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The Changing Face of Australian Health Care

Part One: Corner Store to Supermarket

This article considers the major changes to Australia's healthcare system, especially the corporatisation of general practice. It also includes a discussion of the relevant ethical issues for the community.

In the years since the introduction of Medibank and its eventual transformation into Medicare, we have witnessed a great amount of change in health care in this country. It is not so long ago that the picture of health care in Australia was that of public hospitals, private not-for-profit hospitals, mostly run by religious orders or other charities. Visiting the doctor usually meant going to the family doctor who practised either on his/her own or with one or two others in a local surgery. But considerable changes to general practice took place with the move to 24-hour clinics and the shift from simple brass plates to major advertising. Sydney people will remember the early 1980s and the coming on the scene of Dr Geoffrey Edelsten and the fuss about grand pianos in the waiting rooms of his new clinics.

Last August in the Health Report on Radio National, Norman Swan and Geraldine Doogue made a joint broadcast entitled 'The Big Business of Medicine'. In a 90-minute program they examined the interaction of business and medicine on the Australian scene. Among their guests were leading health professionals, policy analysts and business commentators as well as Dr Michael Wooldridge, Federal Health Minister and Jenny Macklin, the Opposition spokesperson for Health. The program examined the impact of large corporations buying up and integrating large parts of the health system, from pathology and radiology to general practice, pharmacy and private hospitals.[1]

This paper will examine the corporatisation of general practice and some of the ethical issues it raises. This is not to imply that all aspects of

"There are many issues to be addressed with the prospect of radical changes to what we know as traditional family medicine."

FEATURING

corporatised general practice are negative, but it does suggest serious questions for community discussion. A second paper will look at the impact of corporatisation on hospitals, nursing homes, the moves towards vertical integration of the health system, and the impact of this on the quality of health care in this country.

Corporatisation of general practice

This usually involves doctors entering into agreements with companies who provide them with the use of consulting rooms and practice-management services in exchange for a percentage of their income (often 50%). In most cases doctors are not employees of the company but retain their independence. The consulting rooms are usually in a medical centre, along with other specialists and facilities such as dentistry, pharmacy, physiotherapy, and pathology collection. Such a grouping clearly has advantages for doctors and patients.[2]

as well as the financial costs of running a general practice, there is the stress of continual work and the need to keep up to date with medical developments

For years we have heard complaints about the difficulties of general practice and how hard it is for the average general practitioner to make an appropriate income. The costs of running a practice are quite high. There is need for proper administration and record keeping. Bulk billing of Medicare patients has its advantages, but it also imposes considerable costs of compliance, to say nothing of the fact that payments to the doctor are capped. Computerisation is a great boon, but it requires properly trained staff. Any general practice is a small business and requires good business skills. The doctor has to manage human relations of staff, payrolls, superannuation, insurance costs which are huge and rising. The technological advances of medicine in terms of medication, drugs, radiology and pathology impose new demands. But as well as the financial costs of running a general practice, there is the stress of continual work and the need to keep up to date with medical developments. For many in small practices, especially in rural areas, this imposes huge demands on doctors and their families. According to Dr Nathan Pinskier, Chairperson of the RACGP's National Practice Management Committee, it is very hard for solo practice to survive in the current decade. To ease the burdens many doctors moved into small group practices, but this is not always possible and does not resolve all the issues.

Beth Quinlivan estimates that 'a bulk-billing general practitioner wanting to generate an after-expenses but pre-tax income of $130.000 (assuming the cost of running the business is taking 35% of revenue) needs to conduct 37 standard consultations a day, five days a week, 48 weeks a year. In other words, one patient every 11 minutes, seven hours a day, with public holidays and a few weeks off over Christmas.'[3]

So when corporations come and make an offer for the practice, it can be seen as a perfect solution. The corporation will provide trained staff and administration. The doctor will be free to concentrate on patient care. Of the more than 6,500 general practitioners in Australia a growing number are signing contracts with health care corporations.

The corporate presence

If there is no real money to be made in general practice why would corporations be interested in buying them? The returns are not from the general practice as such, but in the opportunity provided by having access to patients. General Practitioners are the gatekeepers. They are the one who prescribe medication, order pathology tests or refer to specialists and to radiology. And it is here that the real money is to be made. This explains the desire of corporations who run radiology and pathology businesses as well as hospitals and nursing homes to gain access to the doctors' patients. There is not much use in setting up a pathology business unless one can encourage doctors to use it by referring patients. They are tapping into the food chain.

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As a result corporations like Mayne Health, Endeavour Health Care, the Gribbles Group, Sonic Healthcare, Revesco, and Foundation have moved quickly to sign up general practitioners and specialists for their medical centres. They are bringing their entrepreneurial expertise to the health market. They are expanding their business and will eventually make a considerable impact on Australian health care. Already in Western Australia nearly 50% of general practitioners are signed up to corporates. In the other States the percentages are smaller.

The AMA outlined its key concerns about corporatisation as: 'The potential loss of capacity of doctors to maintain clinical independence, the potential for corporate priorities to influence the ethical standards of doctors, the potential for corporate interests to influence the volume and direction of referrals and the tension between the role of the profession (meeting the needs of the patient) and the objectives of corporatisation (meeting the needs of shareholders) and the implications for professional control of quality and standards'.[4]
In recognition of the concerns raised by corporatisation, some of the

companies involved drew up a Code of Conduct for Corporations Involved in the Provision of Management and Administrative Services in Medical Centres in Australia. It seeks to address, among other issues, that of clinical independence of doctors. It was published on November 1, 2001, but so far only two companies have signed it.

Ethical issues

The changing face of general practice in this country raises some interesting ethical questions because of a possible change of values. This is not to say that the corporations are not ethical. It simply means that they come from a different perspective than that of traditional medicine.

Underlying values

Arnold Relman, the former editor of the New England Journal of Medicine, wrote about the effect of market forces on the practice of medicine in America:

> 'From its earliest origins the profession of medicine has steadfastly held that physicians' responsibility to their patients takes precedence over their own economic interests. Thus the Oath of Hippocrates enjoins physicians to serve only "for the benefit of the sick," and the oft-recited prayer attributed to Moses Maimonides, a revered physician of the twelfth century, asks God not to allow "thirst for profit" or "ambition for renown" to interfere with the physician's practice of his profession.'[5]

He goes on to argue about the importance of distinctions between medical practice and commerce. Medicine is based on the implicit trust that patients have in the doctor doing what is in their best interests. Commerce on the other hand works on the assumption of 'buyer beware'. The doctor acts as patient advocate and counsellor. In commerce, market competition is supposed to protect the interests of consumers.

George Soros reaches a similar conclusion in an address to Columbia University College of Physicians and Surgeons:

> The marketplace is threatening medicine in very specific ways. Clinical care is now dominated by for-profit corporations that place the interest of shareholders above the interests of patients and often disregard the ethical obligations of doctors. Health care companies are not in business to heal people or save lives; they provide health care to make profits. In effect, in the necessary effort to control health care costs through the market mechanism, power has shifted from physicians and patients to insurance companies and other purchasers of services.[6]

the fear is that once market forces take over medicine, economic factors might take precedence over medical considerations

In and of itself the profit motive will not necessarily have a negative impact on care. Doctors have always had to make a living, and while altruism has often been practised, it is not a necessary requirement. The fear is that once market forces take over medicine, economic factors might take precedence over medical considerations. Management can request or influence doctors to adjust treatment for the sake of profits. It seems there is a danger of the intrusion of market forces into health care in this country.

While not making any judgement on the individuals involved, the background of the companies and their leaders provides food for thought. Mayne Nickless is a transport giant. It is now headed by Peter Smedley, former chief executive of Colonial Bank. Revesco until a few years ago was a defunct gold mine called Kiwi Gold. Foundation Health emerged from the shell of a failed technology company. They have been schooled in the search for better profit margins. It is the responsibility of executives of public companies to focus their attention on returns to the shareholders. That focus may not always coincide with the demands of patient care. It is simply a question of different underlying values.

Doctor-patient relationship

The intrusion of a third party into the traditional doctor-patient relationship brings with it the need to attend more carefully to the needs of the patient. Traditionally, doctors have seen themselves as patient advocates and carers. Will their loyalties be divided between the interest of the patient and the interest of the company? Will the doctors lose clinical independence in the way they manage particular patients? Let us hope we never reach the stage of a recent case of a woman in the USA who sued her doctor only to lose the case and then learn the court ruled that under a Managed Care Plan the doctor's duty to maximize profits legally outweighs his or her duty to the patient.[7]

Equity

We have seen what happens when banks decide to close branches for the sake of efficiency or profits. Will the future of corporatised general practice lead to the closure of less efficient centres? This might well mean greater hardship or disadvantage to the elderly and infirm. Doctors working in a centre would be aware of the economic performance of the centre through regular briefings from the managers. There will be a temptation to look for higher paying patients. It could lead to a concentration of medical centres in higher-income suburbs.

Quality of care

Will care for the individual patient suffer because of the need to be more efficient? Already this happens in some cases because of pressure for throughput of patients due to time constraints. The elderly, the chronically ill, those with sick children and those with language difficulties all require more time than the average. Continuity of care is another important factor. The disappearance of smaller practices could result in a greater difficulty in establishing an on-going relationship with a particular doctor. Patients may simply have to deal with the rostered doctor rather than the one of their choice.

Alternatives to corporatisation

If small general practices are no longer really viable in many cases, and if we are worried about the move to corporatisation, there is a need to find some alternative. One such alternative is being promoted by the Hunter Urban Division of General Practice with moves to provide a wholly GP owned cooperative.[8] The aim is to provide support and co-operation for doctors and greater efficiency for their practices, while allowing them to maintain their independence in being able to act in the best interest of their patients. To date they have supported doctors with information technology, evidence based best practice recommendations, and in providing the best immunization rate of any region in the country for children. Such co-operatives might be able to take a stand for greater independence from the corporate giants.

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Conclusion

On the assumption that corporatisation of general practice is here to stay, it is important the issues it raises be discussed more widely in the community. It is important that we gain the benefits offered by more economically efficient medical practice and avoid the pitfalls of a system driven by an excessive economic rationalism.

ENDNOTES

[1] http://www.abc.net.au/rn/talks/8:30/helthrpt/stories/s353637.htm
[2] B Quinlivan, 'Strategy: Corporate medicine', *Business Review Weekly* 22/38.
[3] ibid.
[4] AMA, *Scoping Paper on General Practice Corporatisation*, General Practice Department, September 2000.
[5] A Relman, 'What Market Values are Doing to Medicine', *The Atlantic Monthly* March 1992.
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The Pharmaceutical Benefits Scheme and Some Difficult Decisions

This article looks at the difficult decisions faced by the Pharmaceutical Benefits Scheme.

The Pharmaceutical Benefits Scheme (PBS)

I will not discuss the PBS in depth here because I have previously outlined how the PBS operates detailing such things as: how the PBS was established, who is eligible for the PBS, how much medicines are subsidised, formulas used to calculate patient co-payments and the increasing cost of the PBS.[1] In this article I will examine what criteria are used to determine which new medicines are listed on the PBS (that is, will be publicly subsidised) and how the different sub-committees play important roles. I will also look at the part drug companies play in promoting consumer use of medications. These issues are all critically important, as the cost of the PBS had already exceeded $4 billion a year (financial year 2000-01).[2]

The annual cost of the PBS is a concern as the government's health budget cannot be limitless and money spent on the PBS may eventually be cut from other programs or health resources. It is also important to note the cost of the PBS is growing rapidly. From the financial year 1999-2000 to 2000-01 the cost of the PBS increased 19.2%. This increase in cost cannot entirely be explained by an increase in prescriptions because during the same period the number of prescriptions the PBS dealt with increased only 7.2% to 148.1 million.[3] The cost of the PBS will be unsustainable if it continues to rise at this rate, so ways to limit or prevent such dramatic increases must be found to ensure the financial viability of this very important scheme.

How are funding decisions made?

All medications seeking to be funded as part of the PBS go through a fairly rigorous investigation process. Firstly, the manufacturer (drug company) makes a submission to the Pharmaceutical Benefits Advisory Committee (PBAC). Every new medication made available on the PBS must have committee recommendation. The PBAC must consider the new medication's effectiveness, its potential cost to the PBS and its benefits compared with alternatives. The committee is also responsible for recommending maximum quantities of drugs, number of repeats available and can restrict the indications for PBS subsidy. The PBAC meets only four times a year and will only consider medications for subsidy after they have been registered as a new medicine by the Therapeutic Goods Administration (TGA).

the cost of the PBS will be unsustainable if it continues to rise

The PBAC has several sub committees that also provide assistance in evaluating drugs for subsidy the Economic Sub-Committee and the Drug Utilisation Sub-Committee (DUSC). The role of the economic sub-committee is to review and interpret the economic analysis of a medication and advise the PBAC. Their role has become increasingly important as the cost effectiveness of medications has become even more influential in decision making as drug costs soar. While this committee's influence is important it should be noted that the uptake and use of a medication cannot always be accurately predicted, as was the case with the popular arthritis drug Celebrex. The PBS estimated that Celebrex would cost $40 million in 2000-01 but instead the cost blew out to $160 million.

The drug utilisation committee collects data on drug use for the PBAC, they make inter-country comparisons on drug use and generate information regarding the rational use and prescribing of medications. In other words they examine if the appropriate medications are being prescribed in the appropriate situations. Large amounts of money can be wasted on inappropriate use of medications. Doctors need to prescribe the best medications for a situation and patients need to understand how their medications are to be taken or else the entire exercise is useless. I will discuss later the possible influence drug companies have on prescriber as well as consumer behaviour. Both the economic and drug utilisation sub-committees play a pivotal role in helping the PBAC do its work.

After the PBAC decides to recommend a drug be listed on the PBS the Pharmaceutical Benefits Pricing Authority (PBPA) recommends a price range for the medicine to the Minister for Health and the final price is then negotiated with the manufacturer. The PBPA also review the price of already listed medications on an ongoing basis. The Minister for Health receives the recommendation from the PBAC on medicines to be listed on the PBS and then makes the final decision and where necessary, for new drugs expected to cost the PBS unusually large sums, seeks Cabinet approval[4].

What influences PBAC decisions?

The PBS was originally established in 1948 to provide access to 139 life saving and disease preventing drugs to people who otherwise would not be able to afford them.[5] 'Since then, the purpose of the scheme has widened to provide timely, reliable and affordable access for the Australian community to necessary and cost effective medicines.'[6] In the beginning funding of life saving and disease preventing medications seemed logical and useful criteria. However, with the various types of medications available today we can no longer draw such a simple distinction. As of 1 November 2001 589 drug substances, available in 1458 forms and strengths and marketed as 2,459 different drug products (brands), are currently listed on the PBS schedule. This is a dramatic increase in a relatively short period and it is important to note that not all TGA approved drugs are funded.

cost effectiveness is not the only criterion used to evaluate drugs

Once the simple criteria of life saving and disease preventing became insufficient to decide which drugs should or should not be subsidised many medications which could prove their medical effectiveness were approved for PBS subsidy. Many might argue that only life saving or disease preventing medications should be funded but that would exclude many pain reducing drugs that improve many people's quality of life and keep thousands of people out of hospital.

One of the main criteria used to evaluate drugs for PBS listing today is cost effectiveness. Drugs must be able to prove not only that they can be effective in treating a particular disorder but they do so better and at a cost equivalent to currently funded medications or as effectively, but for a reduced cost. Decision-making based on cost effectiveness led the PBAC to establish another sub-committee in 1993 the Economic Sub-Committee (ESC). The role of the ESC is to review and interpret economic analyses of drugs submitted to the PBAC, advise the PBAC on these analyses, and to advise the PBAC on technical aspects of requiring and using economic evaluations. Obviously cost effectiveness is not the only criterion used to evaluate drugs but as the cost of the PBS to the community continues to grow the

work of the ESC will become increasingly significant.

Should all drugs that improve quality of life be funded?

With an ageing population Australia needs to assess whether all drugs which improve quality of life should be considered for PBS funding. Currently worldwide there are nearly 1000 medications under development designed to lengthen life and improve the quality of life for older Australians.[7] One can only imagine the impact to the PBS as these drugs seek subsidies. Drugs such as Viagra have raised further questions about which drugs 'deserve' funding. It could be argued that Viagra improves quality of life and hence should be funded the same as analgesic drugs which help people to continue to live normal lives. Unfortunately, while funding Viagra for everyone who would like it may not be a huge expense in terms of the entire PBS budget it may be only the beginning of a new wave of drugs that with a limited budget we should not fund. This may be the beginning of the development of new criteria for funding. Perhaps we should look at 'need' or at medications that help people maintain or regain normal functioning.

If we use the idea of maintaining or regaining normal functioning as a guide and consider a drug such as Viagra we may find it appropriate to fund it in certain situations but not others. In other words perhaps it would be appropriate to subsidise Viagra for patients with spinal cord damage or multiple sclerosis but not for patients who have penile dysfunction in old age. This distinction may need to be made for other medications, that is, they may be appropriate for some groups of people but not others. This kind of distinction is currently made in the case of some drugs but perhaps it needs to be extended in order to contain the cost of the PBS. Another strategy may be to remind doctors of appropriate prescribing practices and to reinforce their obligation to only prescribe PBS subsidised medications for people who meet the prescribing criteria set by the PBS. Although it can be difficult, doctors should base their prescribing habits on what they consider is most appropriate for a patient, not what drug companies may suggest or what the patient requests or demands.

Advertising prescription medication?

One further way to perhaps reduce the cost of the PBS is to consider restricting (or aim at reducing) the media hype surrounding the release of new drugs. The promotions of 'wonder drugs' can often lead to patient demand for new medications that may be more expensive but no more effective than the medication they are currently taking. The blackout ban on wonder drugs is an idea put to the health minister by doctors. They feel that it would allow them time to evaluate new drugs before patients make demands and to gain independent information about the drugs rather than relying solely on pharmaceutical company promotions.[8] Recent examples include the anti-smoking drug Zyban and the anti-arthritis drug Celebrex which were involved in big cost blowouts associated with the vast positive press they received.

it is imperative that PBS spending be brought under control

If doctors believe this is one way of helping to prevent another blow out in the PBS budget perhaps it is worth a try. It should not be up to drug companies to entice patients to seek particular drugs. Medical professionals need time to reflect on new drugs and consider for whom they may be appropriate before they have patients demanding that they be prescribed new 'wonder drugs'.

Conclusion

The PBS is only one of four elements of a national medicines policy framework. 'The other elements are: supply of medicines of acceptable quality, safety and efficacy; quality use of medicines by providers and consumers; and maintenance of a viable pharmaceutical industry in Australia.'[9] It is imperative that PBS spending be brought under control before we risk being unable to fund the very life saving and disease preventing drugs the scheme was established to fund. It will not be easy because as a community we have come to expect a great deal form our health system. Tighter restrictions on the indications for prescribing and or funding medications may be one way of limiting spending. Drugs should aim to restore normal functioning and aim to improve quality of life to a 'normal' level, not to replace functioning lost due to the natural ageing process. Avoiding media hype would also be a valuable measure in restricting spending but further steps may need to be taken including assessing access to health care cards.

ENDNOTES

[1] Tracey Phelan, 'The Pharmaceutical Benefits Scheme (PBS): Is it Equitable', *Chisholm Health Ethics Bulletin* 5/4 (2000).
[2] Cost to Government of Pharmaceutical Benefits, PBS website, http://www.health.gov.au/pbs/pbs/phbeninf.htm Accessed 26/02/02.
[3] Ibid.
[4] Pharmaceutical Benefits Scheme – Reference Guide. Pamphlet prepared by the Health Insurance Commission. (Administrators of the PBS)
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[6] Australian National Audit Office, Pharmaceutical Benefits Scheme Audit Report No.12, tabled 13/11/1997.
[7] Prescription medications and an ageing population – Statement by the Australian Pharmaceutical Manufacturers Association 28 October 2001.
[8] John Kerin 'Doctors urge ban on drug firm "hype".' *The Australian* 20 February 2002.
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From Human Transplants to Xenotransplants

This article briefly explains the range of scientific and ethical considerations that arise in xenotransplantation. Though the ethical focus is on human subjects, due attention will also be given to the ethical requirements of creating and using transgenic animals for xenotransplants to humans.

Human transplants

Human transplants have been successfully performed for many decades, from live as well as from deceased donors. For a living person to give an organ to be transplanted to save, or improve the quality of life of another is a sacrificial act of heroic love. It is necessary to ensure that the donor is not left incapable of satisfactorily discharging their own personal, family and other social responsibilities. Pope John Paul II in his address to the *International Transplantation Society* supported the ethical donation of organs for transplants: 'Increasingly, the technique of transplants has proven to be a valid means of attaining the primary goal of all medicine – the service of human life. ... That is why in the Encyclical Letter *Evangelium Vitae* I suggested that one way of nurturing a genuine culture of life "is the donation of organs, performed in an ethically acceptable manner, with a view to offering a chance of health and even of life itself to the sick who sometimes have no other hope".'[1]

Xenotransplantation

In recent years, however, the supply of donated organs has not met demands. This has led in some countries to the commercialisation of organs for transplants, even to the point of poor parents selling their organs for a high price in order to support their children. These practices are unethical. It became necessary to seek alternative sources of suitable organs. Hence it was decided to seek an alternative solution and it was suggested to consider the possibility of recourse to *xenotransplantation*, ie inter-species transplantation of organs, tissues and cells.

problems included rejection by the recipient's immune system, the risk of introducing animal viruses into the human and the need to ensure that animal organs and tissues would function adequately across species barriers

The Vatican's *Pontifical Academy for Life* convened a committee of eminent scientists and ethicists, with Bishop Elio Sgreccia as its chairman, to study xenotransplantation. In this article I shall rely much on its report, *Prospects for Xenotransplantation, Scientific Aspects and Ethical Considerations*, which is an excellent document published late in 2001.[2] Early transplant trials on humans using the organs of primates did not result in long-term success. The scientific problems have been identified and need to be solved.[3] The problems included rejection by the recipient's immune system, the risk of introducing animal viruses into the human and the need to ensure that animal organs and tissues would function adequately across species barriers after transplantation into the human. It was imperative to experiment on animal models to improve the immunosuppressive agents used. The pig proved to be an ideal animal model for such trials because its organs are the right size for adult patients and pigs are readily available.

Transgenesis

Transgenesis involves modifying the genetic make-up of an animal by the introduction of one or more genes. This can also be done by 'knocking out' one or more endogenous genes, ie those within an animal, so that these genes become inactivated, ie not expressed. Transgenesis is normally achieved by using a single-cell animal embryo. The successful cloning of pigs by nuclear transfer made it possible to genetically modify the genome of a pig embryo by the insertion of a new gene(s) into the pig's nucleus or by knocking out pig genes that would cause rejection after a transplant to a human. Cloned transgenic pigs would pass on the genetic modifications through future offspring and thereby reduce risks of rejection of any transplanted tissue or organ of such pigs. It would also be necessary to eliminate or reduce any significant risk of transmission of infectious agents from one species to another.

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Precisely what infectious agents need to be eliminated, and the appropriate genes to 'knock-out' or insert are not yet definitively known. This all takes time and needs further research. It is suggested that pig transplants to non-human primates should survive routinely for 90 days before starting clinical trials for humans. Clinical transplant trials of cells from transgenic pigs show promise, but need to improve before using transgenic porcine cells in clinical practice.

Ethical issues

Human beings are created male and female 'in the image and likeness of God'. In virtue of their rational nature they may intervene in the

created order in a morally responsible way for the glory of the Creator and the benefit of humanity. Human persons may use animals for their 'primary needs (food, work, clothing, etc)' since animals, lacking a rational nature, are not persons. As the Report stated: 'the sacrifice of animals can be justified if required to achieve an important benefit to man.'[5] However, in doing so, humans should not inflict unnecessary or disproportionate stress, harm or pain on these animals and due care should be taken to avoid significantly altering 'the biodiversity and balance of the species in the animal world.'[6]

the well-being of the recipients of xenotransplants requires that risks of an objective nature to patients' life and health must be avoided or reduced to an acceptable level

The well-being of the recipients of xenotransplants requires that risks of an objective nature to patients' life and health must be avoided or reduced to an acceptable level. One risk would be graft versus host disease and other infections. Any likely risks of harm need to be assessed carefully as well as the seriousness of the harm in question. A risk that is probable – and there are various degrees of probability – needs to be distinguished from one that is hypothetical, ie not theoretically impossible but practically too improbable to warrant moral significance in our choices.[7]

The taking of risks of predictable and substantial harm to the subjectivity of recipients are likewise unethical, eg running risks of altering a patient's perception of themselves as a subject with a personal identity, how a patient perceives their personality, memories, relationships and friends, appreciation of the genetic bonds they share with their children and broader family ties. For these reasons it would be unethical to transplant gonads or the human brain or significant parts of it because their specific functions, regardless of their symbolic implications, are closely connected to patients as future parents and more so their personal identity as unique persons. Pope John Paul II referred with approval to the ethical criteria given by Pope Pius XII in 1956 for a *xenotransplant* to be licit: 'the transplanted organ must not impair the integrity of the psychological or genetic identity of the person receiving it; and there must also be a proven biological possibility that the transplant will be successful and will not expose the recipient to inordinate risks.'[8]

Danger to public health

Furthermore, new infections could be introduced into the human population via xenotransplanted organs or tissues. Viruses are well known to be able to cross the species barrier. A very common example is influenza where there is a risk of horizontal spread of highly contagious airborne bird viruses which may even cause a pandemic.

informed consent must be given by all persons to participate in any experiments or clinical xenotransplant trials

Another example is *BSE* – mad cow disease, a less risky disease which only infects humans who eat the contaminated meat. There is, then, a need to balance the individual patient's benefit of xenotransplant over the potential societal cost of transmitting new infections into the community. A risk that is deemed acceptable to experts or the community does not mean it will be accepted subjectively by all patients. Prudent caution and gradual experimentation is needed in xenotransplantation and participants should be selected carefully. At the same time informed consent must be given by all persons to participate in any experiments or clinical xenotransplant trials.[9]

Protection of the genotype

Manipulations of gametes or early embryos could damage a person's *genotype*. Each person has a *unique genotype* that must never be put at risk of harm by manipulation. The genotype of each individual is morally inviolable because of its relation to the good of the person. The human formative process during, and after, fertilisation is morally inviolable on account of its relation to the constitution of each individual's *genotype*. In its turn, the genotype is fundamentally important for the constitution of the human person when a spiritual soul is created in the newly formed embryonic individual. The genotype

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does not exist alone or independently: it is an important material constituent of a human embryo, a fetus or an adult. Once the person is formed with the creation of the soul within the embryo, the whole genotype is one with the person, sharing the person's dignity and moral inviolability. In the case of monozygotic twins, for all practical purposes, their genotype is identical but the quantified matter or body of each twin is distinct.

It is well known that about 97% of human genes are found in primates. What is unique to the human genome and each person's genotype is its configuration and dynamism as a whole and its resultant expression, ie a human individual. The human genotype does not exist by itself but, in varying degrees of activation and inactivation of genes, is found in the embryo, the fetus and the adult. The genotype is more vulnerable in the early embryo, especially before its genes are activated or expressed. The integrity of a human person's genotype as a whole must be

protected from non-therapeutic interventions and manipulations.
Individual genes in the human body control the making of individual proteins whereas a whole array of genes would be responsible for complex phenotypes such as facial appearance. Thus, expression of one

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or several human genes in an animal results in changes in specific proteins but does not transfer complex human characteristics. Consequently, such individual genes have no special moral significance that would *in principle* prevent them being transferred to a pig embryo to make a transgenic pig in order to transfer transgenic tissue or an organ to a human patient by xenotransplantation.[10] Hence these xenostransplants to human patients could pose no risk to their personal identity, subjectivity nor human symbolic significance.

Resource allocation

At present recourse to xenotransplantation in clinical practice would not be cost beneficial. However, from the perspective of a research project on the way to the clinical trial phase, it seems justified to pursue this research coupled with transgenesis in view of the great therapeutic potential it has for treating patients' need of organs who otherwise could

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not receive a lifesaving transplant. We need to remember that many therapies that are certainly cost beneficial today were once queried at the research stage, eg, neonatal intensive care units.

Patents

It is generally accepted that a *discovery*, as distinct from an *invention*, cannot be patented. It seems that a transgenic animal should not be patented, but a case could be made in favour of patenting a procedure for creating a transgenic animal. In saying this, the therapeutic factor should not be forgotten so that access to xenotransplants made possible by using transgenic animals should become financially impossible for those in need of such therapies.

Practical guidelines

The insertion of human genes into bacteria is integral to molecular biology. This is how genes are cloned. This has not been ethically controversial, but the proportion of human genes in the bacteria is greater than what is done, say, in a pig. Indeed the introduction of human genes into bacteria and animal cell lines is the basis of the recombinant protein pharmaceutical industry. Many drugs used in secular and religious hospitals are made in this way, eg., human erythropoietin, a hormone which stimulates the production of red blood cells and is used routinely by dialysis patients. Likewise for the last two decades transgenic animals, especially mice, have been generated for many years without moral concerns being raised.

it would be unethical to insert a whole chromosome into a normal pig egg or embryo

In the light of what has been said above, the following *genetic modifications would be ethically permissible:*

1 The insertion of some human genes into a pig embryo. Even six genes out of about 30,000 - 40,000 human genes is very few indeed. The genes used code for very minor differences between pigs and humans, eg., the shape of proteins which control blood clotting. Surrounding DNA would consist of regulatory sequences which control when and how genes are expressed.

2 The cloning of pigs by nuclear transfer for the purpose of producing genetically identical transgenic pigs whose tissues will be suitable for xenotransplantation to humans.

3 Other human genes for insertion could include coagulation regulators and immunosuppressive factors.

The following genetic modifications would be unethical:

1 Transferring a human somatic nucleus into an enucleated porcine egg. The offspring would be a pig-human hybrid with porcine mitochondria. Such cloning, if possible, would be unethical, even if the nucleus was inserted into a normal pig egg or embryo.
2 Likewise it would be unethical to insert even half a human somatic nucleus into a pig egg or pig embryo.

"it is fitting to treat human germ cells with respect on account of the human patrimony which they bear"

3 I believe it would be unethical to insert a whole chromosome into a normal pig egg or embryo. We should not run the risk of producing human phenotypic traits in a pig, eg a pig with ears similar to a human being. This would be offensive to human dignity.

4 Again it would be unethical to insert a human sperm into a pig egg (enucleated or not) or into a pig embryo. Pope John Paul II recently gave a strong reason against this when he said (15 November 2001) in his address to the President of the Catholic Social Weeks of France: "It is

fitting to treat human germ cells with respect on account of the human patrimony which they bear." We should avoid the offence of mixing human gametes with animal gametes or early embryo and *vice versa*.

ENDNOTES

[1] *Address of John Paul II to the 18th International Congress of the Transplantation Society*, 29 August 2000, *www.vatican.va*, N.1.
[2] *Prospects for Xenotransplantation. Scientific Aspects and Ethical Considerations*, Pontifical Academy for Life, *L'Osservatore Romano*, Weekly Edition in English, Special Insert, 29 November 2001.
[3] See the excellent article by A S Daar, 'Animal-to-human organ transplants – a solution or a new problem?', *Bulletin of the World Health Organization*, 77/1 (1999) 54-61.
[4] *Prospects for Xenotransplantation*, Introduction and N. 1-6.
[5] *Ibid*., N. 9.
[6] *Ibid*. N. 9.
[7] *Ibid*., N. 13.
[8] *Address of John Paul II to The 18th International Congress of the Transplantation Society*, N. 7.
[9] *Prospects for Xenotransplantation* N. 13-14.
[10] *Ibid.* N. 11. ✣

Norman Ford SDB

REVIEW ARTICLE: *Life and Death in Healthcare Ethics: A Short Introduction*

Helen Watt, London and New York: Routledge, 2000, vii + 97 pp £7.99.

Dr Helen Watt has adopted a 'natural' philosophy approach without recourse to religious premises in the arguments she employs. This gives her book an appeal to believers and non-believers alike. Her book begins with the presentation of a well publicised case of the death of a newborn baby with Down's syndrome. The consultant paediatrician decided to comply with the wishes of the parents and ordered 'nursing care only' and very high doses of a pain-killing drug for the baby, who died a few days later. This opens the way for a meaningful discussion on euthanasia and the distinction between *killing* and *letting die*. The crucial ethical importance of the agent's intention is also discussed, both in cases of positive actions and omissions. In this case it was the morally reprehensible neglect of feeding a baby with a disability and thereby causing the child's death.

Watt rightly believes in moral absolutes and argues well against consequentialism, particularly in cases of the life and death of innocent human beings. The foundation for these absolutes is to be found in the intrinsic worth and moral inviolability of all human individuals, including babies and fetuses, with or without disabilities, as personal beings. She argues well that all newborns have interests in living even if they cannot yet have a desire to live. Hence they may not be denied morally due life saving treatment, including nutrition and hydration.

Watt deals with euthanasia in its various forms – voluntary, non-voluntary and involuntary. She rightly argues that an agent may never choose to bring about the death of any patient, competent or incompetent, regardless of their present or previously expressed wishes for assistance to die. The same moral principles apply for persons in a persistent vegetative state. They should not be unduly deprived of the necessary fluids and food, even artificially delivered, in order to bring about their death. She admits 'extraordinary' or morally unwarranted medical treatment may be withheld or withdrawn in the appropriate circumstances; she does not deny that quality of life issues need to be given due consideration in the circumstances. It would be unethical, however, to comply with the wishes of a clearly suicidal patient to refuse medical treatment. The principle of double effect is clearly explained and used to show in such cases how accepting a foreseen harmful side-effect differs morally from intending or wanting the same.

Watts, without making judgements on the persons who perform or have abortions, tackles directly the liberal moral views of those who see nothing intrinsically bad or wrong with abortion as such and who give scant attention to the right of the unborn child. She shows how a pregnant woman has the right to make decisions in caring for her body, but not at the moral cost of deliberately terminating the life of the fetus. Both mother and unborn child share membership in *the human kind*. However, life-saving therapies are ethically permissible in some cases of tubal ectopic pregnancy, provided the therapeutic procedure used does not involve a direct assault on the life of the fetus. Hence Watt holds that the removal of the damaged part of the tube with the fetus inside would not be a direct assault on the fetus if the purpose is to save the mother's life. This procedure need not necessarily involve an intention to kill the fetus nor to *directly attack* the child (p 54).
Watt strongly defends the thesis that a human individual is formed at fertilisation with its own active devel-

opmental potential. Consequently she opposes any attitudes of treating human embryos as disposable products. In principle, an early embryonic human individual could split to twin: either the same human individual continues in one of the newly formed embryos or the original embryonic human individual ceases to exist and two new embryonic human individuals are formed. While this explanation is possible and even plausible, this hypothesis is far from convincing. However, she rightly defends the moral inviolability of the early embryonic human individual from fertilisation, thereby opposing morally all destructive embryo research. She holds the new embryo and individual begins once the sperm enters the egg's cytoplasm, but is unconvincing in her arguments for this rather than at syngamy when the chromosomes of the male and female gametes mingle to give rise to a new joint life force. Watt rightly opposes human cloning and holds cloning human embryos is 'morally indefensible' on account of the moral status of naturally conceived, IVF and cloned human embryos. Both IVF and cloned human embryos have the inherent capacity to continue human development, granted a suitable environment.

Watt suggests some commonly used contraceptive pills, eg minipills, at times act as abortifacients rather than contraceptives. This statement warranted the provision of some scientific evidence and more discussion granted its potentially disturbing moral implications for many in the wider community. She finishes the book with a clear explanation of the conditions under which one may be justified in materially cooperating in the immoral acts of other people.

Watt's book achieves its purpose of being a short introduction to the ethics of healthcare in relation to life and death issues. It has been written for the benefit of general readers, students and healthcare professionals in nursing, law and philosophy and the broader community who wish to become acquainted with the moral problems regarding life and death.

Watt's approach is philosophical: she did not wish to rely on religious premises. However, not all religious teachings presuppose a religious faith. Much of Catholic teaching is supported by valid philosophical underpinnings. An example in point would be what Pope John Paul II said with great nuance about artificial nutrition and hydration to the US Bishops: 'the omission of nutrition and hydration intended to cause a patient's death must be rejected and that, while giving careful consideration to all the factors involved, the presumption should be in favour of providing medically assisted nutrition and hydration to all patients who need them (Address to US Bishops, *L'Osservatore Romano*, English Edition, 7 Oct. 1998).' The implication is this presumption, in the appropriate circumstances, may need to give way to another moral solution.

Notwithstanding the couple of reservations mentioned above, I heartily recommend Watt's instructive book to its intended readership, whom I am sure, will greatly profit from reading it attentively. ✣

Norman Ford SDB

From the Director

I would like to bring readers up to date on changes to the Centre's research staff in the last few months. Last October Deirdre Fetherstonhaugh resigned from the Centre as a research officer to take up a new position elsewhere. The Centre appreciated Deirdre's valuable and thorough research work on many ethical issues over the last six years. We wish her well in her new employment.

I would like to announce that Michael Herbert signed on to work for the Centre as a research officer before Christmas and commenced work early in February 2002. Jane Turner has also joined the Centre's research staff and begins work later in March 2002. I wish Michael and Jane well in their research work for the Centre. Soon some of their research should appear in the pages of our *Bulletin.*

The ethical concerns surrounding the therapeutic use of embryonic stem cells shows no signs of abating. As a community we should be wary of embarking on the unethical path of deliberately creating human embryos destined to be destroyed to obtain embryonic stem cells in the hope of curing some diseases. It would be far better to put more resources into adult stem cell research to hasten the day when these cells can be successfully used for therapeutic purposes instead turning to human embryos.

This Centre held a one day conference on *Human Embryo Research, Manipulation & Ethics* on 2 May 2002. The proceedings of this conference have now been published and are available to be purchased for $22.00, including postage and GST. ✣

Norman Ford SDB

Forthcoming conference

Ethical Issues in the Care of the Aged

- **Date**: Thursday 18 April 2002
- **Venue**: St Vincent's Hospital, Fitzroy
- **Topics include**:
  Dignity of the Person & Ethical Practice;
  Responsibility, Accountability & Funding;
  Employment Practice;
  Privacy, Confidentiality & Information;
  Autonomy, Duty of Care & Restraint Issues ;
  End of Life / Point of Death Issues;
  Dementia, Depression, Suicide;
  Physical Contact, Intimacy, Sexuality.

This conference was held last year in response to the increasing number of elderly Australians in care and the associated increase in ethical issues in the Aged Care Sector – at home, in public and private residential care centres, both for profit and not-for-profit. Such was the enthusiasm of those who attended, that it was decided that the conference would be repeated for those unable to attend last year.

The aim of the conference is to benefit all staff who care for the aged in any setting and in any capacity – carers, health professionals, support staff, chaplains, pastoral care workers, director and managers, officers of the Department of Aged and Community Care.

Registration forms are available from the Centre,
tel. 9270 2681, fax 9270 2682,
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