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Ethical Reflections on the Separation of Conjoined Twins

World media attention focussed on the predicament of the parents of the Maltese conjoined twins in Manchester last year. This article separates the various ethical strands in this complex ethical dilemma. It shows that more than one reasonable answer could have been given by the people involved in this case.

The most recent media reports about the conjoined twins who were separated in Manchester in November, 2000 reveal the babies' actual names — Rosie and Gracie (Rosie the weaker twin died as a consequence of the separation). Their mother, Rina Attard, is quoted as saying, 'we are happy that the decision to separate was taken by the judges… it meant we didn't say, "Yes, kill Rosie to save Gracie"'. At the time of the court case, the parents thought the court was acting wrongly. However, it is not too late to ask whether the parents are now right to be happy with the court's decision.

It is well known that the difficulty of this case was due to the fact that the twins were joined at the abdomen, and that Rosie depended on Gracie's heart and lungs because her own were too weak to support her. Surgical separation was sure to result in Rosie's death, and yet without separation, both twins would eventually die (though there were conflicting predictions about how long they could survive while joined). This case raises two main ethical issues: Who were the *proper decision makers*, and what was the *right course of action* to take?

The decision makers

Contemporary Catholic moral theology emphasises that moral evaluation should always be undertaken from the perspective of the 'acting subject', that is, from the perspective of each person as moral agent cognizant of his or her proper responsibilities (see John Paul II, *Veritatis Splendor* s. 78). The many ethical issues raised by this case thus involved different questions and responsibilities for the different agents concerned with it, including the referring doctor on Gozo (who had studied at Manchester), the doctors in Manchester, the hospital authorities, the church advisers and so on.

It is from the perspective of the moral agent that the importance of the

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intrinsic *meaning* or *object* of one's action becomes apparent. The parents' moral object was to care for both their babies, and to evaluate the reasonable and likely benefits of treatment options, and the tolerable burdens for the twins and for themselves. The doctors' moral responsibilities centred on the information, advice and prognosis that should be given, and the procedures that should be offered. The hospital authorities' responsibilities concerned the legal requirements to be met, and so on. Each of these issues (and the many further issues they involve) needs to be explored in the light of the responsibilities of the distinct agents and institutions concerned.

Once we take seriously the perspective of the acting subject, it

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becomes apparent that ethical questions are never just abstract questions for detached observers trying to determine the best outcome and how to achieve it. That is the tempting *utilitarian* approach to ethics – to suppose that ethics is simply about *outcomes* and 'the greatest happiness for the greatest number'. In the Catholic moral tradition, however, ethical reflection must always focus as much on the intrinsic *meaning* and *purpose* of our actions, as it does on their outcomes. Hence, the importance in this case of evaluating the kind of surgery proposed to achieve separation: would this constitute an assault on the weaker twin? Or, worse, would surgery involve killing one to save the other? These questions remain unasked in a *utilitarian calculation*, and yet they are central to sound ethical reflection on how a prudent and conscientious person would act in the situation.

In the end, of course, the rival decision makers were the parents and the court. Much discussion has focussed on the role taken by the English Court of Appeal. The Court understood its responsibility to be that of deciding this case *in its own right*. While it said it respected the parent's wishes, in the end the court reached its own independent decision, despite the fact that it also said the hospital – without blame – might have acted on the parents' request not to separate the twins.

It is surely arguable, however, that the key question for the Court should have been 'what should we as a

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Court do, in the light of statute and common law, in the face of the parent's request that their babies not be separated'? The proper decision makers in this case were the parents – in the first instance the responsibility was properly theirs, not the State's or the Court's or the doctors'. The parents were in the best position to assess the burdens and benefits of separation, to appreciate the demands on the twins and themselves, to assess their resources for caring for a surviving child back on Gozo, and so on. Only if parents are clearly failing in their proper responsibilities, should a court intervene and take the parental responsibility on itself. Since the Court agreed the parents' position was not unreasonable, the Court's own determination should simply have been that the parents' reasonable wishes be respected.

Nonetheless, given the latest reports, and with the surviving child doing reasonably well, many will wonder if in hindsight the court was right to overrule the parents' request. Was the parents' request at the time unreasonable? Would it have been open to the parents to request separation as a morally upright course of action? The most critical ethical question to be addressed is whether the decision to separate the twins amounted to a decision *to kill Rosie so that Gracie could live.*

The ethical issue in itself

Was surgery to separate the twins *permissible?* It is reasonable to assume that the goal of the surgery was good – at least for Gracie, the stronger twin. [I set aside discussion of the relative benefits and burdens of separation for Gracie, her prognosis, and her foreseeable life. The new *Code of Ethical Standards* published by Catholic Health Australia notes that the appropriateness of extensive surgery for a new born baby 'is to be determined in the light of the child's condition and of the foreseeable benefits and burdens of the treatment options for the total good of the child' (2.32).]

But even when 'the goal' of our action is good, the goodness or badness of 'the means' chosen must also be assessed, and assessed in its

one of the three judges held that separating would not be killing, since the purpose was not the death of Rosie, even though that was the inevitable consequence

own right. The difficulty in this case, of course, is that 'the means' was a surgical act that would be lethal for Rosie. Is the principle of 'double effect' or 'side effects' applicable to this case? Was clamping the shared aorta 'one act' with 'two effects' – independent life for Gracie, but death for Rosie? Two judges in the Court of Appeal, Ward LJ and Brooke LJ, held that 'double effect' was not applicable on the grounds that the benefit and the burden concerned different individuals. They held that the death of Rosie was not a 'side effect' of the 'act', but was so much the direct 'result' of the act as to make that act one of killing Rosie to benefit Gracie. One of the three judges, Walker LJ, held that separating would not be killing, since the purpose was not the death of Rosie, even though that was the inevitable

consequence.

I am not convinced the Court's rejection of 'double effect' reasoning was justified. This surgery could be considered a non-lethal act *in itself*, albeit with a lethal consequence. While it is usually easy to distinguish between 'a bad act of killing which has a good effect' and 'a neutral act of surgery which has a good effect and a bad effect', the difficult cases are precisely those in which there is some ambiguity over what object or meaning an action truly embodies. We can imagine some surgical procedures that clearly involve killing one to save another, and we can imagine other procedures that would truly be in themselves non-lethal actions with a lethal side effect. The surgery required in this case would seem to sit on the boundary between these two possibilities.

It is unfortunate that two of the judges persisted in describing this case as a matter of killing one to save another. If that is what the doctors took themselves to be doing, if that is

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what the judges thought they were approving, then I believe they were acting wrongly. However, my understanding of the surgery involved is that it need not be taken to embody the intention to kill, and the submission by the Catholic Archbishop seems to acknowledge this possibility.[1] Rosie died because, once separated from Gracie, her own body could not sustain her life (see above Walker LJ).

There is a further worry, however, which served as the basis for the parents' and the Archbishop's opposition to the separation – viz. that even if the surgery involved no intention to kill, it did involve an *assault* on Rosie, given the extent to which the twins shared their organs and tissues. The Archbishop wrote: 'the invasion of [Rosie's] bodily integrity is nevertheless intended… that violation of her bodily integrity is in the nature of the case lethal for her. It therefore cannot be justified.'[2]

Is it correct to describe the surgery as an 'invasion of Rosie's bodily integrity' which, in the absence of any benefit to Rosie, was not morally permissible? I believe this is the most difficult question raised by this

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case. 'Invasion of bodily integrity' is a moral term (like *murder* or *mutilation*), and connotes moral wrongdoing. While the surgery involved *physical interventions* with respect to Rosie, it does not automatically follow that these constituted an unjustified invasion of bodily integrity in the moral sense. That was the key issue the parents and doctors had to address: would it be accurate to describe the required surgery as an unjustified invasion of bodily integrity?

I do not believe there is a black and white answer to this most troubling of questions. 'Bodily integrity' in the case of conjoined twins is a complex phenomenon, because tissue and bodily resources are shared. Furthermore, assessment of the benefits and burdens of separation in the case of conjoined twins requires more than a straightforward allocation between two distinct persons. On the one hand, perhaps it is an 'objective' benefit *to both* that at least one of these twins survives? On the other hand, might Gracie later feel a 'subjective burden' of guilt and responsibility knowing that she is alive because of an intervention that caused Rosie's death? These questions and others like them are so imponderable that the decision should have been left to the prudent and conscientious judgment of the people closest to the situation, and most closely related to the twins, to those most intimately acquainted with the concrete circumstances of the case, with a clear understanding the procedures proposed, and so on.

At this distance, I cannot say whether or not surgery amounted to an unjustified invasion of Rosie's body. I do think the parents might have reached the conclusion that an operation to separate the twins was justified. On the other hand, we can understand the parents' reluctance to request a procedure that would surely lead to the death of one of their children. I think it may have been open to the parents to seek a court ruling for something they themselves did not wish to decide. That is why I suggest there need be no inconsistency in the parents *now* feeling happy the court decided as it did.

One thing that must be regretted in this case is *the explanation* given by the court, namely that they were approving (as a matter of necessity) the killing of one to save another. No one, and no court, is entitled to approve either a deliberate killing, or an invasion of bodily integrity, as a 'means' to an 'end'. The procedure of separation was only permissible if prudent and conscientious people would truly see it, not as a killing or a mutilation, nor as an invasion of bodily integrity, but only as appropriate surgery to save life in tragic circumstances.

ENDNOTES

[1] *Origins,* (October 5, 2000) 269-272.

[2] *Ibid.,* 271. ✣

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Blowing the Whistle

This article will discuss whistleblowing and the ethical dilemmas that it highlights.

Whistleblowing can be defined as the 'public disclosure, by a person working within an organization of acts, omissions, practices, or policies perceived as morally wrong by that person and is a disclosure regarded as wrongful by that organization's authorities.'[1] It is not necessarily the nature of the information that is disclosed that makes it an act of whistleblowing. Different people can disclose the same information with one disclosure being an act of whistleblowing and another not. What makes something an act of whistleblowing is whether or not the person has been authorised to disclose the information. According to William De Maria 'whistleblowing is ethical resistance against the usually protected existence of wrongdoing.'[2] De Maria believes that to be a whistleblower one must suffer, initiate the action oneself, act of one's own will, directly perceive the wrongdoing, perceive wrongdoing in a work setting, disclose openly, act to stop the wrongdoing and act in the public's best interest.[3] Whistleblowing *should* be an action of last resort. It is far better for institutions themselves to be responsive to claims from within of poor standards of care or allegations of malpractice.

Whistleblowing incorporates the following three elements. Firstly, there is a perception by someone within an organisation that something is morally amiss within that organisation. Secondly, there must be communication of that perception of wrongdoing to parties outside the organisation. Finally, there must be a perception by at least some of those in authority in that organisation that such a communication ought not to have been made.[4] The ethical issues that arise with whistleblowing may include questioning: the nature and scope of responsibility and accountability at a corporate, managerial, professional and employee level; the openness and accountability of organisations and whether this is reflected in their policies, procedures and actual practices; the justifiability of going 'public' (what does the whistleblower stand to lose); and the conflicting claims of confidentiality and freedom of speech and of loyalty and honesty.

In the workplace the relationship between employer and employee is one

whistleblowing should be an action of last resort

where there is an uneven distribution of power. There is an exchange of services on the part of the employee for remuneration from the employer. This means that the employer is in a position to determine the terms and conditions under which the employee works and therefore it takes much courage and conviction to publicly report perceived wrongdoing.

Whistleblowing contexts

There are many types of perceived wrongdoing that may prompt a potential whistleblower to act and these include: negligent treatment of patients or clients and professional malpractice; scientific fraud where research findings are manipulated, fudged or misreported; unfairness or injustice in the workplace which may include racial, sexual or disability discrimination; danger and detriment to the workplace or the public in the form of health and environmental hazards and finally, threats to autonomy and integrity when professional judgement is overridden.

A whistleblower may act because of several modes of behaviour in their workplace. It may be because of a single act or omission that has wide reaching ramifications even though it appears to have been only a one-off occurrence. It may be because of a practice or procedure that is routinely performed that is risky and has real or potential detrimental effects or, a practice or procedure that should be performed to ensure safety or quality control but isn't. It may be because a policy has been implemented that is directly or indirectly detrimental to the public because it puts the employees of an institution under considerable stress. Finally, it may be that the general culture of the organisation is so laid-back and laissez-faire that no-one takes their responsibilities seriously and therefore take shortcuts whenever possible. In the latter case no-one even recognises what is wrong. There is an accident waiting to happen because there are no safeguards and no-one appears to care and either the general public or the employees are at grave risk. It often takes a new employee to even see the problems in such a workplace.[5]

Two well publicised whistleblowers of the 1990s, Steve Bolsin and Jeffrey Wigand spoke out about situations in which they perceived there

authorities took no action but the figures were leaked to the press

was moral wrongdoing. In 1988 Steve Bolsin was employed at The Bristol Royal Infirmary (BRI) as a consultant cardiac anaesthetist. He noticed that operations, which should have taken a relatively short time (at another hospital), were taking far longer at the BRI. This meant that the patients (in this case babies and children) were spending long periods on cardiopulmonary bypass, which increased the possibility of complications. Bolsin kept a logbook and questioned the time taken in surgery with surgeons and fellow anaesthetists. He also discovered that compared with the rest of England the BRl had twice the number of child deaths related to heart surgery as anywhere else. He reported these facts to the chief executive who basi-

cally did nothing. The surgeon whose skills were being queried was angry that the unit's performance was being questioned and nothing was investigated or improved. Meanwhile, however, outside the BRI it was becoming increasingly apparent to other doctors that the unit's performance was poor and so they were not referring their paediatric heart patients. Bolsin and a colleague did a more systematic investigation of the unit's performance and found that not only was the death rate higher at Bristol for the operation arterial switch, but that one particular surgeon was statistically worse than the others. He showed these figures to the head of the college of anaesthetists and to a professor of cardiac surgery but no change was effected. In 1992 Bolsin removed himself from the team performing heart surgery on the children. He did however continue to audit what was happening in the cardiac unit and presented his findings to the Health Department's senior medical officer. The authorities took no action but the figures were leaked to the press. The deaths continued, Bolsin had difficulty finding work in the UK and eventually moved overseas for employment. An inquiry by the General Medical Council several years later found that two cardiac surgeons and one medical administrator had failed to pay sufficient re-

twice the number of child deaths related to heart surgery

gard to the safety and best interests of patients. Two of them were struck of the medical register and the third was banned from surgery for a period of time. It was concluded that if the medical system in England was more open to scrutiny many of the deaths at Bristol could have been prevented.[6]

Jeffrey Wigand, a PhD in biochemistry (and the subject of the film *The Insider*) was the vice president of a large tobacco company who was unable to morally reconcile himself any longer with the practices of his employer. He went to the media about how the company had known about the addictive effects of nicotine and how nicotine was chemically altered to make it stronger. Wigand exposed corporate deceit and wrongdoing. Both Bolsin and Wigand suffered for their moral consciences in their personal and professional lives. Their actions however have meant that the wrongdoings were proven as having happened, and now no longer take place in those particular contexts and hopefully checks have been put in place to prevent such wrongdoing from occurring again.

What factors contribute?

There are several historical forces that may have contributed to the rise of whistleblowing as a contemporary ethical and social issue. Firstly, there is the undermining of the professional role, especially in the public sector, whereas in private sector commercial values are well established. Secondly, there is the growing recognition of human rights – patient, consumer and employment and particularly freedom of speech and freedom of information. Thirdly, there is the growth of citizenship and stakeholder notions, in connection with social concerns and corporate responsibility. Finally, there is the demand for greater equality and political correctness.[7] There has also been of recent times an increased emphasis on advocacy roles especially amongst nurses who often perceive that they have a duty to advance patients' rights.

Advanced technology has impacted on our value systems in that it has increased our range of options and created new and complex questions. According to Leah Curtin advanced

has heightened moral responsibility in the workplace

technology 'has heightened moral responsibility in the workplace. Technological developments have compressed both time and the tolerable margin for error – and, in so doing, have magnified the consequences for error.'[8]

Why does someone blow the whistle?

Often in a whistleblowing scenario the eventual 'whistleblower' has already tried to seek redress for perceived wrongdoing through several avenues such as their managers or professional organisations. When none of these groups deal with the issue the 'only' place left to go is the public eye via the media. In many situations the whistleblower is dismissed from their employment either directly for a 'breach in confidentiality' or indirectly because their workplace becomes an intolerable place in which to work.

It is easier for someone to be a whistleblower if what they feel morally obliged to disclose, is a breach of the law. In such a situation the law may offer some protection from the personal difficulties experienced by whistleblowers. It could be said that the disclosure of illegal activity is ethically obligatory. However, just because an activity or behaviour is legal doesn't mean that it is ethical. Much of what is disclosed has no legal ramifications at all but it doesn't sit well with the whistleblower's conscience or ethical code so they feel obliged to divulge it.

When is blowing the whistle justifiable?

According to Geoffrey Hunt the justifiability of an act of whistleblowing revolves around such things as the manner of disclosure, the motives for it and the reasons behind the disclosure. Hunt elaborates further by claiming that 'a justifiable disclosure is arguably one which does more good than harm; serves some purpose in correcting or preventing the wrongdoing concerned; is made in a responsible manner; and follows upon the exhaustion of internal channels of complaint and redress.'[9] There are problems, however, in deciding what constitutes 'good' or 'harm'. It is also difficult to identify and then prioritise the stakeholders

who will be affected by those 'good' or 'harmful' consequences. A utilitarian analysis whereby the consequences of the whistleblowing determine its justifiability ignores the wrongness of the action or behaviour that is being disclosed. The action or behaviour can be unethical in itself regardless of whether its disclosure brings about good or harmful consequences.

For a whistleblowing act to be justifiable it must be done in a responsible manner. This means that one must make sure that the facts and information are accurate and correct,

the action of behaviour can be unethical in itself

that personal vindication is not a motive for disclosure, that as far as possible the right time for disclosure has been chosen and that the most appropriate party has been chosen to whom the information will be disclosed.

Some countries have whistleblower protection legislation but much of this legislation 'needs to be amended to shift the onus from the whistleblower, who currently has to justify disclosure from a presumption in favor of commercial or government confidentiality, to the employer, who should have to justify gagging from a presumption in favor of freedom of speech and freedom of information.'[10]

How to prevent the need for whistleblowing

According to Hunt there are some common cultural patterns in the unethical organisation that may create the impetus for a whistleblower to act and these include; a laissez-faire culture, a climate of fear, a culture of corruption and finally a culture of hypocrisy.[11]

Many institutions have developed codes of ethics that should guide the behaviour of employees to achieve the mission of the organisation. These codes of ethics should complement those of individual professions, which are developed in order to guide the profession in their conduct. If a workplace agrees to a mission and code of ethics and develops a code of practice there needs to be a strategy in place so that they can be incorporated into any decision making and the day to day running of the institution. It must not be just an exercise in *looking ethical* but one where everyone actually *acts ethically*. If an organisation is committed to its mission, values and code of ethics then it should ensure that they are prominently displayed, that all employees and those served by the organisation are fully aware of, and understand them and, that they are constantly reinforced. When new employees are oriented to a work environment inducting them into understanding the organisation's mission and code of ethics is as imperative as educating them about fire safety.

An organisation that is serious about its mission and standards must have a process by which any lapse in adherence can be reported, heard and acted upon. It maybe that there is a

one where everyone actually acts ethically

designated person to whom any concerns can be taken or, that there is an open door policy where any concerns can be taken directly to management who 'ideally' will deal with them. Accountability is imperative. According to Diane Longley, accountability is evaluative in that its 'processes are the means by which the efficiency and effectiveness of an institution may be judged and ultimately the means by which legitimacy is lent to its conduct.'[12] Accountability is a vehicle for improvement. An essential prerequisite for genuine accountability is openness whereby there is accessibility to information. This openness is essential so that any tendency to control, distort or corrupt information can be counteracted. Information, however, must not only be accessible but it must also be generated and in the right way. Managers and administrators should explain and justify their actions and decisions and thereby instil trust. When it is a matter of public concern there should be participative decision making so that the making of decisions is opened up to all levels of the public through representation, public meetings and other

accountability is a vehicle for improvement

methods.

Conclusion

'Whistleblowers are moral people of action.'[13] They perceive wrongdoing and cannot stand by and allow it to continue to happen. They often suffer professionally and publicly for blowing the whistle. It is the responsibility of all of us as employees, employers and members of the public to ensure that there are ethical standards that promote good and the doing of good.

ENDNOTES

[1] Geoffrey Hunt, 'Whistle-blowing', *Encyclopedia of Applied Ethics 4*, Ruth Chadwick, ed., (California USA: Academic Press, 1998) 525.
[2] William De Maria, *Deadly Disclosures*, (South Australia: Wakefield Press, 1999) 34.
[3] *Ibid*., 25-28.
[4] G Hunt, 'Whistle-blowing', 525.
[5] *Ibid*., 527-528.
[6] Ian Munro, 'The whistleblower', *The Sunday Age*, 14 June 1998.
[7] G Hunt, 'Whistle-blowing', 527.
[8] Leah L Curtin, 'Damage Control and the Whistleblower', *Nursing Management* 24/5 (May 1993) 33.
[9] G Hunt, 'Whistle-blowing', 530-531.
[10] *Ibid*., 534.
[11] *Ibid*., 533-534.
[12] Diane Longley, 'Freedom of Information', *Whistleblowing in the Health Service*, Geoffrey Hunt, ed., (London: Edward Arnold, 1995), Part 2, Chapter 8, 100. ✣

Deirdre Fetherstonhaugh

Ethical Issues Involved with Using Stored Tissue Samples for Genetic Research

This article considers the consent requirements of using stored tissue samples in various types of genetic research projects.

Various types of stored tissue samples can be used for genetic research

Genetic research can be conducted on a variety of tissue samples. Any source of DNA (deoxyribonucleic acid) or RNA (ribonucleic acid) can be tested for genetic information and this includes single cells or parts of tissue as well as previously extracted DNA or RNA. Any genetic material can be valuable for genetic research. People who have tissue excised for therapeutic reasons or want to undergo genetic testing must give their informed consent for the tissue to be used in any kind of research, especially genetic research, before the tissue or sample is taken. That is, they will be provided with information about the research project and asked whether or not they wish to participate prior to their tissue being extracted.

any stored tissue samples that can provide genetic material

However, the ethical issues, in particular informed consent, are not so easily accounted for if the genetic research is to be conducted on stored tissue samples. Any stored tissue samples that can provide genetic material would be useful for research. The tissue may have been taken for other genetic purposes or for unrelated diagnostic or therapeutic reasons. These tissue samples may have been stored without the patient's knowledge and certainly without their consent for them to be used in research. Many stored tissue samples would be of interest to genetic researchers including simple things like blood samples taken for tests and tissue removed as a result of skin cancer.

Various types of genetic research could benefit from the use of stored tissue

One type of research using stored tissue would be epidemiological research, tracking the prevalence of certain genes in the general population as well as their prevalence in particular sub-groups. Sub-groups could include different ethnic groups thus raising 'new' difficulties for the use of anonymised (de-identified) samples because although individuals would not be known to researchers, the research might result in ethnic groups being labelled and/or stigmatized.[1]

Research using stored tissue could also seek to discover the links between particular genes and diseases. For example, a large number of skin cancer samples could be used to investigate if all, many or some have a particular genetic mutation. It could then be concluded that people with this mutation have a higher risk of developing skin cancer. In order for this type of research to be conducted tissue could only be coded not completely de-identified. In other words not every researcher will know whose tissue they are studying but if the need arises each sample can be linked to its donor using a code.

Tissue samples can be used in various ways

Identifiable genetic material 'allows the identification of a specific individual'.[2] Identifiable genetic material can easily be linked to identifiers such as name and date of birth. Using tissue in this way is not usually required for genetic research using stored tissue samples and would generally only be conducted on samples taken after consent has been given. If a project was to suggest that stored tissue be used in this way, questions about the necessity for consent must be addressed.

Potentially identifiable genetic material is also referred to in some literature as coded or re-identifiable. Unlike identifiable material the link between the material and its donor is not immediately apparent. The material might be labelled male, 36 years old with a history of a given condition. When material is used in this way a code can be used to re-identify the person to whom the material or tissue relates. The code is only known to a few people and often by researchers who are not directly involved with the research. The use of potentially identifiable samples can be used very effectively to ensure people's privacy is respected.

Anonymous genetic material has had all identification markers removed irreversibly. In National Health and Medical Research Council (NHMRC) documents this information is also known as de-identified. However, in other literature de-identified is used to describe potentially identifiable material. For my purposes I will use the term anonymised. Anonymous material is of greatest value to epidemiological research although with minimal details left on the sample, for example gender and disease, such samples might be useful for other projects.

What do relevant guidelines have to say when considering the use of stored samples?

The NHMRC's *National Statement on the Ethical Conduct of Research*

involving Humans [3] provides some guidance regarding the use of stored tissue samples in Section 15. The statement deals with both consent and confidentiality issues related to genetic material, however, I will not consider the confidentiality issues related to genetic material or information, as they require a detailed discussion of their own.[4] The statement states that if stored samples are to be used for a research purpose, for which consent was not given when the sample was acquired, or the sample was originally acquired for reasons other than research, then consent for the new research should generally be obtained.

The statement makes provisions for

consent for the new research should generally be obtained

individual Human Research Ethics Committees (HRECs) to waive this requirement with or without conditions taking into account such things as: the nature of any existing consent, how difficult it might be to obtain consent, privacy arrangements (de-identification) and the risk to privacy, the possibility of commercial exploitation of sample derivatives and any relevant law.[5] These issues are central to deciding if consent can be waived. It is a very important decision and one that HRECs should consider carefully. Privacy of any medical information should be respected but the powerful nature of genetic information requires that it be treated with increased sensitivity.

NHMRC guidelines on genetic registers do not consider the use of stored tissue samples without consent. They require that informed consent be sought from registrants, people who have agreed to have their genetic details 'registered', to access previously stored tissue, genetic material or information. If people are on a genetics register they will be easy to contact making this consent requirement not only ethically appropriate but also very easily achievable in practice.

Who 'owns' these stored samples?

I think the question of ownership of stored tissue samples is important because it directly relates to the issue of consent. For example, if I do not 'own' a tissue sample should my consent for its use in research be required?

At first glance perhaps it seems obvious to suggest that the owner of the sample is the person from whom the sample was originally obtained. It is surprising then that in many cases people are not even aware their tissue has been stored.[6] If they were informed of the situation, then I think that they would probably feel some sense of ownership, as genetic material and information is often closely linked to how we see ourselves. I think it is this feeling of ownership that would impact on whether they would consider that their consent should be sought for the sample to be used in identifiable or potentially identifiable research.[7] In other words, I own the sample so I should be asked whether or not it can be used. If genetic research is to be conducted on stored tissue in identifiable (or potentially identifiable) ways then it would only be ethically acceptable if consent is sought.

At the same time no such consent requirements exist if the research is to use the sample in an anonymous way, ie if the information cannot be linked to particular persons, then any sense that one owns that particular information is diminished. One exception might exist. This would be when information may not be linked to individuals but to particular subgroups of society. Imagine a project that is investigating the prevalence of a gene mutation in one ethnic population. The information may not be linked to any one person but it will impact directly on a given population and perhaps in a stigmatizing or discriminatory way. Does the group have a sense of 'ownership' of their shared genetic material? Perhaps they do and in cases like this perhaps their consent as a group might need to be sought. How this might be done is a difficult question but once something is discovered it cannot be undiscovered so consent of subgroups should be sought where at all possible.

Another way of viewing the ownership of stored tissue samples is to see them as the property of the doctor

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who ordered the procedure or the hospital or facility where the procedure was performed. Medical records are considered the property of either public hospitals or private doctors. As a result HRECs can approve research using them (in certain circumstances and under specific conditions) without requiring the consent of patients whose information is being used. The same might arguably be true of stored tissue. If it seems acceptable that doctors or hospitals own the stored tissue this would support the idea that HRECs' approval is all that is required if the stored tissue is to be used in an anonymous fashion. However, if any link could be made to individuals I think it should be seen as their decision for the information to be used and their consent sought whatever practical difficulties this creates.

Does an ethical obligation exist to contact subjects if research results may have an effect on them?

When potential research subjects are asked for their consent to participate in research they are usually made aware of the research's proposed plans for subject follow-up and the information that will be provided to them. However, when stored samples are used in an anonymised project consent may not have been sought prior to the research being conducted. If the research results demonstrate that a particular gene mutation is linked with potential heart problems, for example, the

question of whether or not all the subjects whose samples were used should be contacted and offered testing should be referred to the relevant HREC.

When samples are used in an identifiable or potentially identifiable way then subjects should be notified about the results of the research unless the subject requested that they not be informed of the research's outcome. As detailed above their consent should have been sought and if at that time they requested that their own genetic status not be revealed to them then their right not to know should be respected. It is easy to respect a person's right not to know if there is currently no effective preventive treatment related to the particular gene mutation in question. It will be increasingly difficult for researchers and health professionals to respect this decision if an effective or potentially effective treatment is available.

subjects should be notified about the results of the research

Conclusion

The potential value of future genetic research is great. Stored tissue samples will be one source of information that researchers can use. However, the importance of this valuable research should not overshadow the ethical requirement of informed consent. Even if people are unaware that their tissue is being stored they have a very real interest in its use. Consent for the use of stored tissue should be sought unless two exceptions are met. Their identity will never be linked with the tissue or resulting information and any group they belong too, ethnic or otherwise, will not be potentially stigmatised or discriminated against.

ENDNOTES

[1] M Schwartz et al, 'Consent to the use of stored DNA for genetics research: A survey of attitudes in the Jewish population.' *American Journal of Medical Genetics* 98/4 (Feb 1 2001) 336-42.

[2] NHMRC, '*Guidelines for Genetic Registers and Associated Genetic Material*', Commonwealth of Australia 1999, 39.

[3] NHMRC, '*National statement on Ethical Conduct in Research Involving Humans*', Commonwealth of Australia 1999.

[4] These issues have been discussed in Vol 5 No 2 of *Chisholm Health Ethics Bulletin*.

[5] NHMRC, '*National statement on Ethical Conduct in Research Involving Humans*', Section 15.8 p 45.

[6] N Haites et al, 'Stored tissue may be important for the future care of families.' *British Medical Journal* 322 (28 April 2001) 1060.

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Tracey Phelan

Who Should be Protected from Infection?

This paper will look at infection control, in particular the control of bloodborne viruses such as the human immunodeficiency virus (HIV) and hepatitis B and C. The rights and responsibilities of the infected as well as those of the uninfected will be discussed.

Infection control is a vital component of quality health care. Both patients and health care workers can be potential sources and hosts for infectious agents and as such they both have an ethical responsibility to control or minimise the spread of infection where possible. There can be conflict between the rights and interests of infected individuals to privacy, confidentiality and the best available health care *and* the rights and interests of other patients and health care workers to be protected from infection. We all have an ethical obligation not to cause harm. We also must not unduly risk harm. 'If a person' – health care worker, 'patient or otherwise – infects another person negligently and causes serious illness, he or she can be charged with an offence of causing grievous bodily harm by negligent act.'[1]

an individual's resistance or susceptibility to infection varies

Human hosts or sources of infectious agents may be 'people who are acutely ill, people who have no symptoms but who are in the incubation or window period of a disease (ie the time after infection has occurred but before a diagnosis is possible), or people who are chronic carriers of an infectious agent.'[2] An individual's resistance or susceptibility to infection varies. It can depend on their health status, underlying disease condition, age and other factors that may compromise immunity, such as immunosuppressive therapy or irradiation. Hospitals are risky environments for infection transmission as many invasive procedures are performed in which the natural barrier of the skin is broken and indwelling devices such as catheters or intravenous lines provide an ideal tract for infection.

Health care institutions have a responsibility to prevent the spread of infection by ensuring that their personnel adhere to best practice guidelines. *Standard precautions* require health care workers to assume that the blood and body substances of all patients must be considered potential sources of infection independent of diagnosis or perceived risk. Standard precautions that should be ob-

served by health care workers include: the use of hygienic practices in particular washing and drying hands before and after contact with a patient; use of aseptic technique when doing a procedure such as a wound dressing; use of protective barriers such as gloves, eye goggles, masks, or aprons when necessary; appropriate reprocessing of reusable equipment and the use of environmental controls. 'Additional precautions are recommended for specific patients known, or suspected to be, infected or colonised with disease agents that cause infections in health care settings and that cannot be contained by standard precautions alone.'[3] These precautions may include isolation nursing, special ventilation requirements and dedicated patient equipment and facilities.

The administration of health care in-

there is potentially a high risk of transmission of bloodborne disease

volves many invasive activities and even if these are performed following the appropriate procedures, there is the possibility of a needlestick injury and the potential for the transmission of a bloodborne infection from a patient to a health care worker or from a health care worker to a patient. An *exposure-prone procedure* is any situation where there is potentially a *high* risk of transmission of bloodborne disease from a health care worker to a patient or vice versa, during a medical or dental procedure.[4] This high risk is due to the fact that there is direct contact between the skin and sharp instruments or the skin and sharp tissues such as bone or teeth, and the procedure is being conducted in a confined or poorly visualised body site.

The Law

The Victorian Health Act 1958 recognises the need to prevent or limit the spread of infectious disease but stipulates that this must be done without imposing unnecessary restrictions on personal liberty and privacy. The Act also states that 'a person with an infectious disease must take necessary measures to ensure that others are not unknowingly placed at risk of becoming infected'.[5] This could mean declaring one's infectious status so that others do not place themselves at unnecessary risk of infection. *The Health Act*, while recognising that a person who has an infectious disease or who is at risk of contracting an infectious disease has certain rights, stipulates that these rights should not infringe on the well-being of others. Interpreting this part of the *Act* creates ethical dilemmas as the rights and responsibilities of all those involved must be acknowledged and balanced to achieve the 'best' possible outcomes.

Risk of infection transmission

By the end of 1997 there were ninety-five documented cases of HIV infection among health care workers globally following a specific occupational exposure to blood or body fluids, including five cases in Australia. The risk of HIV transmission following a single percutaneous exposure to HIV was estimated as 0.32% whereas the risk of HIV transmission following mucocutaneous exposure was estimated to be 0.03%.[6] 'The estimated risk of hepatitis C transmission was substantially higher than the risk of HIV infection following percutaneous exposure to infected blood; in cases where the source patient had detectable hepatitis C viraemia, the risk of transmission was 6.1%'.[7]

The incidence or risk of transmission of a bloodborne virus from an infected health care worker to a patient

testing is not compulsory

is not easily quantifiable. The actual numbers of infected health care workers is unknown and, the numbers of infected health workers actually performing exposure prone procedures is also not known. Given that testing is not compulsory the onus must be on health care workers to know their infectious status especially if they are performing exposure prone procedures.

Needlestick injuries

Needlestick injuries pose the greatest risk for health care workers of occupational exposure to bloodborne viruses. Most hospitals have clearly defined policies that should be followed in order to report such incidents. There are procedures to follow for testing both the patient and the injured worker. Informed consent from the patient and the injured worker is mandatory before testing and both parties must be counselled both before and after the testing as the results can have extensive implications. If a patient refuses to be tested, which is their right, the health care worker may face a very anxious few months waiting for results of their own blood. If the patient source is positive for a bloodborne virus a decision will have to be made about the appropriateness of postexposure prophylaxis for the health care worker.

Reporting the incident, giving details of exactly how it happened, means that prevention strategies may be put

both parties must be counselled

in place in the future. It is not a matter of blaming a health care worker for being careless. These incidents can occur without any breach in procedure protocol and extensive documentation may lead to the development of safeguards that may prevent future injuries.

Even though policy and procedure dictates that needlestick injuries should be documented and followed through with the appropriate action the real incidence of such injuries is unknown as they are not always reported. The perception of needlestick injuries as a means of infection transmission is also underestimated. According to one survey reported in the Medical Journal of Australia 39% of the anaesthetists in the study suffered needlestick injuries in the

previous twelve months and 43% did not always report such accidents.[8] According to the National Centre in HIV Epidemiology and Clinical Research as reported in the Melbourne *Sunday Age* 'two per cent of patients tested in 1997 after needlestick or splash incidents had HIV, five per cent had hepatitis C and 2 per cent had hepatitis B'.[9] According to Bill Birnbauer a 'NSW study found every surgical-unit doctor and 57 per cent of medical-unit doctors at a Sydney hospital had cut themselves with a contaminated sharp instrument over a two-year period. Less than half the doctors reported their injuries.'[10] A study in the United Kingdom found that 49% of a group of nurses who worked in higher risk areas such as intensive care, haematology or haemodialysis believed that a needlestick injury with a needle contaminated with infected blood was an unlikely source of infection and 60% of a group of nurses who worked in lower risk areas such as medical wards or orthopaedics believed the

patients and health care workers who are unknowingly put at risk

same.[11] This lack of reporting of needlestick injuries and the incorrect perception that they do not pose a significant risk of infection transmission is of great concern. Concern not only for health care workers who themselves may contract a serious infection but also for other patients and health care workers who are unknowingly put at risk. It is ethically imperative that health care institutions reinforce to their staff the importance of reporting needlestick injuries, the subsequent adherence to the appropriate procedural processes and the fact that there is no emphasis on apportioning blame. Given that needlestick injuries can occur at any time in a 24 hour period the process also needs to be user friendly and all staff need to be cognisant of it so that the appropriate counselling and blood testing can be done at the right time.

The infected health care worker

All health care professionals have an overriding ethical as well as legal duty to protect the health and safety of their patients. Those who believe that they may have been exposed to a bloodborne infection, in whatever circumstances should seek advice and confirm their infectious status.[12] The Australian Medical Association's (AMA) position statement on Blood-Borne and Sexually Transmitted Viral Infections 1995 advocates that a doctor who suspects that they have been infected has an ethical responsibility to seek testing and counselling. All health care workers should assess their individual risk of exposure to bloodborne viruses within the context of both their personal and professional life and act accordingly. Health care workers who perform exposure prone procedures and recognise that they are at a higher risk of occupational exposure to bloodborne viruses should perhaps have a baseline check to establish their status and then monitor their status with routine testing.

Infected health care workers may not be legally obliged to advise their employer of their infectious status but they do have an ethical obligation not to put other people at risk. They also need to know that they may be liable if firstly they knowingly undertake procedures during which patients or other people risk being exposed to infected blood, *and* secondly, this exposure could have been preventable. An infected health care worker who knows their status and performs exposure prone procedures for which consent is required from the patient is not satisfying the ethical or legal requirements of informed consent if they do not declare their status as a risk of the procedure. Informed consent means that the doctor has a duty to provide the patient with sufficient information about a treatment or procedure, including the risks and side effects in order that the patient can make an informed choice or decision about the treatment or procedure. Exposure to a bloodborne virus is a risk of the procedure if the surgeon is infected.[13] This risk should be declared to the patient in order to obtain their informed consent just as they should also be informed of the risks associated with the anaesthetic, post-operative wound infections or any other potential outcomes that could impact on their decision whether or not to have the procedure. Patients may decide not to have a procedure because of the risk of exposure to HIV or hepatitis and this is their right.

Health care workers who are infected with a bloodborne virus should be assessed in consultation with their doctor to determine that they 'are ca-

exposure to a bloodborne virus is a risk of the procedure

pable of performing their tasks adequately to the accepted professional standard; practise recommended techniques; comply with standard precautions; and adhere to approved recommendations for sterilisation and disinfection.'[14] If it is deemed that there is a risk to patients employers should make every effort to arrange suitable alternative work and retraining opportunities for infected health care workers in accordance with good general principles of occupational health practice. In most instances the risk of transmission is very small but in the case of exposure prone procedures the risk is much higher.

Conclusion

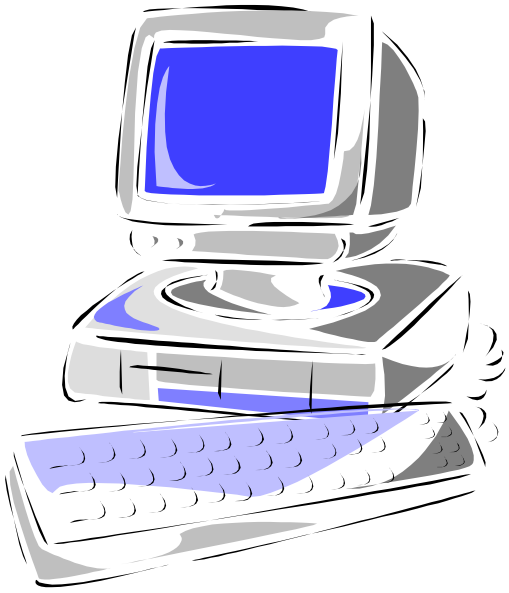
Infection control in health care institutions is about effectively protecting people, both patients and health care workers, from the spread of infection. These institutions have a responsibility to ensure that their infection control policies are based on best practice that they are easily accessible and user friendly. Health care workers have an ethical obligation not to put patients or other workers at risk of exposure to a bloodborne virus. They must, however, feel secure that if they are in-

fected they will be supported by their employer and not discriminated against.

ENDNOTES

[1] Communicable Diseases Network Australia New Zealand, *Infection control in the health care setting: Guidelines for the prevention of transmission of infectious diseases*. Draft for public consultation 22 July 2000, 41.
[2] *Ibid*., 3.
[3] *Ibid*., 7.
[4] *Ibid*., 4.
[5] *The Health Act 1958*, Act No. 6270/1958 Reprinted 1/1/1999, Section 119, (d).
[6] National Centre in HIV Epidemiology and Clinical Research, *Australian HIV Surveillance Report*, 15/2 April 1999, 1.
[7] *Ibid*., 1.
[8] M J Richards, G A Jenkin and P D R Johnson, 'Universal Precautions: attitudes of Australian and New Zealand anaesthetists', *Medical Journal of Australia*, 166 (3 February 1997) 139.
[9] B Birnbauer, 'Toiling at the sharp end', *Sunday Age*, 4/6/00.
[10] *Ibid*.
[11] C Leliopoulou, H Waterman and S Chakrabarty, 'Nurses failure to appreciate the risks of infection due to needle stick accidents: a hospital based survey', *Journal of Hospital Infection*, 42 (1999) 53.
[12] There is of course the 'window' period during which infectious status cannot be determined.
[13] The significance of the risk depends on the virus and other factors.
[14] Communicable Diseases Network Australia New Zealand, *Infection control* 72.

Deirdre Fetherstonhaugh



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