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Is Every Isolated Embryonic Cell an Embryo?

Many interventions which involve early human embryos modify their human development, e.g. embryo splitting or cloning. Is every cell that is removed from an embryo an embryo itself? This article tries to clarify what should, and should not, count as an embryo.

Respect for the Human Embryo

When a human egg and sperm fuse during fertilisation, a new cell is formed, a zygote, which is the beginning of a new human life and of a human embryo. This single-cell embryo and the multi-cell embryo that is generated through cell divisions, has a special moral status in the eyes of the law and is rightly accorded unconditioned moral respect in the Catholic tradition. Recent Catholic teaching goes further and holds that the early human embryo ought to be treated as a person from conception because there are reasonable grounds to believe the embryo is a human individual and a person. It is now necessary to define as best we can what an embryo is, regardless of whether it is formed naturally or artificially. This is required for the due protection of human embryos for ethical and legal reasons.

Preimplantation human embryos. *Photograph key: 1. A 1-cell human embryo 12 hours after fertilization; 2. A 2-cell human embryo 30 hours; 3. A 4-cell human embryo 40 hours; 4. An 8-cell human embryo 55 hours. All these embryos have been photographed alive, in sterile culture media, using a non-invasive technique. (Reproduced in part with permission from The Journal of Reproduction and Fertility, the authors, Trounson, AO., Mohr, L., Wood, C. and Leeton, JF., and Professor A Trounson.)*

Definition of a Human Embryo

We may ask why is it that legislation worldwide accords special moral respect for the human embryo from conception. I believe this is because it already has the intrinsic active capacity to continue human development from its inception, to become a fetus, a baby and an adult in a continuous and coordinated process, given a suitable environment. Following several cell divisions, when there are about 60 cells some 100 hours after fertilisation, a blastocyst is formed, which has a spherical shape. The outer trophectoderm cells differentiate into trophoblast cells and are destined to become extraembryonic membranes and placental tissue, while the inside cells are clustered into an inner cell mass (ICM) and most of these are destined to form the fetus. Contact and signals between ICM and trophoblast cells are essential for the blastocyst to continue species specific, or typical, human development, to generate a body plan and to complete implantation.[1]

FEATURING

Reflection on the process of typical human development suggests the following definition of a human embryo: *a cell, or group of cells, which has the inherent active capacity to continue organised species specific human development, given a suitable environment*. Clearly, the product of an unsuccessful attempt at fertilisation that is inherently incapable of human development from the start is not an embryo. So if the fusion of two gametes is unable to form a new cell at syngamy, fertilisation would have failed, new human life would not have begun and an embryo would not have been generated.

Totipotency

It is sometimes said that all totipotent cells are embryos. This needs clarification. An embryo is said to be totipotent if it is inherently capable of producing the entire offspring, including the blastocyst. This is the strong sense of the term *totipotency* and it provides grounds for the moral status of an embryo. In a weaker sense, *totipotency* can also refer to the capacity of the progeny of one or more cells to become all types of cells in the offspring. This is not a morally relevant meaning of the term. Totipotent cells in this weaker sense should not be deemed embryos. Cells are also said to be *pluripotent* if their cell progeny can give rise to many, but not all, cell lines of an offspring. Pluripotent cells are likewise not embryos.

Embryo Manipulation or Manipulated Embryos

The timing of blastocyst formation (blastulation) and the minimum number of cells required for its success is species specific.[2] If there are too few cells to form both trophectoderm (outer) and ICM cells, blastulation cannot occur. Sometimes the ICM splits and forms genetically identical twin embryos within the blastocyst and organised human development continues in both, with the necessary support provided by common placental tissues. Granted it would not be ethical, the removal of the ICM destroys a blastocyst and although the ICM cells may still divide for a while, it is not part of organised typical human development. They are unable to continue typical human development without maintaining contact with trophoblast cells. Isolated ICM cells are not an embryo and their cell progeny soon degenerate and perish. But if some ICM cells were isolated from a blastocyst and were promptly surrounded by trophoblast cells from another embryo, a new embryo would be formed, which, after transfer to the uterus, could result in a live birth of an offspring genetically identical to the source blastocyst.

a human embryo is a cell, or group of cells, which has the inherent active capacity to continue organised species specific human development, given a suitable environment

If a two-cell human embryo is split, each half could continue species specific human development and identical twin offspring could be formed if each one is placed in an empty zona pellucida (ZP) or shell and then transferred to the uterus. The same would apply to each half or quarter of a four-, eight- or 16-cell embryo. The cells of each fraction could form a new embryo, inherently capable of typical human development after being placed in an empty ZP and then in the uterus. Blastulation could occur about the same time in all cases – about 100 hours after fertilisation.

The simultaneous blastulation of entire, 'half'- and 'quarter'- embryos when placed in a ZP and then in the uterus has led embryologists to suggest that the timing of early differentiation at the blastocyst stage is governed by a 'clock' mechanism inbuilt into the DNA of each cell of the embryo. It seems to be set from the time of fertilisation, with each cell's 'clock' running dependent on, and in coordination with, what is happening in its surrounding cells.[3] The clock seems to work by controlling growth and development throughout all stages of the life of each human individual in conjunction with environmental influences. The freezing of embryos practically suspends all metabolic activity and development.[4] Frozen embryos are not dead – they are dormant, living in suspended animation, and human development continues after thawing has succeeded.

As mentioned above, if a single cell were isolated from a four-cell embryo, placed in an empty ZP and transferred to the uterus, its cell progeny would probably succeed to blastulate. This means a cell excised from a four-cell embryo could become a new embryo. The same could possibly be said of a single cell from an eight-cell embryo.

But if a single cell were to be excised from a 16-cell embryo and placed in a ZP their cell progeny would attempt to blastulate at the preset time. Blastulation, however, would almost certainly fail as there would be insufficient cells to form the inner and outer cells of the blastocyst. The critical cell mass would be lacking since a single cell from a 16-cell embryo results from the fourth division after fertilisation and would attempt to blastulate after two further divisions when there would be only four cells. This means even if an isolated single cell from a 16-cell embryo were to be placed in an empty ZP and then in the uterus, it could not itself become a new embryo because it would lack organised species specific human development.

Embryonic Stem Cells

Recently James Thomson and his colleagues removed totipotent (in the weaker sense) human ICM cells from a blastocyst, treated them for culture and placed them on a feeder layer where they flattened out. They continued dividing into undifferentiated cells indefinitely. These cells are called embryonic stem (ES) cells and after they have been removed from culture, they could produce many hu-

man cell line types with great potential for use in transplantation medicine.[5]

ES cells by themselves, however, are not embryos – they do not have the

ES cells are not embryos - they do not have the inherent active capacity to continue organised species specific human development

inherent active capacity to continue organised species specific human development. As Thomson commented: 'If a clump of ES cells were transferred to a uterus, the ES cells would not form a viable fetus.'[6] He also said it not known whether human ES cells could become an embryo by any method.[7] Mouse ES cells, however, have been successfully aggregated with mouse embryos to produce viable offspring which were genetically derived from the ES cells.[8] The trophoblast cells required to combine with ES cells to form an embryo were supplied from other mouse embryos. Even if it were possible, human ES cells would not form an embryo prior to aggregation.

Human Clones or Human Cloning

After the birth of *Dolly*, the sheep, the first live born mammal cloned from an adult cell, scientists realised that once a body cell nucleus is dedifferentiated or re-programmed back to the undifferentiated state and fused with an enucleated egg, development is activated and a cloned embryo could be formed. A cloned embryo could have the inherent active capacity to continue typical human development and to produce the entire offspring, almost genetically identical to the nucleus donor.[9] The success of Dolly and of other cloned mammals raises the possibility of cloning a human individual. It is unknown whether the transfer of a nucleus from human body cell or of a human ES cell to an enucleated egg could form a human embryo. Nobody has produced an embryo from an ES cell in primates. The ES cell, however, would not be an embryo before the cloning succeeded.

It might also be possible to dedifferentiate an adult somatic cell nucleus and modify it by the insertion of a 'knock-out gene' which would inhibit the formation of trophoblast cells. Even if such a non-totipotent human embryo was cloned in an enucleated egg, its typical human development would cease when it could not produce the required trophoblast cells. I think this would be an embryo up to the time it irreversibly ceased typical human development. Such an 'abnormal embryo' could possibly be treated by removing the 'knock-out gene' which inhibits its development. In practice, prudence would dictate granting moral status to such an embryo. The same could also be said of a naturally conceived embryo with a lethal genetic defect which causes death in the early fetus. Finally, it might be possible to obtain human ES cells by a partial reversal of differentiation of adult somatic

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cells.[10] This would not involve creating or destroying IVF or cloned human embryos. These ES cells would likewise not be embryos themselves and growing them in culture for valuable medical purposes would not involve an offence against human life.

Parthenogenesis

A mouse egg can be stimulated to begin developing without fertilisation by a sperm – this is known as parthenogenesis. Mouse parthenogenetic development can go to mid-gestation and then the fetus dies, presumably of malnutrition, because the contribution of the sperm is required for the formation of the placenta which supplies nutrients for the fetus. Clearly, such a parthenogenetic mouse fetus would be a mouse, developed from a mouse embryo. There is no evidence of mammalian parthenogenetic development going beyond the early fetal stages.[11] Parthenogenesis has also been observed in IVF clinics, but organised typical human development does not take place and these cells soon perish. While there is no scientific evidence of the existence of human parthenogenetic embryos, this does not exclude the possibility of their artificial, albeit unethical, creation, by an unscrupulous scientist.[12]

Conclusion

Human embryonic cells are found in malignant embryos affected by cancer. They could also be produced, unethically, by aggregating different embryonic cell lines or produced by mixing human and animal gametes. Not all of these cases would involve true human embryos – and it may often be hard to give a certain answer. The challenge for scientists is to find an ethical way to engage in ES cell research for medical purposes without the risk of harming or cloning human embryos, to the satisfaction of the community.

ENDNOTES

[1] For more details see Norman M Ford, *When did I begin? Conception of the human individual in history, philosophy and science.* (Cambridge: University Press, p/b 1991) 151-56; 170-77.

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[4] Ford, *When did I begin?* 155.

[5] James A Thomson *et al*., 'Embryonic Stem Cell Lines Derived from Human Blastocysts'. *Science* 282 (1998) 1145-1147.

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Conventional and Complementary Therapies

This article will discuss complementary health care practices especially in their relationship with conventional scientific medicine. I will mainly use the term 'complementary' to describe these therapies as they are mainly used in conjunction with 'mainstream' practices. This article will not focus on one particular complementary therapy.

Conventional medicine may be considered the 'accepted' practice of health care because it is funded either through public or private health schemes. Conventional medicine is seen by many (especially those involved in its delivery) as a 'rational enterprise built on a scientific tradition that operates with logical arguments, the laws of causality and the epistemic strategies of observation and experimentation.'[1] However, it *is* criticised because its scientific approach operates with objective generalities while the art of medicine has to be practised on sick individuals. Other types of health care existed before the establishment of western scientific medicine and currently continue to be practised. Many of these operate on entirely different premises from conventional medicine.

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It is difficult to define alternative, complementary, unconventional or unorthodox therapies because they can encompass a huge variety of belief systems and practices. It may also depend on whether specific therapies are used exclusively or in conjunction with others. Complementary and alternative medicines may be identified as those therapies and beliefs that incorporate 'all health systems, modalities, and practices other than those intrinsic to the politically dominant health system of a particular society or culture' and include 'all practices and ideas self-defined by their users as preventing or treating illness or promoting health and well-being.'[2] Different categories of complementary therapies may include herbal medicine, diet and nutrition therapies, manual healing methods or manipulative therapies, mind-body interventions, pharmacological and biological treatments, bioelectromagnetic therapies and, treatments based on alternative health belief systems. According to the Consumers' Health Forum there are approximately 200 different modalities of complementary therapies available in Australia and these include practices such as naturopathy, acupuncture, Traditional Chinese Medicine, iridology, reflexology, therapeutic massage and herbal medicine.[3]

Some conventionally trained doctors and nurses use complementary practices in addition to their standard approaches for treating patients. A survey by Easthope et al about the use of acupuncture in general practice in Australia found that 15.1% of general practitioners in Australia claimed for acupuncture.[4] While this finding is significant it must be acknowledged that acupuncture performed by a medical practitioner does attract a Medicare rebate in Australia.

According to a study by MacLennan et al consumers spend more money on complementary medicines and products bought over the counter than on their personal contribution to prescription medications.[5] A survey of a representative population in South Australia in 1993 found that half the population use alternative medicines and that a fifth visit alternative medicine practitioners.[6]

The Goals of Health Care

If we accept that 'health' is the experience of well-being and integrity of the mind and body and not merely the absence of disease, then health care interventions should aim to prevent disease and promote health, they should cure if possible and if cure is not a possibility they should endeavour to control symptoms and relieve pain and suffering. While I am not familiar with all modes of complementary health care it must be acknowledged that generally such practices aim to achieve these goals with their respective methods and, as such their *intention* is good. Evaluating whether or not these goals *are* achieved is a debated issue. Efficacy of a scientific treatment or therapy involves assessing its differential effect by comparing it with a placebo or other treatment modality using a double blind controlled trial and a rigidly developed and approved protocol. There are, however, currently accepted and publicly funded conventional medical treatments that have not been rigorously and scientifically evaluated in this way. Many complementary therapies cannot be evaluated using the scientific method, as the health care paradigm that is central to them is different from that of conventional scientific medicine. Proponents of complementary medicine say that because such therapies work within a holistic philosophy whereby it is believed that there are many factors that influence the balance of the whole being, individual effects of therapy cannot

be measured. Given these beliefs it may be better to look at a package of outcomes such as symptom improvement, pain control and control over nausea and vomiting rather than trying to use a measurable biologic effect for assessing such therapies.[7] While this sort of evaluation is more holistic it does rely on the patient's own assessment of how they feel rather than objectively measured parameters.

This problem in measuring the outcome of complementary therapies is seen by the exclusion of complementary medicines from the Pharmaceutical Benefits Schedule. While complementary medicines are not excluded per se from the Schedule the inclusion criteria is based on comparative safety, efficacy and cost effectiveness. All of these criteria are difficult to evaluate with complementary medicines where the benefit may be derived from improved general quality of life rather than from an easily measured specific clinical outcome.

Differences Between Complementary and Conventional Medicine.

Conventional scientific medicine was developed predominantly in Western culture while complementary therapies have derived from a variety of other cultures. It must be acknowledged though that prior to the mid-1800s Western medical care consisted of a mix of naturopathic, homeopathic and botanical remedies that were derived from many different cultures. By definition, alternative medicine offers or represents a different approach to health and healing. Specifically, complementary therapies tend to view the human body more holistically rather than conventional medicine, which tends, apart from perhaps preventive interventions, to apply treatments to specific diseases and particular parts of the body. In complementary medicine therapeutic intervention aims to restore internal balance and enhance the body's own ability to heal itself. Those people who regularly use complementary medicine tend to perceive the methods and modalities used as more in accordance with their views towards health care.[8] Complementary therapies for the most part tend to be less invasive than conventional medical treatments such as surgery.

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According to Zollman and Vickers, complementary 'practitioners are not generally concerned with understanding the basic scientific mechanism of their particular therapy. Their knowledge base is often derived from a tradition of clinical observation and treatment decisions are usually empirical. Sometimes traditional teachings are handed down in a way that discourages questioning and evolution of a practice, or encourages reliance on their own and others' individual anecdotal clinical and intuitive experience.'[9] Like conventional medicine complementary medicine has its own language which is not easily translated into something understandable, especially since many of these practices have developed from other cultures that have different belief systems about health and the causes of disease.

Why Do People Use Complementary Therapies?

Eisenberg et al's study found that the majority of people who used complementary therapies did so for chronic rather than for acute life-threatening conditions.[10] These conditions included back problems, anxiety, headaches, chronic pain, and cancer or tumours. According to Ernst, alternative medicine provides benefits that are lacking in the normal doctor-patient encounter such as time, empathy, personalisation, expectation of a cure in chronic disease states, counselling, and a general emphasis upon health rather than disease.[11] At a workshop organised by the Consumers' Health Forum there were a number of reasons put forward by participants as to why people choose complementary medicine. These included the following: that by actively choosing complementary therapies people felt that they were actively participating in decisions about their own health care; that conventional medicine does not meet peoples' needs or expectations and complementary therapies provide an alternative; that complementary therapies are used together with conventional medicine to improve quality of life especially when an illness has no 'cure'; that cultural backgrounds (and there is no doubt that Australia is a multicultural society) can have an impact on the attitudes of different people in their use of complementary therapies and; that complementary therapies provide an alternative for people who are prescribed large doses of potentially toxic prescription medications and who want to move away from such medication.[12] A study conducted by Astin found that along 'with being more educated and reporting poorer health status, the majority of alternative medicine users appear to be doing so not so much as a result of being dissatisfied with conventional medicine but largely because they find these health care alternatives to be more congruent with their own values, beliefs, and philosophical orientations toward health and life.'[13] Another reason for why people use complementary therapies may be that they 'work' for those who have long-standing chronic conditions for which conventional medicine has not been effective in relieving symptoms. While there may be some merit in scientifically evaluating treatments, the increasing use of complementary therapies shows that the public is willing to try different types of treatment without scientific evidence of efficacy.

Ethical Concerns About Complementary Therapies

Some of the ethical issues related to the use of complementary therapies are pertinent to all health care inter-

ventions. In a society that values autonomy and individual rights people should be free to make their own choices as far as health care is concerned. This is provided that these choices are informed. The potential 'user' should be informed about what the intervention does, whether it is likely to work, whether there are any associated side effects or risks, who provides the therapy and what sort of qualifications or registration are required in order to practise and, how much the therapy will cost. These things are more easily discovered about the practice of conventional medicine and in a publicly funded health care system the cost may not be an issue for the individual patient. Several legal precedents have made conventional medical practitioners aware of the requirements of informed consent. This same emphasis on providing the patient with adequate information needs to be reinforced in the area of complementary medicine. Limitations of treatment should be highlighted as often people turn to complementary therapies when conventional medicine has nothing more to offer.

Is there an ethical responsibility to protect vulnerable people from the inflated and often erroneous claims that a particular therapy may work when there is no evidence that it will? While some may claim that this is paternalistic, a duty of care must be recognised. Given that many people accessing complementary therapies also use mainstream medicine this duty of care should extend to the conventional medical practitioner who should make it their responsibility to find out about all the health care interventions that the patient is using. Currently, many people who use complementary therapies do so without the knowledge of their medical doctor. Knowing exactly what treatments a patient is receiving is vital so that a health care plan can be made in consultation with the patient, and appropriate treatments will be used. It is also essential so that any potential harmful interactions between different types of health care therapies can be foreseen.

Given that in many developed countries conventional medicine is available at no great cost to the individual and not all treatments have been scientifically evaluated, there may be a valid argument about making complementary therapies available through public funding. There is however a move towards evidence based medicine and best practice and, given that there is not much research into the efficacy and outcomes of many complementary therapies the onus would be on providers to supply such evidence if these therapies were to be made available. On the other hand it could be argued by some that if people are increasingly using complementary therapies and thereby casting a vote of confidence in such treatments, perhaps funding should be responsive to community demand rather than strict evaluation.

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Currently there is a great variation between the type and amount of training undergone by different complementary health practitioners. Chiropractors and osteopaths for example obtain university degrees that entail a long time of intensive training and are universally recognised while others are internally assessed and the training programs are not very long and may not even be recognised within their own discipline. There should be minimum standards set, which could include universal regulation, participation in research and adequate note keeping so exactly what treatment has been given has been documented.

There is also a need to develop less adversarial, more cooperative relationships between practitioners of conventional medicine and of complementary therapies. This could be achieved through education programs and there would be greater understanding of what treatments are appropriate for specific conditions. In conventional medicine the general practitioner acts as a gatekeeper for referral to specialist medical interventions as well as for care given by other health professionals. While there are criticisms of such a system it does mean that the general practitioner can gather the relevant general contextual information from the patient that will hopefully ensure that they access the most appropriate help. Complementary therapies have no such referral system, as government funding requirements do not control them. Without someone coordinating, or at least knowing what treatments are being used, there is a risk that the patient may abandon or not access 'proven' therapies, and this may not be in their best interests.

Conclusion

Conventional medicine does not have all the answers. For many chronic diseases all that conventional medicine can do is to palliate the symptoms and monitor for complications. Many complementary therapies do work but there needs to be more regulation, more stringent requirements for the practice of complementary medicine and more attempts at researching and documenting the effects and outcomes of such interventions. The public are placing their faith and trust, and sometimes last hope, in many complementary therapies by virtue of the numbers using them. This is especially significant given that they carry the financial cost. This is, however, not equitable as there are large groups in the community who cannot afford such choices. We cannot ignore that there is a place for valid complementary therapies in our multicultural society and that the way to achieve the best outcomes for patients is for all health care providers to work together cooperatively.

ENDNOTES

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Genetic Privacy: Families, Healthcare Professionals and the State

The aim of this article is to highlight the differences between genetic information and other types of medical information and then consider the implications of these differences for privacy and confidentiality.

Genetic Information

Before detailing the unique nature of genetic information I will briefly outline some basic genetics in order to clarify exactly what genetic information refers to. Every cell of the human body contains 23 pairs of chromosomes, one set from each parent. Each chromosome consists of hundreds or thousands of genes, with each gene having a unique position on one of the chromosomes. Deoxyribonucleic acid (DNA) is the inherited genetic material that forms each gene. While every member of the human race has the same set of genes, which explains the similarities between us, the precise DNA sequences vary between individuals by about 0.1-0.2%, which helps to explain our individual differences[1]. Any information gained from investigating an individual's DNA or genetic make-up is referred to as genetic information. This information includes the actual DNA sequences and any inferences that can be made based on the knowledge of those sequences. For example, genetic information includes both the presence of a genetic mutation, such as that found for Huntington's disease, as well as the fact that an individual found to have that specific genetic mutation will at some time in the future develop that disease.

Genetic information can be generated from various sources, including genetic screening programs for either genetic disorders or carrier status, susceptibility testing, prenatal testing and diagnostic genetic testing. The information gained from these types of test can in turn refer to a variety of types of disorders including; single gene disorders, polygenic disorders and multifactorial disorders, as well as to diagnoses, predictions about future health, susceptibilities and carrier status. The sheer variety and complexity of genetic information makes establishing appropriate ways of dealing with it difficult. However, further issues arise amid the difficulties of communicating genetic information between health professionals and patients. These include: the rights of individuals to genetic information and their expectations of privacy and confidentiality, the responsibility they may have to family members, the interests of third parties, including the State, as well as others who may be affected by the information. I will address the issues of sharing genetic information within families before considering the interests of third parties in general. Due to space restrictions I will leave to another time the important ethical discussion about the communication of genetic information to individuals, and the necessary pre- and post-test counselling.

The Shared Nature of Genetic Information

Genetic information, unlike other medical or personal information, has a shared nature. As a result of how genetic inheritance works, genetic information regarding an individual can also allow inferences to be made about other members of their family. For example, if as a result of a carrier screening test an individual discovers that they are a carrier of cystic fibrosis (CF), then it can be inferred that their siblings might also be carriers of CF and that one of their genetic parents also carries the same mutation. Because genetic information can impact directly on the lives of family members, questions arise regarding possible obligations and responsibilities. Questions like, does an individual have an obligation to his/her family to share genetic information, especially when the information can impact so dramatically on important life decisions, such as, whether or not to have children? On the other hand, testing for some genetic mutations requires genetic samples from several family members.

These family members may be affected, unaffected or carriers of the genetic mutation under investigation. Providing a genetic sample is as easy as giving a blood sample so the provision of it is not a difficult procedure. With this in mind should such family members be obligated to provide a sample? If they have a right not to know about their genetic status, how can this be protected? Genetic information can be a powerful predictive tool, but, it also has the potential to change family relationships forever, in both positive and negative ways, strengthening or weakening bonds.[2]

Before considering the issues created by the sharing of genetic information I will briefly outline two important concepts related to dealing with personal information, privacy and confidentiality.

Privacy

Privacy is generally understood to refer to an individual's claimed right to control information about him/herself. While this partly captures the concept of privacy, an individual's privacy can also be maintained even if they do not have control over personal information or conversations, etc. For example, others may just ignore them. A loss of privacy in a broader sense refers to people gaining access to an individual's areas of intimacy, secrecy, anonymity or seclusion[3]. Medical information in general is considered to be private and with whom an individual shares such information is left up to their discretion. While genetic information resembles general medical information in many ways, as we have seen above, it has a unique relationship to other people that medical information does not. It is generally agreed that an individual's privacy regarding genetic information should be maintained, however, as we will see below, there are instances when an individual's claim to privacy might place others at risk of harm and therefore it might be acceptable to override a claim to genetic privacy. In an attempt to ensure that privacy is maintained the NHMRC has produced guidelines, *Aspects of Privacy in Medical Research*, which aim to relate principles in the *Privacy Act 1988* to medical research and practice.

Confidentiality

Confidentiality refers to the requirement of protecting information given to health professionals (or others) in confidence. In other words, if a patient has disclosed information to a health professional in confidence, and the health professional has an obligation of confidentiality, then they should not disclose that information to another party without the patient's consent[4]. The difference between a patient's claimed right to privacy and confidentiality is not always clear. Put simply, an infringement of a patient's right to confidentiality occurs only when a person who has been told information in confidence fails to protect that information or willingly discloses it without the patient's consent. On the other hand, a patient's privacy would be violated if a person enters a hospital without authorisation and views information about that patient. Confidentiality can only be violated when a confidential relationship exists.

Sharing Genetic Information Within Families

As we have seen, genetic information cannot always be considered personal, since it has a shared or common status amongst blood relatives. As a result of this common nature of genetic information within families, both pre- and post-test genetic counselling should encourage individuals to share any information gained, especially when it can allow family members to have their own genetic tests and then either seek preventative treatment, make informed decisions about having a family and if preventative treatment exists, have their children tested. While individuals may manage to keep their genetic information private, the Australian Medical Association Code of Ethics states, 'Exceptions [to the obligation of confidentiality] may arise where the health of others is at risk…'.[5] It would appear then that while encouraging an individual to divulge genetic information to their own family members would be the most ethically appropriate outcome, this may not always be possible. If this cannot be achieved then it seems ethical, and possibly lawful, for doctors to breach confidentiality and inform relatives. When doctors know a patient carries a harmful genetic mutation they may be justified breaching confidentiality and advising a relative who could 'take measures to avoid or minimise disease, or who is about to start a family, to undertake testing for the mutation'.[6]

Sharing Genetic Information Amongst Healthcare Professionals

Medical information about a patient is generally shared amongst a team of healthcare professionals who are treating the patient. Information might also be exchanged between different specialists treating the same patient. However, the sharing of genetic information is perhaps not so ethically permissible. It is important that everyone treating a patient understands their current condition, for example, that the patient has a gastric ulcer in need of treatment. It is not necessary that the same healthcare professionals know that the same patient has the gene for Alzheimers, which will not affect the patient for decades to come. While the late onset of this disease is genetically predicted it should not have a bearing on the treatment that a person receives for other medical conditions, nor should it influence the reactions of healthcare professionals. Restricting access to genetic information that does not pertain to a patient's current condition is necessary to ensure the patient's current treatment is unaffected. Restricting access in this way is the responsibility

of the referring medical practitioner and is also at the discretion of the patient. However, genetic information that is relevant to a current medical condition should be shared and treated with the same standards of privacy and confidentiality as other medical information.

Another instance that may require

the demands of informed consent must be met

the sharing of genetic information is when doctors treating different, but related, individuals require information from one another. Every attempt should be made to obtain patient consent to this information disclosure. However, if a patient does not consent then it is up to the doctor to decide if failing to disclose the genetic information places another person at risk of serious harm. If there is a preventative therapy for a late onset genetic condition then I would consider it ethically acceptable for a doctor to share that information with a fellow doctor in the hope of preventing the second family member developing the disorder. Again, I think it is important that these types of situations are explained to people before they undergo genetic testing. Explanation of these types of situations would be a necessary part of gaining informed consent. Consenting to genetic testing involves a great deal more than consenting to most medical examinations, but the demands of informed consent must still be met.

Sharing Genetic Information With Third Parties

The AMA state their opposition to divulging genetic information to third parties very strongly. 'Unless required by law, there should be no compulsion on, or coercion of the person, the attending doctors or the staff of a genetics laboratory to acknowledge or, in any other way reveal, that a genetic test may have been undertaken, or divulge the results of any test which may have been undertaken.'[7] While this standard seems ethically appropriate there are exceptions. There may be instances when divulging genetic information may be in the individual's best interests. For example, if an individual knows that they have a genetic predisposition to lung cancer, which will be exacerbated by being exposed to a highly polluted environment for extended periods, and such exposure is part of their current employment, then it would be in their best interests to inform their employer. Hopefully their work environment can be improved or an alternative placement can be found. Appropriate legislation will be required to ensure that employers do not discriminate against individuals on genetic grounds.[8]

The possibility that individuals will have to divulge their genetic information to employers or insurers should be clearly explained to them prior to undergoing genetic tests. Life and disability insurers may require that genetic information be disclosed in order to determine risk classification before granting cover. This does not mean that insurers can demand that people undergo genetic tests before granting cover, only that if individuals are aware of their genetic information that they must disclose it. The same is also true of the requirement to disclose existing medical conditions and family medical histories. While it may not always seem just that some people pay more for their life insurance than others, disclosing genetic information is unlikely to alter the balance. For example, a person whose family has a history of high cholesterol and heart disease may discover they do not carry the genetic mutation that places them at risk and as a result they may receive a reduction in their insurance premiums. Perhaps the most prudent advice for people considering genetic testing is to take out life or disability insurance prior to undergoing genetic testing, in which case they will be guaranteed of insurance cover (provided there are no other reasons for denying cover) and may even receive a reduction in premiums.[9]

Conclusion

Genetic information has a unique nature and as a result must be dealt with in very delicate ways. Genetic information should always be handled with great care. Privacy and confidentiality have a very important role to play in ensuring a trusting and open relationship continues between individuals and their healthcare professionals, however, there are cases, as we have seen, where these valuable principles might justifiably be overridden. Education is required to ensure that when genetic information is appropriately shared, either within families, with health professionals or with the community in general, that it is well understood. Most genetic information has a probabilistic nature and needs to be properly understood in order to avoid panic, overreaction, discrimination, stigmatisation and misuse.

ENDNOTES

[1] National Health and Medical Research Council, *Draft Guidance on Ethical Aspects of Human Genetic Screening* 14 May 1999, 4.

[2] Chapter 1, 'Daily life and the new genetics: some personal stories'. *The troubled helix: Social and psychological implications of the new human genetics.* Theresa Marteau & Martin Richards eds., (Cambridge: University Press, 1996).

[3] Tom L Beauchamp & James F Childress, *Principles of Biomedical Ethics Fourth Edition* (New York: Oxford University Press 1994), 407-412.

[4] Ibid, 418.

[5] Australian Medical Association, *AMA Code of Ethics 1996*. http://domino.ama.com.au Under Position Statements.

[6] Loane Skene & Max Charlesworth, 'The new genetics: legal and ethical implications for medicine'. *The Medical Journal of Australia* 165 (1996) 301-303, 301.

[7] Australian Medical Association, *AMA Position Statement on Genetic Issues – 1998*. http://www.domino.ama.com.au.

[8] The *Genetic Privacy and Discrimination Bill* is an example of the type of legislation that may be required.

[9] 'The new genetics…302. ✣

Tracey Phelan

Patient Records

Access to patient medical records is a much contested issue and one that is becoming more pertinent as electronic storage of information is becoming the norm. This article will examine patient records and discuss some of the issues that are raised when deciding who should have access to these records.

What is a Patient Record?

A patient's medical or health record is a profile of their history with a particular health care provider whether that be a specific health professional or, an institution where many health care professionals have been involved in their care. It *is* the patient's career while under the care of a particular professional or institution. Patients' records held by hospitals can include: doctors', nurses' and allied health professionals' progress notes, operation and anaesthetic notes, investigation and diagnostic reports of all kinds from microbiology, biochemistry, haematology, radiology, and pathology departments, drug orders and charts, admission and discharge forms, letters and other referral information, post-mortem reports, discharge summaries and/or discharge letters, delivery and perinatal summaries. They can also include scans, photographs, X-rays and electronically stored information. A patient record in a public hospital also provides valuable and absolutely essential information for funding purposes. Usually patient records are centrally filed and if a patient is admitted to the hospital the record goes to the ward with the patient. If the patient has to go to other departments for treatments and procedures the record goes with them so that subsequent treating health care professionals can have access to any relevant medical information that could affect what they are doing to, or for, the patient.

'Patient records held by a private practitioner may include the doctor's notes of what the patient has said about the patient's background, family history and condition; the doctor's handwritten notes of his or her observations in examining the patient, perhaps with speculative diagnoses; referral letters and replies from specialists; investigations reports (including X-rays and CAT scans); photographs and correspondence with the patient.'[1]

Health care providers should ensure that the information they record is accurate, objective, observable and relevant. The amount and breadth of information contained in many medical records can provide a detailed picture of the person concerned. It can include vital information about a person's well-being and their lives and a mistaken or negative judgement could influence their health. From the perspective of the health care professional what is in those records is about the quality of their work, and what they record or leave out can have consequences for their livelihood.[2]

provide a detailed picture of the person concerned

Medical or health records are compiled to create a patient history showing a sequence, a progression of events in the patient's life. An inpatient history shows the patient from admission to discharge and, if necessary, any follow-up care plan. Records kept by private practitioners also document the sequence of consultations historically. Health records, in this era of economic rationalism, evidence based practice, quality control, and ongoing research, are also used to collect information, evaluate treatment and care and allow for future funding and health care policy planning.

Doctors have used medical records in research for many years for identifying the side effects of drugs, the effects of toxic substances in the environment, and, the effectiveness and safety of medical procedures. According to Melton, the study of medical records is important because the health of the population can be monitored, populations at high risk of disease can be identified, the effectiveness of treatment can be determined, prognosis can be quantified, the usefulness of diagnostic tests and screening programs can be assessed, administrative functions can be supported, the adequacy of care can be monitored and, through cost-effectiveness analysis policy can be influenced.[3]

Who Owns the Health Record?

Medical records are generally owned by the institution in which they were prepared or, in the private sector, by the treating doctor. They are compiled *in order* that the doctor or health care team can treat the patient. Although most of the information in the record is *about* the patient it has been supplied *by* the doctor and other health professionals often through *their* observation of the patient. The health care provider directly uses the record whereas the patient does not.

Access to the Health Record

Current access to records in Victoria is basically restricted to the public sector where people can utilise the Freedom of Information legislation to gain information. Two principles embodied in the Victorian *Freedom of Information Act 1982* are firstly, that every person has the right of access to documents held by ministers, government departments, prescribed authorities, including public hospitals and local government, except those for which there are specific exemptions, and secondly, that every person has a legally enforceable right of access to their own personal records, or other documents relating to their personal affairs and, if a document relating to personal affairs contains wrong or misleading information, a

person may use the Act to have that information corrected or amended.[4]

Under the Victorian legislation an application for access to medical records must be made in writing to the specific institution, many of which have particular people who deal with such requests. A payment must accompany the application (except under special circumstances where it may be waived) and the institution must deal with the request within 45 days of receiving it. If access is granted the individual concerned will be notified of any costs incurred such as photocopying and search fees, and, upon receipt of payment, they will be sent the required information by registered mail or given the opportunity to inspect the record.

There are, however, several grounds where access to the record in a public institution may be refused. These circumstances are when 'the disclosure of the information to that person might be prejudicial to the physical or mental health or well-being of that person…..'[5] Access may be given via an intermediary rather than to the patient themselves if the holder of the record believes that the patient could not understand the document, for example, if the patient is a child or a person with an intellectual disability.

Disposal of Patient Records

In Victoria there is a general disposal schedule for public health services patient information records established by the Department of Human Services and the Public Record Office that sets out how long publicly held health records must be kept and when they can be disposed of. The requirements are different dependent on the type of record and the age of the individual. Childrens' records must be kept for a period after they have reached 18 years of age. The time periods for disposal are the minimum required. Some records may be deemed worth preserving permanently.

The Health Services (Private Hospitals and Day Procedures Centres) Regulations 1991 have requirements for the retention of records held by private institutions which, for the most part, except for those under 18 years of age, is seven years after discharge or death.

Access to medical records is hotly contested. Consumer groups consider that patients have a right to their records and it has even been suggested that they be the keepers of those records either with a hard copy or stored electronically using a 'smart card'. Others, particularly health care professionals, have objections to giving patients open access to their records. I will now enumerate some of the reasons given that either support or object to, the open access to medical records.

Support

It has been suggested that increased access to health records may lead to people being more involved in decisions involving their health care.[6] According to Amanda Cornwall access to health records would mean that 'consumers become more involved and informed, more attentive to their health care and more in control. It helps with continuity between different health services and when people move or change doctors. If a consumer has access to their records they can better understand who else has access to the information and be reassured that the information is being kept confidential.'[7]

It could be surmised that patients may be more likely to follow prescribed treatment as they may be more informed, and this may encourage self-management and personal responsibility which, are especially important concepts when there is increasing chronic illness in the community. The records may be more accurate. Patients have a vested interest in their records being accurate not only for the benefit of their own health care and treatment, but also because the accuracy of the health record can have far reaching effects if seen by others outside the health care system such as insurance companies, workers compensation organisations or by those conducting medical research.

Patients may be less worried about what is being kept from them if they can access their records and the presumed higher level of patient satisfaction and improved communication may reduce the likelihood of complaints or litigation against providers. Access to records may enable the patient to understand the kind of information that is disclosed to other people and therefore they may be able to give informed consent to any information disclosure and thereby protecting their privacy.

Objection

There are concerns about the negative effects of allowing patients open access to their records. Patients may not understand the medical information and they may become confused and anxious, especially those who are terminally ill or who have psychiatric disorders. Health care professionals may be less inclined to document specific information that may be very useful, especially if a diagnosis is only speculative. The medical records are part of the doctor's business and therefore provide an economic advantage over which, the doctor should have control.[8] The medical records are seen to belong to the health provider and finally, providing access may be too time consuming and too expensive for health service providers. There is also a fear that increased access to medical records may mean increased litigation.

These concerns regarding either the giving, or not giving, of unrestricted access to medical records are regularly enunciated in the press, magazines, academic journals and de-

bated in the public arena. To my knowledge there has been little vigorous research conducted to investigate the truth in any of the claims made. One thing however does seem apparent. Why do patients want access to their records? One would have to surmise that it is because they are dissatisfied with the amount, or clarity, of information that they are being given about their health status and treatment. Historically, health care professionals did not tell their patients all, and indeed, not all patients want to know everything. There is almost an 'implied secrecy', a 'covering up' if patients are not allowed access to their records. If patients, however, received the appropriate amount of information and in the appropriate language so that they could understand and internalise it, there may not be the need for patients to want to see their records. Medicine and the business of health care are not objective and exact. Doctors especially need to speculate and confer with each other about a possible diagnosis or treatment and it may not be in the patience's best interests to see lists of queried diagnoses in the record.

patients may be more likely to follow prescribed treatment

Privacy – an Ethical Issue

The medical record involves private information about a person but they do not own it. They do however have an interest in maintaining the privacy of the information. This means that they have an interest in controlling access to, and use of, any information personal to them. This is particularly pertinent in a computerised age where information can be stored electronically and transferred nationally and internationally. Technological developments and space requirements have meant that there is an impetus to change from traditional paper based files to computerised records. A doctor has a confidential relationship with their patient and as such has a responsibility to maintain that confidentiality. However, not all those who have access to an electronic medical record have this relationship of confidentiality and the privacy of the patient may be threatened without appropriate safeguards. According to Meredith Carter 'Australia has national privacy legislation but it covers only the Commonwealth public sector. As most health care is provided in State hospitals or by private sector practitioners, consumers in this country have very little ability to control the flow of their personal health records around the health system and beyond it.'[9]

Conclusion

The state of Victoria allows people to access their health records held in public institutions using Freedom of Information legislation. This should probably be expanded to include records held privately so that there is equity across the public and private systems.[10] Such a recommendation was made just this year in the Health Services Policy Review Discussion Paper put out for the Victorian Department of Human Services by Phillips Fox and Casemix Consulting. There is however an obvious need for improvement in communication between health care professionals and patients. If patients were already in possession of the necessary knowledge and had the appropriate understanding they may not request access to their medical records.

ENDNOTES

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[5] *Freedom of Information Act 1982* (Vic) Section 33.(4).

[6] Meredith Carter, 'Should patients have access to their medical records? *MJA* 169 (1998) 596.

[7] Amanda Cornwall, 'Whose medical records?' *Health Issues* 47 June 1996, 9.

[8] Colleen Krestensen, 'Access to Medical Records: Time for change!' *Health Forum*, No32, December 1994, 22.

[9] Meredith Carter, 'Protesting consumers' interests in their health records' *Australian Health Law Bulletin*, 8/2 September 1999, 14.

[10] As is the case in the ACT with the *Health Records (Privacy and Access) Act 1997*. ✣

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