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The Changing Face of Australian Health Care

Part Two: Vertical Integration of Health Care

My previous paper examined the corporatisation of general practice and some of the ethical issues it raises. This paper will look at the vertical integration of the health system and its impact on the quality of health care in this country. There are also ethical issues here.

The vertical integration of health care means the gradual takeover by corporations of general practices, diagnostic services, pathology, pharmacies, radiology, private hospitals, and possibly health insurance. In terms of economic efficiency, there is much to be said for such moves. The linking together of these services provides a rationalization and can be a way to cut costs. It can also provide a good centralized service to customers. It is more convenient for patients to be able to obtain such services under one roof, rather than have to travel around from one centre to another. But there can be drawbacks, for health professionals, patients, and for the health care system.

There are a number of major players on the Australian scene. Mayne Health, Ramsay Healthcare, Healthscope, Gribbles, Endeavour Health are the leaders. There are differences of focus and management style among them. Some concentrate on diagnostics and pathology, other on private hospitals. Mayne is involved in most areas, and had made a conscious effort at vertical integration.

Diagnostic Services and Pathology

Mayne has established itself with a strong reputation in this field. In recent years it has acquired and developed some smaller firms, and last year opened new high tech laboratories in NSW and Victoria.

FEATURING

Because they are such big players in the market, Mayne have been able to invest in the latest technologies and to provide a high standard of service. The recent problems with some erroneous pathology reports did not stem from their laboratories. They are providing a good service to the community and have required the investment of many millions of dollars. The laboratories in Sydney and Melbourne cost at least $30 million to establish.

Pharmaceuticals

In July 2001, Mayne made a successful takeover bid for Faulding's Pharmaceuticals. They now have a large portion of the Australian pharmaceuticals market. It expands the Mayne healthcare model to include injectable pharmaceuticals, generic drugs, consumer health products and distribution services to hospitals and pharmacies. In competition with API and Sigma, Mayne-Faulding controls about 39% of the market. If the ACCC approves the plan for Sigma and API to merge, Australia will be left with a duopoly controlling the pharmaceuticals market. Peter Smedley, Chairman of Mayne, says that he has never seen a player hurt in a duopoly.[1] One wonders if all consumers would feel as confident.

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Mayne Health is now providing a range of services to community pharmacies, including wholesale distribution. Mayne Logistics is now a specialist health care distributor, managing the supply of sensitive pharmaceutical products to pharmacies nationwide. Mayne also operates four leading Australian pharmacy brands - Terry White Chemists, Chem mart, HealthSense and The Medicine Shoppe. They and others may soon be distinguished by the big red dot. Mayne Health manufactures and markets a wide range of leading consumer health care products, ranging from over-the-counter pharmaceutical products to vitamin and mineral supplements, sunscreens and soaps.[2] They are also providing pharmacy loans "which are financing young pharmacists into the industry and providing superannuation for old ones going out."[3] As long as they keep pharmacists on side, things are looking bright for Mayne.

Hospitals

In the nineteenth and early twentieth centuries, most Australian hospitals were run as nonprofit charities. With the increase of government funding after World War II, many of these hospitals were transferred to government ownership and control. A few, run mainly by Catholic religious orders, were funded as public hospitals but remained nonprofit in their ownership. Private hospitals received no direct government support. Some of these are nonprofit, others are for profit ventures. Nonprofit provision is shrinking as the economics of the hospital industry demand much more capital these days.

The major corporate players in the private hospital field are Healthscope Limited, Ramsay Health Care and Mayne Health Care which has some 60 hospitals offering a range of services. The collocation of some of the corporate private hospitals on the campus of major public hospitals has the advantage of enabling access to the facilities of the public hospital if needed.

The moves of State governments towards the privatization of some public hospitals have raised concerns. Public hospitals, especially the major teaching hospitals, as well as caring for patients, have important roles in the teaching of young doctors, and in undertaking clinical and basic research. These two latter functions are quite costly and there is a fear that private corporations might try to reduce costs by cutting back in these areas, especially in basic research. In an article in the Medical Journal of Australia, Dr Peter Brooks expressed his fear of the risk that "teaching and research may not be as well supported and that the privatized facility will concentrate on the high-return services at the expense of looking after the elderly and chronically ill."[4]

Insurance Funds

Private health insurance funds are an important feature of Australian health care. They provide a supplement or alternative to Medicare. They offer a range of choices in type and extent of cover against health costs. Their importance in the field was clearly demonstrated by the government's financial encouragement to people to take out membership. There have been rumours that Mayne is positioning to take over one of the funds, but Peter Smedley has denied them. He says he does not want Mayne to operate a health fund, but adds, in light of the fact that there are 44 health funds in Australia, "The industry is crying out for rationalization. The cost of health is multiplied to a significant degree by the amount of administrative time spent between the health funds and the hospitals."[5] It will be interesting to see if his views change if the government decides to sell Medibank Private.

There could be advantages for a corporation to have control of doctors who admit patients to hospitals and health funds that pay for their treatment. It would complete the vertical integration of health care. Currently private hospitals have to negotiate with health funds about repayment, but there is a move towards "episodic funding". In this case the hospital receives a flat fee based on the national average of what a particular treatment costs. It makes an assumption on the average length of stay required. If the patient makes a quicker recovery, the hospital profits. If the patient requires a longer stay, the extra cost is borne by the hospital.[6]

Ethical concerns about vertical Integration

The main ethical concerns in our changing health care are based on the different value systems of health professionals and corporations. Paul Fitzgerald expresses it this way: "Directors of corporations have an ethical responsibility to protect the interests of their shareholders. Successful businesses focus on their customers, but only within the limits of their obligations to deliver security and profit to their shareholders. Ethically conducted medical treatment, on the other hand, puts the healthcare needs of patients ahead of profit."[7]

Vertical integration of health services, while offering patients the convenience of one-stop shopping, often 24 hours a day, has the potential for abuse if doctors are pressured to see as many patients as possible and to refer only within the organization for pathology, diagnostic tests and pharmaceuticals. The Professional Services Review Committee has warned of this problem[8]

Another major area of ethical concern is with the efforts to cut costs within the hospital sector. Apart from the questions of possible cutbacks on teaching and research, there are other problems about nurse staffing, the selection of patients, and cost cutting in general.

Nursing

Nursing costs account for more than 50% of the costs or running a hospital. If a company wants to reduce costs, this is an obvious area to start. But it can have very bad consequences for patient care. A paper leaked towards the end of 2000 revealed that Mayne was planning a strategy to reduce nursing costs by between $15 and $30 million per year. It planned to restructure its hospital care "with much greater reliance on nurses who provide 'lower' levels of care, such as assistants in nursing."[9]

Ethically conducted medical treatment...puts the healthcare needs of patients ahead of profit

Nursing unions in Victoria and Queensland reacted strongly. The Queensland Nurses' Union objected to Mayne's plan to substitute some licensed nurses with unlicensed personnel, saying it raised serious concerns about the standard of nursing care that might be provided and additional workloads placed on licensed nursing personnel. It also raised questions for them about accountability mechanisms for the expenditure of public funds.[10] Opposition to their plans in Victoria caused Mayne to increase remuneration to nurses, making them competitive with conditions at public hospitals.

Patient selection

Private for-profit hospitals, with an eye to the bottom line, need to be able to control to some extent the type of patients who are admitted to their hospitals. The preference is for medical/surgical short-stay patients. Quick turnover of beds is significant. Long-term chronically ill patients impose a cost burden. The selection of more profitable patients to the exclusion of the costly is described as "cherry-picking". It is illegal in the United States, though some health care organizations are finding loopholes or ways to sidestep the problem by concentrating their advertising on the younger and healthier. In Australia, cherry-picking is not yet illegal, but has been condemned by the AMA.

Dr Mukesh Haikerwal, Victorian President of the AMA, told the Australian Financial Review: "The evidence presented to me by my members shows Mayne-Nickless is discriminating against people with complex medical problems, in favour of people needing straight-forward surgery."[11] Mayne has denied the charges, but Dr Alan Zimmit, Federal Treasurer of the AMA, and an oncologist who works at Mayne Hospitals in Victoria, says he has no doubt that cherry-picking is going on, and his organization is determined to show how extensive it is.[12]

The problem for some patients is that, despite being privately insured, they may not be able to gain admission to the hospital of their choice because they are viewed as being too costly. Another issue is that some patients may be discharged too quickly to cut costs. If they have to be readmitted, it will register as a new episode and costs can be recovered from the health fund.

Other cost cutting

Driven by cost cutting concerns some corporations, such as Mayne, have gone in for a very centralized management and purchasing system. This has caused a number of problems. Doctors and directors of nursing at hospitals have become frustrated at being unable to make decisions on capital expenditure and cost cutting. Doctors had first been taken aback at a surgeon's conference when Paul Tissot, recently sacked as Mayne hospitals general manager, talked about financials - revenue, profit, throughput, costs and so on. No mention was made of employing the best doctors, quality of care, or handling the nursing shortage. The reaction of frustrated doctors has been to send patients to other private hospitals, resulting in the recent collapse of Mayne share prices[13]. It highlighted the different value systems at work between corporates and health professionals.

Conclusion

Vertical integration of services worked well for Peter Smedley at Colonial Bank, but the efficiencies it represents in banking do not easily transfer to health care. Establishing corporate clinics where doctors refer patients for in-house diagnostics and radiology, prescribe medications to be purchased from linked pharma-

cies, or admit them to private hospitals, which gain most by taking short-term patients, may make excellent financial sense. This is more so if good arrangements have been made with private health funds for episodic payments. But it can lead to risks of over servicing when tests are paid for by Medicare, and a further blow-out of the pharmaceutical benefits scheme. If cherry-picking is allowed, it can disadvantage the chronically ill. And worst of all, if the focus is on the financial bottom line rather than the provision of high quality care in hospitals, the prospects for a changing Australian health care do not look that enticing.

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The Science and Ethics of Using Spare IVF Embryos for Research

This article examines the scientific therapeutic and ethical aspects of human cloning and embryonic stem cell research and the policy of the Australian Council of Governments.

Introduction

Many diseases and terminal illnesses, such as Parkinson's disease, Motor Neurone Disease and Diabetes, afflict many people, yet have no cure. A strong rationale exists, then, for finding a source of replacement cells and tissues which could alleviate such conditions.

Research and use of ES cells

Scientists believe that so-called 'therapeutic cloning', indeed the emerging field of Regenerative Medicine, offers the best solution to this burgeoning shortfall.[1] Regenerative Medicine includes tissue engineering and basically aims to replace diseased or damaged cells, tissues and ultimately organs of the body. Although complete organ regeneration may be a long way off, certain tissue and cells, such as skin cells, can now be cultured in the laboratory.

Below is an outline of the technique underlying therapeutic cloning. Basically, the nucleus is first removed from a recipient human egg. The nucleus, or the whole cell (such as skin) from a patient, is inserted into the enucleated egg, thereby enabling reprogramming and initiating embryonic development. By 4 to 6 days, the developing embryo has reached the blastocyst stage, consisting of a group of about 30 cells (the inner cell mass – ICM) surrounded by a spherical monolayer of trophoblastic cells. While these cells go on to form the placenta and extraembryonic membranes, the ICM gives rise to the fetus. About five days after fertilisation, the ICM cells are harvested in order to derive embryonic stem (ES) cells, thereby destroying the embryo. These ES cells could theoretically be coaxed to differentiate into any specialised cell the patient requires. Since the patient's nucleus, containing DNA, is already in these cells, the resulting tissue would be genetically matched to the patient. It is hoped such tissue may then be used to replace diseased or damaged tissue without the risk of rejection.[2]

Currently, ES cells are grown in the laboratory by co-culturing with animal cells and products. A feeder layer of mouse embryonic, immortalised cells supports human ES cells and prevents them from specialising and losing stem cell status. Serum containing proteins and other factors from calf blood is also used to support human ES cells. Such culture conditions present serious hazards to any clinical applications of ES cell technology. The overriding concern is that of spreading viral infections – from mouse or cattle sources – into the human population. The species barrier has been jumped before, and numerous occurrences have been well documented of avian and other species spreading pestilence to the human population.[3]

A major problem facing ES cell technology is nuclear reprogramming. The mechanisms involved are not well understood. However, natural reprogramming is normally accomplished during the production of sperm and eggs, a process that takes months and years respectively. This enables correct expression of the appropriate genes within the nucleus.

During therapeutic cloning, the reprogramming of the donor nucleus occurs within minutes or hours between the time that nuclear transfer is completed and the onset of embryonic development. Forcing crucial events into such a short time creates many developmental errors. Mounting evidence suggests numerous nuclear programming defects resulting in genetic abnormalities in animals cloned to date.[4] This would indicate that ES cells derived after nuclear transfer (ie, the product of therapeutic cloning) would also carry genetic defects making them totally unacceptable for any clinical use. Although it offers much promise, this process is not yet safe and involves the inevitable destruction of human embryos every time ES cells are obtained.

It is also possible to derive ES cells from frozen IVF embryos. The embryos, frozen at the blastocyst stage, are thawed and the ICM isolated. The resulting ES cells would not be genetically matched to the patient. However, these cells could well be used for research. For instance, the efficacy and long-term safety of therapeutic cloning in humans is doubtful. Neither are the processes underlying nuclear reprogramming well understood. Thus ES cell research could be used to improve cloning techniques and promote the acceptability of therapeutic cloning.

Government Policy

The Report of the House of Representatives Standing Committee considering the scientific, ethical and regulatory aspects of human cloning and stem cell research (in August 2001) says that although all members of the committee agreed to ban the cloning of a complete human individual, they were divided on whether to permit destructive human embryo research using excess IVF embryos. In particular, there was dissent about utilising stem cells obtained from embryonic sources. While the majority of members (six) believed it should be permissible for spare IVF embryos to be used in clearly defined, limited circumstances, others (four), including the chairman, the Hon Kevin Andrews, believed that procedures that involve the destruction of embryos, such as therapeutic cloning, are unethical and should be rejected.[5]

Federal, state and territory leaders adopted the Standing Committee's recommendations at the Council of Australian Government (COAG) meeting (April 2002). Legislation, to be introduced before the end of June, would not only allow scientists to perform research on ES cell lines that have already been established, but would also permit them to derive new ES cell lines from surplus IVF embryos created before April 5 2002, that would otherwise be destroyed. Informed consent would have to be obtained from the donors; they would also be able to specify restrictions on the research to be conducted.

The legislation would prohibit all forms of cloning, including so-called therapeutic cloning. An ethics committee would be established expressly for the assessment and approval of protocols, in addition to the National Health and Medical Research Council reporting within 12 months on the adequacy of the supply and distribution of embryos. The regulation forbidding the use of surplus embryos created after April 5 2002, would expire in three years, although this time could be reduced by COAG. Other aspects of the legislation, if implemented, would be reviewed in three years (June 2005).

The new rules are even more lax than the conditions imposed on federally funded US researchers, who can use ES cells *only* from cell lines created before 9 August 2001.[6] Australian researchers estimate that of the 70,000 frozen embryos potentially available nationwide, about 10,000 of these will not be needed by the donors.[7] Although the legislation would reconcile what until now has been a patchwork of state and territory rules, it would permit, for the first time, destructive human embryo research on Australian soil.

Suitable alternatives

There is a lack of definitive evidence showing greater effectiveness of ES cells over adult stem cells. However, many scientists strongly advocate the use of ES cells for two main reasons:

- therapeutic cloning has the potential to overcome tissue rejection after transplantation, and secondly
- ES cells purportedly display greater developmental flexibility; meaning they could be of greater use because they are able to give rise to a wider range of daughter cells.

In the last two years, scientific reports of stem cells in major organs of adult mice – including skin, digestive system, retina, liver and pancreas – have cast new light on the adult body's inherent capability to replenish its own tissues.[8] This discovery points to their existence in humans. If these cells are found, then stem cells may be taken from the patients themselves and coaxed to produce the desired tissue outside the body. This approach would obviate the need for therapeutic cloning as rejection of the transplant would not be an issue.[9]

Recent evidence also suggests adult stem cells might in fact possess a degree of plasticity, enabling them to give rise to a large number of specialised daughter cells from a range of tissues. One study has, in fact, demonstrated that a single blood, or haematopoietic, stem cell (HSC) transplanted into a mouse generated not only blood components but also cells lining the

lung, gut and skin.[10] Although unconfirmed, developmental plasticity has also been demonstrated in neural stem cells (NSC) found within the central nervous system.[11] If scientists could control cell lineage when implementing adult stem cell therapy, there would be little clinical need for ES cells.

adult stem cells, as opposed to ES cells, are naturally poised to generate particular tissue, making them ideal for transplantation

Furthermore, no clinical benefits have ever been achieved from human ES cell research. For over 40 years scientists have not only been aware of, but actually utilising, adult stem cells.[12] Stem cells found within bone marrow, such as HSCs, have been routinely used for many years to overcome bone marrow failure, congenital immune deficiencies [13] and blood disorders such as leukaemia.[14] And there are recent studies which are most encouraging: eg, researchers have overcome immunological diseases, such as severe combined immunological disorder using adult stem cells. So-called 'bubble babies', confined to existing in plastic sterile bubbles to avoid infection, have been cured of their genetic disorder and can now lead normal lives.[15] Using adult stem cells from a patient's bone marrow, German scientists were able to significantly recover heart function after a cardiac arrest.[16] These are a few of the examples, and new findings are emerging weekly, of promising clinical results utilising adult stem cells.

Further advantages

Apart from the ethical aspects, the idea of employing adult stem cells in certain therapeutic applications is appealing for several practical reasons. Adult stem cells, as opposed to ES cells, are naturally poised to generate a particular tissue, making them ideal for transplantation. In addition, adult stem cells appear to be able to migrate to injured tissue or other discrete sites of the body; for example, neural stem cells will migrate to tumour sites in the rodent brain.[17] This is advantageous as it might provide more flexibility in choosing where to transplant the stem cells and more predictability in where they will localise after transplantation. Other groups of stem cells, such as those isolated from the umbilical cord, are still being discovered and properly characterised. Research elucidating the full capability of these cell types, and other adult stem cells mentioned above, should be vigorously pursued.

Ethical considerations

It is agreed by biologists that empirically verifiable human life begins with the formation of a developing human embryo. It makes no difference whether the embryo is naturally conceived, an IVF or a cloned human embryo. The Second Vatican Council confirmed the Christian tradition on the inviolable status of embryonic human life: 'Life must be protected with the utmost care from conception'.[18] Once formed, a human embryo is ethically inviolable regardless of the potential therapeutic benefits gained by their destruction even if they are destined to perish. Human life is a condition for the enjoyment of other values we cherish and protect. John Paul II rightly said in his Encyclical Letter *Evangelium Vitae* that 'from the standpoint of moral obligation, the mere probability that a human person is involved would suffice to justify an absolutely clear prohibition of any intervention aimed at killing a human embryo.'[19]

The moral need to show respect for embryonic human life is a profoundly human insight and reflects the respect due to our shared humanity. It arises in our hearts and not only from religious sources. People have moral responsibilities for embryonic human life, but never direct dominion over life itself. We should not settle for the reductionism that sees embryonic human life as no more than mere genetic material, devoid of value. Ethical respect for human embryos should take precedence over pragmatic and utilitarian considerations of governments or biotechnology companies.

Pope John Paul II, speaking to the 18th International Congress of the Transplant Society in Rome on 29 August 2000, and referring to therapeutic procedures involving the use of human embryos, said:

'… these techniques, insofar as they involve the manipulation and destruction of human embryos, are not morally acceptable, even when their proposed goal is good in itself. Science itself points to other forms of *therapeutic intervention* which would not involve cloning or the use of embryonic cells, but rather would make use of stem cells taken from adults. This is the direction that research must follow if it wishes to respect the dignity of each and every human being, even at the embryonic stage.'[20]

Granted the promising and ethical alternative of using adult stem cells there is no need for COAG to go down the unethical path of making laws to authorise the destructive therapeutic use of human embryos.

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Clinical Practice, Clinical Audit, Quality Assurance, Research

This article considers whether or not the same consent requirements apply to clinical practice, research, clinical audit and quality assurance.

Consent and The National Statement

In an earlier issue of the *Bulletin The National Statement on Ethical Conduct in Research Involving Humans* has been discussed in detail.[1] The statement identifies four key values underlying the ethical and legal responsibilities which investigators bear towards participants in research. They are integrity, respect for persons, beneficence and justice. But adherence to these values is not confined to investigators and the research context. Each of these values is equally central to *clinical practice, clinical audit and quality assurance* activities. All these activities, for instance, are clearly directed towards *beneficence*, eg., to conducting reviews to ensure that the risks of harm or discomfort are minimised and the overall health and welfare of patients is promoted. A concern for *justice* is apparent, too, when a health care facility audits its operations to ensure that its services are accessible to all patients without unjustifiable discrimination on the grounds of race, age, sex, disability or religious or spiritual belief. And, of course, the *integrity* of health care professionals and administrators, both in practice and in conducting reviews and audits, is a *sine qua non* not only of professional responsibility but also of personal ethical standards.

It is, however, in the area of respect for persons that many of the accepted quality assurance and audit activities have a more ethically questionable impact. Values like personal autonomy, confidentiality, and privacy may seem to be compromised where audits are conducted without specific attempts being made to obtain a patient's consent. The new Privacy regulations, for instance, have made access to patient records a more sensitive area of ethical concern.[2] And while no one doubts both the necessity and beneficence of these reviews, it is important that a system be instituted that also respects the personal consent and autonomy generally of patients.

The *National Statement* is explicit in prescribing the need for consent in most research activities. It identifies two main aspects of consent: the provision of information and the capacity to make a voluntary choice. At the outset it prescribes:

'…Obtaining consent should involve:

(a) provision to participants, at their level of comprehension, of information about the purpose, methods, demands, risks, inconveniences, discomforts, and possible outcomes of the research (including the likelihood and form of publication of research results); and

(b) the exercise of a voluntary choice to participate.

Where a participant lacks competence to consent, a person with lawful authority to decide for

that participant must be provided with that information and exercise that choice.'[3]

The *National Statement* also acknowledges circumstances in

in clinical practice, exceptions to informed consent and to demands for confidentiality are

which it may be ethically acceptable to waive consent for certain types of research. Examples of this include de-identified data in epidemiological research, observational data in public places, or the use of anonymous surveys.[4] The sections on the *Use of Human Tissue Samples* (Section 15) and *Human Genetic Research* (Section 16) specify these waivers further.

'In determining whether consent may be waived or waived subject to conditions, an HREC (Human Research Ethics Committee) may take into account:

- the nature of any existing consent relating to the collection and storage of the sample;
- the justification presented for seeking waiver of consent including the extent to which it is impossible or difficult or intrusive to obtain specific consent;
- the proposed arrangements to protect privacy including the extent to which it is possible to de-identify the sample;
- the extent to which the proposed research poses a risk to the privacy or well being of the individual;
- whether the research proposal is an extension of, or closely related to, a previously approved research project;
- the possibility of commercial exploitation of derivatives of the sample; and
- relevant statutory provisions.'[5]

There is, then, a balancing between the demands of informed consent and personal autonomy on the one hand, and those of public beneficence on the other. The rubric adopted by the *National Statement* is that the waiver of consent may be ethically justifiable where 'the public interest in the research outweighs to a substantial degree the public interest in privacy'.[6] To facilitate and guide this "weighing" the *Guidelines under Section 95 of the Privacy Act 1988* specify numerous considerations which an HREC should consider in reaching a decision to accept or reject a research protocol that does not seek the participants' consent.

It is accepted that there are circumstances, then, in the conduct of *research* where the need to seek the consent of participants may be waived subject, of course, to approval by a HREC. Informed consent and personal autonomy are very important values especially in the research context where participants may not necessarily expect any direct or immediate personal benefit to arise from their participation. But they are not the only values to be taken into consideration, nor do they necessarily trump the values of public beneficence or social justice in all research contexts.

Clinical Practice

At the other end of the spectrum, however, in *clinical practice*, exceptions to informed consent and to demands for confidentiality are rare. It is only where the patient is unconscious or the disability from which they suffer makes it impossible for them either to comprehend, or to exercise consent to, the projected procedure that informed consent may be waived. Even in these circumstances the consent of a surrogate decision-maker, if available, should be sought. This surrogate is presumed to act in the 'best interests' of the patient. The determination of 'best interests' includes as an integral, and even an overriding, element the known or presumed wishes of the patient – thus the doctrine (or fiction) of 'substituted (or interpretative) consent'.

Further, the personal autonomy of the patient is protected by the requirements of confidentiality. The health care professional is expected to communicate clinical details only to those who have an immediate or consultative relationship to the patient. Medical records, too, are classified as highly sensitive, and the presumption is that they will not be divulged without the specific consent of the patient.

There are, however, exceptions to this general rule. Publicly notifiable diseases where the public health of the community may be compromised by contagion are the best known examples. Once again the public interest rubric is invoked to weigh public beneficence against personal autonomy. But these exceptions are rare. Because of the immediacy and intimacy of the relationship between patient and health care professional and its fiduciary character, the protection of personal autonomy is presumed to be paramount. The onus of proof lies with those who seek to specify circumstances in which the requirements of informed consent to treatment, patient confidentiality and autonomy generally should give way to more public interests. Nor is it only personal autonomy that is at stake here. Protecting autonomy is not only part of respect for persons. It is also, *prima facie* at least, an exercise in personal beneficence and justice.

Clinical audit and quality assurance

In between *clinical practice* and *research* stand the activities of *clinical audit* and *quality assurance*. Here the values of practitioner integrity, public beneficence and social justice are more to the fore. Do we require the same strictures on obtaining informed consent and maintaining confidentiality as we do in *research* and *clinical practice?* It is interesting that in the recently

published *Guidelines under Section 95A of the Privacy Act 1988* an organisation's quality assurance and clinical audit activities are construed as "directly related secondary purposes" (to the primary purpose of obtaining information for clinical practice) not requiring a patient consent further to that presumably elicited in the original clinical practice interaction.

'Directly related secondary purposes may include many activities or processes necessary to the functioning of the health sector.
Where the use or disclosure of de-identified data will not suffice, and provided it is within the reasonable expectations of the individual, no extra steps need be taken when using or disclosing relevant personal information in circumstances, such as:

- Providing an individual with further information about treatment options;
- Billing or debt-recovery;
- An organisation's management, funding, service-monitoring, complaint handling, planning, evaluation and accreditation activities; for example, to report an adverse incident;
- Disclosure to a lawyer for the defence of anticipated or existing legal proceedings;
- An organisation's quality assurance or clinical audit activities, where they evaluate and seek to improve the delivery of a particular treatment or service; and
- Disclosure to a clinical supervisor by a psychiatrist, psychologist or social worker.'[7]

It is, of course, necessary to note the two conditions that are specified in the preamble: 'when the use of disclosure of de-identified data will not suffice, and provided it is within the reasonable expectations of the individual'.[8]

In many cases of clinical audit and quality assurance de-identified data will be sufficient. Further, consent forms may need to be revised so that

consent forms may need to be revisd to advise patients of the possibility of such reviews

these activities fall explicitly, rather than implicitly, "within the reasonable expectations of the individual". This is so particularly in those areas where identifiable, rather than de-identified, data may be required, and where detailed, rather than general, information is audited. Finally, the audience to which the data obtained from these surveys will be released also needs to be considered. On the one hand, privacy and personal autonomy enter into the equation, particularly where identifiable or personal data has been accessed. On the other hand, it is of the essence of clinical audit and quality assurance activities that the results be able to be compared not only within the institution but with the results obtained in parallel institutions. In many instances, then, publication in professional journals may be expedient.

In some institutions it has come to be accepted practice that where such publication is proposed the report be subjected to the approval of the HREC of the institution. These committees are charged with 'the protection of the welfare and rights of the participants in research'[9], and it is seen as a legitimate extension of their responsibilities, particularly where identifiable and detailed personal data are audited, that they should also review before publication reports of clinical audit and quality assurance activities. Some professional journals, too, are requiring evidence of such approval before publication of these reports.

Some institutions are going further and requiring HREC review and approval not only prior to publication but also prior to the clinical audit or quality assurance activity being undertaken. In most instances, however, this should be construed as an overreaction and an excessive concern for personal autonomy. Even in *research* contexts, as we have seen, the claims of personal autonomy may have to give way to those of public beneficence and social justice, and this even though the participants may derive no personal benefit from their participation. In clinical audits and quality assurance activities where the claims of personal benefit, public beneficence, social justice and practitioner integrity are stronger, there seems to be an *a fortiori* argument for not requiring a consent additional to that elicited for the original clinical interaction.

Conclusion

To be sure, consent forms may need to be revised to advise patients of the possibility of such reviews, but it should primarily be a matter of information rather than necessarily of consent. It is of the nature of such audits and reviews that they be conducted in respect of the whole cohort of the relevant patients, and the methodology and results would be severely compromised if permission to withdraw were contemplated. On the other hand, the objects and purposes of such reviews should be clearly delineated and explained, and de-identified data should normally be preferred. Reports should be reviewed prior to publication by an appropriate institutional authority. Sometimes when the clinical audit or quality assurance activity verges on research or it includes identifiable and highly personal data, review by the institutional HREC will be appropriate prior to submission for publication and even prior to the audit being undertaken. In most instances, however, where audits are routine, are clearly explained, and de-identified data is used, institutional management, rather than the HREC, should be the appropriate authority to authorise the audit and review the report prior to publication.

ENDNOTES

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Wrongful Life and Wrongful Birth

This article attempts to highlight the differences, both ethical and legal, between 'wrongful life' and 'wrongful birth' claims. It also considers where these types of claims may lead us in the future.

Introduction

Medical negligence in Australia is definitely a growth industry. It seems the more information we can have access to the greater the inclination we have to blame someone when things go wrong. Before we had prenatal testing, such as ultrasounds and blood tests, having a baby was usually an exciting event, where the gender and health status of the baby were relatively unknown. Parents, midwives and perhaps even obstetricians crossed their fingers, did their best and hopefully achieved the optimal outcome of a healthy baby and mother. Today we can discover so many details about the unborn baby including such things as their gender and health status including genetic disorders, congenital abnormalities and other disease states. If information is power then it is no surprise that many parents seek out as many details about their unborn child as possible. What individuals do with this information varies according to their beliefs, moral code, coping mechanisms, understanding of the information presented to them, and the advice offered by friends, family and health professionals.

Wrongful Birth

Wrongful birth and wrongful life claims both rely on claiming that because of someone's negligence, usually a health professional's, a child has been born that would not have otherwise not have been. In the case of wrongful birth the parents or guardians of the child make this claim. Wrongful birth action is now fairly well established in Australian jurisdictions. The parent must claim that 'but for the defendant's negligence, the child would not have been born'1. These types of claims can involve such events as failed medical sterilisation procedures and alleged negligence in prenatal diagnosis or counselling. Wrongful birth claims can be made even when the unwanted child is born healthy, however, many involve parents claiming they would have terminated a pregnancy had they been fully informed. Terminating a pregnancy on the basis of prenatal testing or other medical information is not an ethically acceptable course of action. Unfortunately though it is a course of action that is allowed within the law.

Wrongful Life

In contrast, wrongful life actions are brought against the mother's health care provider, (medical partitioners, genetic counsellours etc), not by the parents but by the child who has been born with a disability or disease. The child alleges that a failure to inform his or her mother of the risk of congenital or heritable conditions, so that she could have either avoided conception or, if she was already pregnant, terminated the pregnancy, resulted in them being born. In other words, the child, or a guardian on their behalf, must claim that the life they have is worse than not having been born. Obviously this claim raises complex legal as well as ethical and philosophical problems. Questions arise including can non-existence really be better than a life with a disability and how, or should someone be financially compensated for being born when the only other option was not to have been born. Put simply, can healthcare professionals be held responsible for 'negligent' acts which have resulted in children being born that would not otherwise have been?

Legal Cases

There are currently three wrongful life cases being pursued in the New South Wales Supreme Court2. I do not wish to comment on the content of these particular cases but I hope that by outlining them we can identify some of the issues involved. I also hope by raising this issue we realise how important it is that we as a community decide how we feel about such claims and identify and acknowledge where these types of cases may lead us. In considering these cases, for the time being it will be helpful to leave aside the issue of whether or not the negligence of healthcare professionals can be proved. All three cases relate to different stages of pregnancy and different possible causes for the children being born with their disease or disability. The first case involves a physically and mentally disabled girl who was born with these disabilities

because her mother contracted Rubella during her pregnancy. The Rubella was not diagnosed when her mother consulted her GP during her pregnancy. The second case involves a girl born with the very rare genetic disorder, Cri du Chat syndrome, after her father had a failed vasectomy. And the third case involves an IVF baby born with a clotting disease that could have been detected using pre-implantation diagnosis. The disease, along with a difficult birth has resulted in the child suffering brain damage, epilepsy and cerebral palsy.

These cases help demonstrate that there are many stages at which reproduction, pregnancy and birth can unfortunately go wrong. While it is easy to say that the lives of these three children are very difficult and that they may be suffering for their entire lives, it is a very big claim to say that they would be better off never having been born. Before considering the ethical difficulties of this question and where such claims may lead I will look at just one more recent legal case and subsequent legislative changes.

Right not to be born?

A ruling in France's highest court of appeal in November 2001, supporting the decision in 2000 in the Nicolas Perruche case that a child has a 'right not to be born' was very controversial. The court's decision in the 2001 case states that a child can be compensated for being born with a handicap or malformation if a mother had not had the opportunity to ask for a therapeutic abortion, because she had not been informed of the risk and that risk could have been evaluated during prenatal diagnosis.'3 The case involved a six-year-old boy with Down Syndrome. The court ruled that the boy, known only as Lionel, would have been aborted if his mother had known that he would be born with a disability. Her doctor had 'missed key signals' that Lionel had Down Syndrome. This decision came after Lionel's parents had already been compensated for medical negligence. The ruling was met with protests from obstetricians and specialist in prenatal diagnosis. Also demonstrating against the decision were members of associations for handicapped people who claimed the decision reflected contempt for handicapped people. This was the first case in which a child with Down syndrome had been considered worse off existing than not at all.

there are many stages at which reproduction, pregnancy and birth can unfortunately go wrong

The decision in Lionel's case reinforced the earlier Perrruche Judgement. The Perruche judgement involved the court awarding damages to 17 year old Nicolas Perruche who was born deaf, part blind and with severe brain damage in 1983 after a laboratory failed to realise his mother had caught Rubella in the early stages of pregnancy.

These decisions created such uncertainty and unrest within the community, especially within prenatal medicine and handicapped groups that the French government has subsequently introduced a bill, which states that 'no-one can sue for damages for the sole fact of their birth'.4 Perhaps such legislation would be valuable for other countries to adopt as well.

Blame, Harm and Causation

It is distressing that in our society it is becoming increasingly acceptable to seek to blame someone for any injury or harm that occurs. The courts are full of people suing one another and seeking compensation for what they consider negligent behaviour. I do not want to suggest that there should never be recourse to the court system. However, we must look at the increasing number of cases and determine if this is the direction we want our lives, and especially the health services industry, to head. When things go wrong, or not exactly as we had hoped, we can often seek to blame someone. This can make us feel better, even as is often the case, there is in fact no one who is actually responsible for the 'accident'. If the Australian cases I have outlined above do involve negligent behaviour of health professionals, then several questions need to answered. Questions such as whether or not wrongful life claims are coherent and if so can be they be true? Can someone be compensated for the harm of existing? And did the health professionals' actions cause these children's diseases or disabilities?

Coherence and Truth

Some people, including Amos Shapira, have argued that wrongful life actions are a legitimate way of redressing injury caused by negligent behaviour. Shapira also suggests that such actions are in the public health interests because there is currently no other course of action for people born with 'avoidable' disabilities.5 Before addressing these points I would like to consider if it is coherent to claim that one is in a worse situation than if they did not exist. A similar claim is often proposed when discussing right to die issues and euthanasia. However, in the case of euthanasia, one might be more inclined to accept the claim as coherent because as the person currently exists they may be able to say that anything is 'better' than their current predicament, even if they have no knowledge of what the non-existence option entails. However, in wrongful life claims I am not so sure that claiming non- existence is/was preferable to existence can be considered coherent in the same way. Can one really say that they would have been better off never having existed and therefore never knowing that they may have existed?

As any argument against the coherence of wrongful life claims is open to counter arguments I will accept for now that perhaps they can be co-

herent. This leads to the question can they ever be true? None of us has any experience of non-existence and so we cannot make a comparison between the experiences of existence and non-existence. We may be able to equate non-existence with sleep states or other states of unconsciousness. Some may even refer to the period before they came into existence but it is likely that we will all differ in our conception of non-existence and as a result any evaluation of non-existence is also likely to vary widely. So even if a comparison between non-existence and existence is accepted as coherent it is not obvious that a true evaluation is possible.

A way forward

Prenatal information can be very valuable. It can help parents prepare for the birth of their baby and can sometimes help in pregnancy or delivery management. Sometimes the information is used to evaluate whether or not a baby should be allowed to continue development and it is this use which we find ethically unacceptable. Once conceived, babies should be allowed to develop and any information gained about them should be used to either improve their circumstances or prepare for their arrival. Terminating a pregnancy is not an ethically acceptable option. However, while we consider termination of pregnancy unacceptable we must acknowledge that the law views the situation differently.

The law definitely allows people whose lives have been dramatically affected by the 'avoidable' birth of a disabled child to have recourse to the courts to redress the negligent behaviour of health professionals - these people were prevented from making a choice. However, wrongful birth actions should not be exacerbated by supporting wrongful life claims. I also think it is true that as a community we do not provide adequate support for those born with disease and disability. Increasing support, services and funding for these people may help to avoid the need to find financial support through other avenues. Improving support for these people may also help lessen their desire to blame someone for their unfortunate situation and accept that sometimes things just do go wrong.

prenatal infornmation can be very valuable

Some may think it would be hasty to rush into legislation similar to the French government but at the same time it might be a preferable option to an increasing number of wrongful life actions entering our court system. Legislation may also prevent society embarking on a slippery slope. While currently wrongful life actions are reserved for severe disabilities it might not be far fetched to suggest that in the future our criteria of harm might be lessened. With improvements in prenatal genetic diagnosis the reasons for bringing wrongful life claims may be reduced to such things as having to live life with the 'wrong' shaped nose. Slippery slope arguments can be overstated but it is important that we halt the move towards judging imperfections, or perceived imperfections, as avoidable and as someone's fault.

The current increase in wrongful life claims is not because people have only just reached the opinion that non-existence might be preferable to their own existence. Such an idea is expressed by Job when he questions, 'Why did I not perish at birth, and die as I came out from the womb?'[6] The recent increase is because we now have the ability to 'know' information about the unborn. This information has the power to affect whether or not someone is allowed to continue existence or to be conceived at all. This knowledge and associated power a person is in a worse situation than if the person did not exist a person is in a worse situation than if the person did not exist is not necessarily a good thing.

ENDNOTES

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