere of activity — at home, at work and in the community. Hence, individuals are personally responsible for whatever they do in their private, professional, social and public lives.

Morality considers a human action from the point of view of whether or not it befits the dignity of the human person and contributes to the true good of the person(s) affected by that action.¹ One may be an ethical doctor but an immoral person if one is unfaithful to one's married partner.

Something definite and unambiguous is understood when we say that an action is immoral even if we differ in what concrete actions we regard to be

immoral. An immoral act degrades the person performing it because it is contrary to the good of the person. A proposed immoral action generates a moral obligation to avoid it. This obligation is derived from our understanding of what is contrary to the good of the person(s) and serves a summons on our free will to avoid it. There is an absolute and unconditioned necessity to avoid an immoral action, no matter what the consequences are. Race based killing is immoral for all people and cultures.

Statements about a moral issue may be true or false. Some say that surrogacy is always morally wrong while others say it may be morally permissible in some cases. These different moral evaluations of surrogacy show that moral truth is at stake. If we really thought that there were no moral truths there would be no point in arguing about the morality of issues that arise. We inquire about others' likes and dislikes in food, but we do not try to prove they are true or false, right or wrong.

True Good and Moral

Necessity

The notion of good is pivotal for the whole of morality and ethics. Its meaning is not derived from another notion because *good* is a basic or primary notion. For the moral evaluation of actions, good is related to the concept of the human person(s) affected. *Good means good for the person* and this includes a reference to the person's purpose, which in turn depends on their inherent nature. What is truly *good for a person* is also a *good of the person*.² Pope John Paul II referred to the 'goods for the person' which serve the 'good of the person': the good, which is the person's perfection. These are the goods safeguarded by divine laws, which contain the whole natural law.³

This is why *good must be done*, and what is *not good must be avoided*. Moral necessity results from an inability to approve the deliberate and intentional performance of an action, which is known to be contrary to our true good as persons.

It is the true integral good of human persons that provides the foundation

and ultimate *rationale* for morality. Acting in an authentically human way is a requirement of being true to ourselves as persons. In this sense morality is not an outside imposition on human freedom or ourselves.

Believers in God can take the foundations of morality further. They

it is the true integral good of human persons that provides the foundation and ultimate rationale for morality

believe that the true good ultimately depends on God's design in creating us with our nature. We are endowed with a nature and a personal dignity from our conception as human individuals.

Having shown that immorality concerns what is not good and that all should avoid it, it is now a matter of turning our attention to consider how to find out what is good and what is bad, what is right and what is wrong. In other words, we are looking for the *criterion of morality*. I shall touch on two ethical theories before giving my own view.

Emotive Theory of Ethics

Firstly, moral discourse often includes our emotional attitudes of approval or disapproval of particular actions. This is not surprising when we think that our senses, feelings and emotions are an integral part of the human person and are closely linked to human knowledge. Feelings usually signal our first positive or negative response to an action. The philosopher A J Ayer first popularised the expression of emotional attitudes of approval or disapproval of acts with their morality in what is known as the *emotivist theory of ethics*.⁴ On reflection, however, we realise that our emotive attitudes for or against some kinds of actions are the consequence of our recognition of the moral status of these actions. Our feelings and attitudes do not consti-

tute the morality of an action. There is a residue of meaning for some actions that cannot be reduced to our emotive attitudes. It is precisely in this residue that the meaning of morality is to be found.

Utilitarianism

The second theory is *consequentialism*, according to which the morality of actions generally depends on their consequences. One form of this is known as *Utilitarianism* and is quite prevalent in our culture and public life. *Classical utilitarianism* holds that whatever promotes the greatest utility or pleasure for the greatest number with the least pain to the fewest is the morally right thing to do.⁵ This theory does not just expound selfish individualism as it has universal applicability. Peter Singer has recently improved classical utilitarianism by reformulating it:

'I ... begin to think ethically, to the extent of recognising that my own interests cannot count for more, simply because they are my own, than the interests of others... I must choose the course of action that has the best consequences, on balance, for all affected.'⁶

It is to be noted that interests are to be understood broadly to include whatever people desire. Singer believes the utilitarian position represents the bare minimum — the first step to be taken to avoid being locked into a selfish and egoistic perspective.⁷ He admits there is also scope for self-interest and the seeking after happiness; by living ethically we further our best interests.⁸ Singer does not claim utilitarianism is the only ethical theory consistent with a universal ethical point of view. He admits one based on 'justice' could be equally acceptable.

Utilitarianism has its rightful place as a secondary, but not the basic, criterion of morality. To be moral,

we often have to subordinate our interests to the benefit of others. The basic criterion of morality, however, relates to the true good of the agent before any calculations are made about the beneficial effects an act may have for others. A person's obligation to others derives from the duty to be true to oneself in the light of our neighbours' needs. This is so because a person's rational and social nature requires due attention be given to the interests of other persons, and for that matter, of animals as well.

It may be asked how can a person's interests be evaluated when others' interests are not relevant or when several agents' interests coincide? Is there a criterion for personal morality? Interests do not exist in a vacuum. How could interests alone be the criterion of their own ethical value? Could interests be of ethical significance when their subject is disregarded as the foundation of value? Surely, the human individual as the subject of interests is the *foundation* of their ethical value.

For Singer human fetuses and newborn infants enter the moral equation only when they can feel pain, not because they are persons. Once no allowance is made for a rational human nature as the foundation of a person's subjectivity, objective dignity and absolute value, it would not be possible to hold that a newborn infant could be a person prior to experiencing some minimal rational self-conscious acts. A utilitarian like Singer is open to these criticisms because he does not admit there could be a non-material life-principle for a human individual.

Right Reason — Criterion of Morality

We intuitively know the basic and underived first moral principle — *good is to be done and what is not good (bad) is to be avoided*. Intuition has its importance but it alone cannot be the basic criterion of mo-

rality. Difficult moral problems require reason to justify and explain the solutions given. Reason seems to be the basic criterion of moral truth because it alone has the capacity of performing the complex task of analysis, comparison and evaluation required of the criterion of moral truth.

Many people spend much time reasoning on moral problems but they do not always come to the same conclusions. They cannot all be right if there are disagreements. This is why *right reason* has been traditionally adopted as the criterion of objective morality. This implies reason has to be employed with a suitable method and in an appropriate framework in order to be rational and reasonable. This requires that its use be comprehensive and logically consistent. We need to bear in mind that the concept of the human person is the *referral point* for the moral evaluation of all acts with respect to the true good of all persons affected.

When human actions are morally evaluated, it is presupposed they are performed knowingly and voluntarily. When we say it is unethical for a health professional to give a patient an overdose of medication, it is taken for granted that the action which is contrary to the true good of the patient is performed deliberately and intentionally. Circumstances and additional motives may change, but the variations are assumed to be morally irrelevant from the unethical act, say, 'of removing a healthy organ from a patient'. It is the normal situation that is presupposed when we say this is unethical. But the life-

saving removal of a healthy organ may be ethical if it prevents the spread of disease. In a case of prostate cancer, castration would be ethical to prevent the production of hormones in the blood, that could spread cancerous cells throughout a

***right reason is able to discern
that some acts conflict with the
good of persons***

man's body.

In the light of persons' essential nature, integral human experience and important relationships such as marriage, *right reason* is able to discern that some acts conflict with the good of persons and judges them to be bad.⁹ If the immorality of an action does not derive from factors extrinsic to the action, such as custom or others' opinions, it is said to be intrinsically wrong or bad. The deliberate bombing of civilian populations and the torturing of young children are examples of immoral acts that could not be justified under any circumstances. There is, however, no need to put all intrinsically bad acts on the same footing. Some bad actions are more serious than others, like the undue withdrawal of a life-support machine compared to failure to obtain adequately informed consent before treatment of a patient. An appreciation of degrees of immoral actions is important for the mental health of people.

On account of our social nature there is an obligation to positively promote the common good. To some extent we are subordinated to the common good without being reduced to the status of mere means for its

achievement. Each person has an absolute dignity that transcends the social order and the requirements of the common good. We should act responsibly in regard to others the community and ourselves. We may be obliged to make sacrifices of time, energy and money for others and the common good but we may not sacrifice our personal dignity by doing bad actions for the benefit of others. It would be unethical for health professionals to perform abortions on fetuses who have been diagnosed with congenital abnormalities just to comply with the parents' wishes or to adhere to policy agendas that encourage cost saving by reducing the number of babies born with disabilities.

ENDNOTES

¹ Norman Ford SDB, *Live Out the Truth in Love: From Moral Philosophy to Gospel Morality* (Melbourne: Catholic Education Office 1991) 13-35.

² Norman Ford, 'Making Morally Responsible Decisions.' *Chisholm Health Ethics Bulletin* 3/3 (1998) 10-12.

³ John Paul II, *Veritatis Splendor, Acta Apostolicae Sedis* (1993) N.79, 1197, a literal translation of the Latin text; *Veritatis Splendor*, Encyclical Letter (Homebush: St Pauls, 1993) 124.

⁴ A J Ayer, *Language, Truth and Logic*, 2nd. Ed. (London: Victor Gollancz 1946) 107-108.

⁵ Jeremy Bentham, *Introduction to the Principles of Morals and Legislation*, Ch. 1-56. 22.

⁶ Peter Singer, *Practical Ethics*, 2nd. Ed. (Cambridge: University Press, 1993) 13.

⁷ *ibid.* 14.

⁸ *ibid.* 326; 334.

⁹ Norman Ford 'The Human Person and Life's Journey.' *Chisholm Health Ethics Bulletin* 2/3 (1997) 10-11. †

Norman Ford SDB

Caroline Chisholm Centre for Health Ethics

7th fl., 166 Gipps Street East Melbourne Vic 3002

Tel (03) 9270 2681

Fax (03) 9270 2682

email: ccche@mercy.com.au

Copyright © Caroline Chisholm Centre for Health Ethics Inc. 1999

Subscription fees: Single - \$25.00; 5 subscriptions - \$80.00; 10 subscriptions - \$120.00; Overseas [single] - AUD\$35.00

Director/Editor:

*Rev. Norman Ford SDB STL PhD,
Adjunct Professor, Australian Catholic University*

Research Officers:

*Deirdre Featherstonhaugh DipAppSc PGCert BA MA
Tracey Phelan BSc BA(Hons) MBioeth*

Administrative Assistant/Layout/Sub-editor: *Margaret Casey BTheol*