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Who Determines Future Treatment ?

This article will discuss the determination of future treatment, in particular for the incompetent patient.

Medical advances have meant that it is now possible to artificially prolong life. Not everyone, however, desires that their lives be extended especially in conditions that they foresee as being burdensome (for themselves or others), futile or in which they will experience pain, suffering or loss of dignity. People value being able to control what will happen to them and this means being able to put into place a mechanism that will protect this ability. It is one thing to be able to control future occurrences when one is competent, rational and able to make decisions for oneself and yet another when one is no longer competent and decisions have to be made by others.

In Australia there has always been a common law right to refuse unwanted medical treatment. This right stands even if by refusing treatment the person may die. The law of trespass recognises that a *competent* adult has the right to be free of unrequested physical contact (in this case medical treatment) even if others, including doctors, think that it is in the person's best interests.

An incompetent person however cannot actively refuse medical treatment. The only way that their previous wishes can be fulfilled, or at the very least considered, is if they have some form of advance directive.

Advance Directives

"People appreciate being in control."

Advance directives are a means by which the autonomy of patients to determine their medical care is extended into the future to situations when they are no longer competent. It is autonomy and the protection of a person's autonomous right to make their own decisions that is seen as the overriding good in the concept of advance directives. Advance directives are supposed to help individuals and their surrogate decision-makers to avoid unwanted, non-beneficial or futile death prolonging treatments or physical states that are considered to be without dignity. The two types of advance directive to be discussed, are the living will and the appointment of a surrogate decision-maker.

The Living Will

A living will is the documentation of wishes that will govern possible future

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decisions regarding medical treatment. The person, when they are competent, documents their wishes about possible future situations and scenarios that could occur when they are no longer competent. These anticipatory directives are binding. There is much deliberation however about whether living wills can effectively enable a person to determine their future treatment. Criticism of living wills encompasses debate about personhood, practical impossibilities and misunderstandings of their role.

An essentially philosophical concern about the use of living wills is that it is possible that in certain cases a person may undergo a massive psychological change and the individual who exists after the change may be distinctly different from the one who completed the directive. If this is true then there is good reason to question the authority of the directive as it applies to the desires and wishes of the person at the time they completed the directive, rather than those they may value at a future time when a decision about medical treatment has to be made. 'Suppose a fifty-year-old completes a directive that authorizes withholding life supports in the event that he becomes demented, a preference based on his belief that he will despise such an existence while in it. Moderately demented ten years later, he is in fact cheerful much of the time and has no desire to die. The present directive is vitiated by the fifty-year-old's limited ability to know what it is like to be demented.'[1] A person's life may change or they may change in ways that they may not predict or fully appreciate. In the case of dementia, the predemented person may have enjoyed solving difficult mathematical problems and philosophising about life. They valued their ability to do these things and could not imagine a satisfying life without such 'joys'. The now demented person however enjoys watching nature shows on television and sitting in the garden and appears to have no desire to solve a mathematical problem or to endlessly discuss the meaning of life. Their wishes and preferences have changed but the person, before suffering dementia and afterwards, has the same interest in living *per se*. The way they live however has changed. If what a person values can change over time, a living will completed when they are fully competent, does not take into account their values or best interests if they become incompetent in the future. Nor indeed does it even acknowledge that best interests and values may change.

On a practical side it is unrealistic to think that a living will can account for every potential condition and scenario. A living will may in fact have the potential to end a person's life in ways that were never intended. As not every ill-health state can be accounted for, it is likely that more umbrella type terms to group conditions will be used in a living will as an attempt to cover all possible situations. The problem with this however is that the meaning of these terms can be ambiguous. 'Terminal illness' or 'terminal condition' could mean the following: an illness that because of its nature can be expected to cause the person to die, an illness from which the person will not recover, a condition where death will occur in a short period of time regardless of whether life sustaining procedures are given or, a chronic disease for which there is no known cure. What is life-sustaining treatment? It could virtually mean any medical intervention that is administered to a patient in order to prolong life and delay death and therefore would include dialysis, drugs, insulin, intravenous therapy or a ventilator. Signing a living will that includes generic conditions rather than more specific ones could therefore place the person entirely at the mercy of doctors to interpret the 'terminal condition', the 'relatively short time', 'quality of life' and the 'life sustaining treatment'. There is no guarantee that what the competent person wished to happen if they become incompetent would be considered and acted upon.

people are likely to grossly underestimate their desire to have medical intervention

Another criticism of living wills is that there is reason to believe that normal people when evaluating whether it is worth living in a state of ill health in the future will undervalue that existence. According to Christopher Ryan, people are likely to grossly underestimate their desire to have medical intervention should they become ill in the future.[2] Healthy people are not always able to perceive and understand every possible scenario. Written advance directives may therefore be most appropriate for people with chronically progressive illnesses. These people already have some manifestation of the disease and would be more realistic about the future and the implications of certain ill-health states.

Ryan also argues that living wills do not respect a person's autonomy. To be autonomous one must be in possession of all the available information and in this case the person does not know that it is highly likely that the decision they make now which may to be refuse treatment if faced with a hypothetical future scenario, is not what their decision would be if actually faced with the scenario.[3]

Implicit in the use of living will type advance directives is the assumption that all patients want their advance directives followed strictly. One empirical study however that looked at the advance directives of dialysis patients, found that 31% of patients wanted their doctors and surrogate decision makers to have 'complete leeway' to override their advance directives and 30% wanted their surrogates to have at least either 'a little leeway' or a 'lot of leeway' to override their directives.[4] This finding is particularly alarming as it suggests that many people who have written advance directives assume that others will not adhere to these directives if there appears to be good reason not to do so. This is not the rationale behind advance directives. This would suggest that either the

patients themselves do not understand the ramifications of advance directives or, that the concept of written binding advance directives as the ultimate decision maker when a person is no longer capable of making their own autonomous decision, is flawed.

Surrogate decision-maker

A surrogate decision-maker is a person who makes the decision about medical treatment on behalf of the patient. The patient, when they are competent, appoints a surrogate. This person may also be known as an agent with enduring power of attorney (medical). The surrogate relies on substituted judgement in that their decision should be as close as possible with what the now incompetent patient would have made, if they were still competent. In this way the surrogate is protecting and maintaining the autonomy of the now incompetent patient. The patient may even have discussed with their surrogate their exact wishes regarding the situation that they presently, in their incompetent state, face. It is then quite straightforward for the surrogate to make a decision knowing that they are acting according to the patient's own autonomous wishes. If, however, the surrogate never actually discussed a particular scenario with the patient they should take into account the personal characteristics of the patient such as their preferences, religious beliefs, strongly held values, attitudes to treatment, as well as the costs and benefits of treatment and the impact that the decision will have on the patient's family when making a decision.

There is much discussion about who is the most appropriate surrogate decision-maker. Should they be someone who has a close and longstanding relationship with the patient? It could be argued that as the family is the primary social unit in our society and provides the independence from which personal freedoms and autonomies develop and is most probably the best source of information about the person's values and preferences, the surrogate decision-maker should be a member of it. Alternatively, it could be argued that the emotional involvement of an especially close family member, such as a spouse, raises many difficulties. They would have to disregard their own wishes and desires in order that any decision made about treatment is in the best interests of the patient. It is not an uncommon occurrence in cases where the patient has not appointed a surrogate that family members (often with the same closeness of blood relation such as children or siblings) disagree about the continuation or refusal of medical treatment for their incompetent relative.

However, as the patient appoints the surrogate it is hoped that considerable thought has gone into the decision. Some people do not

the family is the primary social unit in our society

want to burden their family with having to make life and death decisions about them and so appoint someone such as their general medical practitioner as their surrogate decision-maker.

Situation in Victoria

The competent patient. Despite the common law right mentioned earlier in this article, some Australian states and territories have enacted legislation so that the competent patient's right to refuse medical treatment is further protected. *The Victorian Medical Treatment Act* 1988 (MTA) not only protects the patient's right to refuse unwanted medical treatment but it also offers protection to doctors who act in good faith according to the express wishes of their patients. The MTA becomes operative upon the completion of a valid 'refusal of medical treatment' certificate, the form of which is outlined in Schedule 1 of the Act. The patient must be considered competent to complete the certificate in that they must be fully cognisant about their condition and the ramifications if they refuse treatment for it. The certificate is only valid for the patient's current condition. The treatment refused can be general medical treatment for that current condition or it can be a specific medical treatment. For example, a patient with cancer may want to refuse any treatment (inclusive of surgery, chemotherapy and radiotherapy) or they may only want to refuse chemotherapy. Palliative care however, defined by the Act as including

> '(a) the provision of reasonable medical procedures for the relief of pain, suffering and discomfort; or
>
> (b) the reasonable provision of food and water.'

cannot be refused.

The incompetent patient. The MTA makes no provision for living wills. It does however allow for a competent person to appoint an agent with an enduring power of attorney (medical) — EPA (medical). Unless a person has been appointed as an agent by the patient, there is no power to refuse treatment on their behalf. If an incompetent patient has not appointed an EPA and their relatives either have a dispute with the health professionals or with each other they can apply for guardianship to the Victorian Civil and Administrative Tribunal (VCAT). A guardian appointed by VCAT has the same powers to refuse medical treatment on behalf of the patient as agents who were appointed under an EPA. If a doctor is concerned about refusal of treatment by an agent or guardian they can apply to VCAT to have the EPA suspended or revoked.

On 1 January 2000, changes to the existing *Guardianship and Administration Act* 1986 by the *Guardianship and Administration (Amendment) Act* 1999 have meant the introduction of the enduring power of guardianship. According to this Act competent adults can appoint a person to act as guardian on their behalf when they are no longer able to make reasonable decisions about matters including medical treatment (consent to health care or medical or dental treatment which is in the incompetent person's best interests), accommodation, access to services and other non-

financial personal decisions. This complements existing provisions, which enable persons to appoint an enduring power of attorney (to make financial or business decisions) under the *Instruments Act* 1958 and an EPA (medical), under the MTA 1988. The EPA (medical) however takes precedence over the enduring guardian in decisions regarding the medical treatment of the incompetent person.[5]

Conclusion

People have a right to refuse unwanted medical treatment based on a respect for autonomy and the fact that individuals themselves are well placed to determine what is in their own best interests. This right should not be ignored when someone becomes incompetent. Advance directives, despite their inadequacies, are an attempt to provide a way of extending the autonomy of a patient to determine their medical treatment into situations when they are no longer competent. In Victoria there is a remarkable public ignorance about the existence of a legal right to refuse medical treatment and the right to appoint an agent with an enduring power of attorney (medical). The mechanisms with which these rights can be enforced are also not understood even by those working in health care. Redress through greater public education is needed.

Sources

Medical Treatment Act 1988 (Vic).

ENDNOTES

[1] David Degrazia, 'Advance Directives Dementia, and "The Someone Else Problem"', *Bioethics* 13/5 (1999) 375.
[2] Christopher James Ryan, 'Betting your life: an argument against certain advance directives', *Journal of Medical Ethics* 22 (1996) 96.
[3] Ryan, 'Betting your ……..', 97.
[4] Ashwini Sehgal et al, 'How Strictly Do Dialysis Patients Want Their Advance Directives Followed?', *JAMA*, 267 (1992) 59–63.
[5] Office of the Public Advocate & Department of Justice Victoria, *All you need to know about the new Guardianship Laws – Recent Amendments to the Guardianship and Administration Act 1986* Dec 1999. ✣

Deirdre Fetherstonhaugh

Should Smokers be Denied Certain Treatments?

Recently the Australian media carried a story of a patient who had been refused treatment because he was a smoker. I will not go into the details of that particular case here. But it raises broader questions such as: should smokers be denied treatment in general, or at least expensive ones or ones in short supply? Should they at least 'go to the end of the queue'? Should others who have 'brought their condition upon themselves' be similarly excluded? Should we prefer those who have avoided risks like smoking?

Resources are increasingly 'stretched' in our public health system. Some — such as hearts and lungs for transplant — are in very short supply relative to demand. Some treatments are very expensive. Even were we to spend more, we could not avoid questions about priorities in the use of limited resources. And *who* should spend more? The present trend in our healthcare 'market' is to shifting costs from the public purse (and thus ultimately from taxpayers) back to the users of healthcare (mostly through private health insurance). So our questions might also include: if smokers are to be treated, should they pay for it themselves, or at least through their own private health insurance?

A clinical case for excluding all smokers

One approach to these questions is to exclude anyone whose past or (likely) future behaviour indicates a poor prognosis after treatment; or else, to prefer those whose past or (likely) future behaviour suggests a better prognosis after treatment.[1] The rationale for such a policy is straightforward enough: there is no point engaging in treatments which are unlikely to work or allocating scarce resources to one person when another could much more clearly benefit from them. And since smokers have a poor prognosis after treatments such as lung transplants they should be excluded, or at least put to the end of the queue…

The problem with this is that a history of smoking is probably not, in itself, good grounds for thinking treatments such as transplants are doomed to fail. If the thought is that smokers commonly suffer such serious damage that such treatments do not work, then this should be assessed on a case by case basis, looking to the actual damage rather than a blanket judgment about 'smokers'. If the thought is that smokers are likely to smoke in the future or be otherwise unco-operative this would again seem to call for a case by case judgment, following good information-sharing and counselling. After all, many smokers do, in fact, renounce smoking for good in these circumstances and comply with whatever regime is required to maximise their chances of full recovery.

The clinical rationale for excluding smokers from treatments such as lung transplants fails because it is premised on misleading generalisations about smokers. Furthermore, care must be taken before judging that withholding various treatments from smokers will save resources. The reality may be that it will actually add to the health bill — because a failure to provide 'a stitch in time'

can lead to graver complications.

An egalitarian case for including all smokers

There are many theories of justice and there is not the space to rehearse them here. Suffice it to say that some accounts of justice begin with a strong *prima facie* position that all people should be treated equally and require very good reasons to act otherwise. Writers such as Braybrooke, Childress, Daniels, Hare, Norman, Sen and others have proposed that 'opportunities' such as health care should be distributed on the basis of equal resources for all, or for those in roughly equal positions, or for those who will gain roughly equal fortune, welfare or satisfaction from such resources.

An egalitarian approach would be made operational by doling out divisible therapies roughly equally among all comers — smokers included — and doling out less divisible therapies on the basis of for-all-or-for-none or random selection including 'first-come-first-served'. These strategies have long been applied in health care and have widespread support in the professional and ethical literature. At least on the face of it, systems of universal health cover such as Australia's medicare system are good examples of this attitude in practice. Such approaches implicitly recognise that no one has the wisdom to judge and rank other people's lives. They help reduce envy and social division, and help to build up self-respect and community. And they well express traditional health care values such as equal care and respect, the sanctity of life and importance of health.

Proposals that health care be distributed equally are not, however, unproblematical. A for-all-or-for-none policy achieves equality only by non-provision where there is a shortage: yet the purpose of society in general, and health *care* in particular, is not just to help people (as far as possible) *equally* but also (and, arguably, first) as far as possible to *help* people. Non-provision equalises but it does not help. A queue tends to favour the better educated and informed as they are more likely to seek medical attention, and sooner; the less-advantaged — as well as the more medically moderate or courageous — will join the queue later. Both egalitarian strategies fail to take sufficient cognisance of morally relevant differences, such as urgency of need and relative ability to benefit from it.

Thus the egalitarian rationale for including all smokers for treatments such as lung transplants also fails. Equality might be enacted symbolically, but only at the expense of actually engaging in health care.

A personal responsibility case for excluding all smokers

Since the 1980s most Western societies have moved away from systems of health care, welfare and education which focussed principally upon equal treatment and have emphasised instead personal liberty, taking responsibility for one's own life-style choices and rewarding those who act responsibly. Writers such as Dworkin, Engelhardt, Friedman and Nozick have suggested that we should not be forever looking to others to 'bail us out'; nor should others too readily do so. 'Equal access' is often well-meaning but ultimately patronising; it infantilises people and discourages responsibility. As Dworkin puts it, 'people should pay the price of the life they have decided to lead'.

Because 'life-style choices' are a significant factor in determining health status, many health professionals favour healthcare being used as an incentive to good choices. Examples of patients who would in principle be affected by this policy include not only smokers, but also over-drinkers and other substance misusers; over-eaters and under-exercisers; sunbathers; players of high-risk sports or adventures; those pregnant or suffering STDs following consensual sexual activity; those who are voluntarily mutilated in some way (e.g. tattoos, sterilisation); those who deliberately mutilate themselves or attempt suicide; those who neglect their own health (by, for instance, not dressing warmly enough).

health care is not just to help people equally but to help people

Once again, however, this argument for excluding all smokers is deeply problematical. First, because *causation* in disease is very complex: rarely is there a single, specific cause. Many diseases, such as lung cancer, are the result of a web of factors including genetic predisposition, environment, psychological state and life-style choices. To say 'Mr Bloggs' cancer is a result of his chain-smoking over the past twenty years' is too simplistic scientifically.

Secondly, even if causality can be traced back to a particular patient choice, difficulties arise with the attribution of *responsibility*. People's knowledge about the health-risk associated with various activities is severely limited; rarely are the probable consequences obvious or adverted to; and the results of the risk they undertake when skiing, for instance, may be out of all proportion to their reasonable expectations. Furthermore, though we are free agents we make our choices in the context of genetic predispositions and acquired addictions, diet, environment and upbringing, psychological instabilities, overwhelming passions, advertising, peer pressure and cultural values. Rarely can we say 'Mr Bloggs brought this illness on himself by freely choosing to do something he knew was very risky'. And health neglect is frequently a symptom of some other disease or disadvantage. There is a risk of pharisaically blaming smokers and drinkers when the community is partly responsible for their plight, and when it does nothing to discourage (and may even subsidise) other equally serious health risks such as car-racing and over-eating.

Furthermore, the question arises as to what kind of risk is a reasonable one. Certain voluntary risks are encouraged by society (e.g. fire fighting, marathon running, transportation, surgery); others are tolerated or ignored (e.g. over-working); others

are half-heartedly discouraged (e.g. sexual promiscuity, smoking); and still others are deplored (e.g. heroin abuse). But should not all risky lifestyle choices be similarly penalised or penalised in proportion to the risk they involve or the cost to others? A rich account of the dignity of the individual and of the common good will recognise that some risk-taking is necessary, other risks optional, some are imprudent but understandable, and yet others are negligent or wicked.

A fourth difficulty with allocation according to personal responsibility for illness is that those who are ill (and consequently experiencing disadvantage in various ways) may already have made significant, even disproportionate, contributions to common funds with a reasonable expectation of health cover. The huge sales taxes smokers pay could be an example of this: would not excluding them from cover represent unjust enrichment for non-smokers? Furthermore, the early deaths of those who take risks with their health may well mean they are less rather than more of a burden on the health and pensions budgets, and so would have some claim to reduced premiums.

Those committed to a non-libertarian ethic, such as the Hippocratic tradition 'Good Samaritan' Christianity will have added difficulties with the notion that 'smokers need not apply' for health care. No community may reasonably abandon some of its members, even those who are reckless or wicked, and even when their care is costly, for to do so is to repudiate solidarity with them and mercy towards them. What is more, the ill-health of any member of a community harms dependants and ultimately the whole community, and thus any effort at 'correcting' or 'deterring' offenders against medical responsibility by denying them care will redound on the community itself and more particularly on innocents such as children.

Sixthly, even were we to establish some sort of rough consensus on what sorts of risks are socially responsible, the process required to put such judgments into practice in health care allocation would be troubling. Health professionals, for instance, would be charged with a detailed 'moral inquiry' into whether their patients had at any time in the past engaged in 'unwarranted risks' which might have contributed to their present condition. To date we have not normally refused people care on the grounds that they have brought their troubles on themselves: attempted suicides are the clearest example, but there are many examples where health care is specifically designed to cater to those whose injury is self-caused, e.g. those with drug problems or sexually transmitted diseases... To ask health professionals to behave differently could undermine the rescue and healing imperative, virtues such as tolerance

no community may reasonably abandon those who are reckless … even when their care is costly

and equal respect, and social commitments to care for the weak. If a community wishes to discourage certain risk-taking, other mechanisms such as education and law would seem better suited to this purpose than the health system.

A case for excluding *some* smokers

A strong case can be made for giving clinical need primacy in the allocation of health care resources, though I have not the space to elaborate it here. Of course, we must carefully distinguish genuine needs from apparent ones, and moderate even those genuine needs as far as reasonable; we must also find ways to sort them when they compete. In practice this means that a doctor would consider:

- each patient's present health, relative to what is reasonably to be expected, including imminence of death or major damage, seriousness of damage, degree and kind of associated pain and disability
- each patient's likely health after each of the various treatment and non-treatment options, taking into account the same range of matters
- the benefits and burdens associated with each treatment option or non-treatment for the patient and others and the resources required
- the probabilities and risks associated with each of these.

Because on this approach ineffective, unproven, barely useful and harmful treatments would be avoided, some smokers *will* in fact be excluded from lung-transplant or other programmes: their prognosis after such treatment would be so poor that it would be clinically contra-indicated or futile. Of course, one person can *need* health care in different ways and to different degrees, and different people can need in similarly diverse ways and degrees. Obviously certain kinds of health care for certain patients will be more or less crucial or urgent in that damage to life or health will be more or less imminent without it. Thus *urgency*, in particular imminence of death or major damage without treatment, is properly part of the assessment of health care need. Thus *ceteris paribus* a patient in *more urgent need of a health care resource is to be preferred* to one who is less urgently in need. And once again this will mean that some smokers are excluded from particular treatments.

A similar case (which need not be spelt out here) can be made for *a series of priority rules. Ceteris paribus* the patient to be preferred will be the one:

- more likely to benefit therapeutically from the treatment;
- likely to gain the greater or the longer therapeutic benefit from the treatment, or the same therapeutic benefit from less of the treatment;
- likely to need the treatment for a shorter time or less frequently;
- less at risk of various ill-effects from the treatment or likely to suffer the lesser burden from the treatment;
- likely to suffer the greater harm without the treatment;
- with fewer or no alternative avenues of satisfying the need;
- more likely to infect others if untreated… and so on.

Applied to our present question that means that some smokers will indeed go without some treatments. So will some non-smokers. And even if in a particular case a decision is made on

a needs basis not to offer a particular treatment to a patient with a history of smoking, they should still be offered such other treatments as are reasonably available and clinically appropriate. A 'not for transplant' order must not amount to abandonment.

Conclusion

In this paper I have argued that any blanket preference against smokers in the distribution of treatments such as lung replacements is ethically unwarranted; but so is a view that their history of smoking is irrelevant. Sometimes it will be highly relevant. But we must be careful as to why. Only where such behaviour bears upon prognosis after treatment and therefore over ability to benefit relative to others or relative to other uses of those resources should it be determinative.

ENDNOTES

1 A similar criterion could be (and probably often is) applied, not just to people who engage in certain behaviours, but also to people over a certain age or who are mentally ill or who have some other characteristic which might be correlated with prognosis after treatment.

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Ethical Guidelines: Are They Enough to Prevent Dangerous Research?

In this article I discuss Professor Bezwoda's scientific misconduct in South Africa, the incidence of misconduct in America and how Australia could possibly try and avoid such problems. [Abridged version of paper given at Australian Institute of Health Law & Ethics Conference, Sydney July 2000.]

Human experimentation and clinical trials

Ethical guidelines for clinical trials and human experimentation need to keep in mind both protecting human subjects from harm and the risk of harm as well as ensuring scientific validity and integrity. While at first glance it may not appear that ethics has a major role to play regarding scientific integrity, this is certainly not the case. If trials are occurring which are not scientifically warranted or the trials are not being conducted according to acceptable standards of scientific inquiry then subjects are being used by scientists unethically and whatever treatment (or lack of) they are receiving as a result, is in vain.

The case of Professor Werner Bezwoda

Professor Bezwoda's scientific misconduct was quite well publicised. The misconduct surrounds two scientific papers presented by Bezwoda in 1999. One at the American Society of Clinical Oncology Annual Meeting, held in May 1999 in Atlanta [1] and the other at the 1999 European Cancer Conference (ECCO-10).[2] Professor Bezwoda was a well known, well regarded investigator into the controversial use of high dose chemotherapy for advanced and high risk breast cancer. The research involved using high doses of chemotherapy drugs along with autologous progenitor-cell transplantation as the primary treatment for high risk breast cancer patients. This type of therapy has had some degree of success with a variety of other types of metastatic cancer but the current treatment options available to women with high risk breast cancer remain very limited. While the risks associated with high dose chemotherapy are constantly decreasing, the use of this type of chemotherapy is still linked with treatment related death and high toxicity.

One of Bezwoda's first reports on his (and his colleagues') research appeared in 1995. The conclusion reached, that high dose chemotherapy was promising, resulted in increased survival in patients with metastatic breast cancer. This research was published under the names of three authors and clearly states that, 'The study was performed according to the principles of the Declaration of Helsinki. All patients entered onto the study gave informed consent and the study was approved by the Committee for Ethics of Human Experimentation of the University of Witwatersrand.'[3] Given these statements it would appear that Bezwoda was cognisant of the importance of ethics committee approval and patient consent. The research showed promise and it seemed worth continuing with that line of investigation. The next major presentation of results was at the 1999 ASCO conference.

In contrast to the 1995 paper, this time Bezwoda was noted as the sole author. In this presentation Bezwoda's results claim that 154 patients were entered into the trial. In the same conference session that Bezwoda presented his impressively successful results of the high dose chemotherapy and cell transplant treatment three other research **groups** reported no such success in their similar randomised trials.

The conference was so impressed with Bezwoda's results that in December 1999 at a meeting of leading oncologists involved in transplant and breast cancer treatment it was decided that a large randomised trial aimed at confirming Bezwoda's results was needed. Before this commenced an on-site review of the Bezwoda data was essential.[4] Following this decision a full investigation of the records of all 154 patients was

requested and initially Bezwoda agreed to the review. However, when the review began Bezwoda only gave the reviewers 2 days in which to complete their review.

The result of the on-site review found the list of patients entered in the trial incomplete, **no** information about research subjects in the control arm and only some patients' records for the high dose treatment arm. The treatment received by patients in the control arm (if they existed) was substandard and was not that outlined in either the ASCO or ECCO-10 presentations. Of the 58 patient records provided only 20 were deemed by reviewers to have fully documented eligibility, presentation data showed 36% of patients were white but only 7% of the 58 records belonged to white patients and it also appeared that the number of patients who had relapsed or died had been understated in both presentations. No signed consent forms were forthcoming nor was evidence of any ethics committee approval.

Since the investigation, Bezwoda has admitted scientific misconduct and misrepresentation of the conventional dose regime (the control arm). Bezwoda claims, 'This was done out of a foolish desire to make the presentation more acceptable to an audience….'.[5] It seems then that Bezwoda had the best of intentions, while he was misleading the scientific community, the public and those suffering from high risk breast cancer. If scientists who mislead and deceive their colleagues and patients, sometimes do so with good intentions, then the incidence of misconduct may be higher than one might first expect. Perhaps the best indication of this is the recent report complied by the Department of Health and Human Services Office of Inspector General into FDA oversight of Clinical Investigators.

FDA oversight of clinical investigators [6]

In June 2000 an examination of the American Food and Drug Administration's (FDA's) selection of clinical investigators for inspection and the discipline of those investigators found in violation of FDA regulations, was published. The FDA's investigations are conducted non-randomly; that is, clinical investigators who have been warned previously are more likely to be investigated again. The FDA can take varying degrees of action against clinical investigators found to be violating research protocols, ranging from warning letters to disqualification.
It should be noted that it is not strictly the role of the FDA to oversee clinical trials on a day to day basis, nor is it ultimately their responsibility to ensure all human subjects are protected. However, research has shown that in 1998 over 50 per cent of sponsors (such as drug companies) failed to ensure that trials conducted by their clinical investigators were properly monitored. In the same year the Centre for Drug Evaluation and Research (CDER) found that 'serious misconduct was not reported by sponsors and the majority of objectionable problems should have been detected with adequate monitoring.'[7] Similar oversight problems have been found with the Institutional Review Board (IRB) system.

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Inspector General's findings

The FDA only inspects a **very few** clinical investigators each year. For example, in 1999 nearly 14,000 individual clinical investigators in over 60 different countries submitted data to the FDA and in the same year the FDA conducted only 497 non-randomly selected inspections. As part of the recent report the Inspector General reviewed 189 official actions sent to clinical investigators between 1994-1999. Of these a surprisingly high number cited human subject protection (67%) and protocol (82%) violations as the reason for official action. Other problem areas included documentation, such as missing documentation and failure to report to appropriate IRB or sponsor.

As of January 2000, the FDA had a list of 133 disqualified clinical investigators, which is a reasonable number considering only about 450 are inspected each year out of a possible 14,000. In response to the Inspector General's report President Clinton was to ask Congress for the authority to levy fines up to US$250,000 on medical researchers who violate federal rules on human research and up to US$1million on the universities that employ them.[8] The aim of such tough measures is to restore public faith in clinical trials and to strengthen the FDA's ability to regulate the research. While this action may improve the behaviour of clinical investigators in the USA, does Australia have adequate guidelines and penalties to restrict these kinds of misconduct?

The situation in Australia

Australia has relatively new guidelines on human subject research contained in the *National Statement on Ethical Conduct in Research Involving Humans.* The document is a well-constructed guide for the review of all research involving human subjects. At the beginning of the Statement the ethical principle of integrity is discussed. 'Among the essential values for research is that of the integrity of researchers.'[9] I agree with the Statement that the honour, honesty and reliability of researchers are of paramount importance. However, even if as the Statement demands, researchers have a commitment to the pursuit and protection of truth, a reliance on appropriate research methods and a commitment to research questions that are designed to contribute to knowledge, some researchers might still exploit, harm, or risk harming research subjects and others.

Would the National Statement have prevented Bezwoda's research here?

Let us imagine for a moment that the trial protocol for the Bezwoda high dose chemotherapy trial is before a Human Research Ethics Committee (HREC) in Australia. The trial pro-

tocol explains how the current treatment options for high risk breast cancer are limited and there are valid reasons for believing this 'new' approach may be of benefit. According to the protocol patient consent will be sought and respected and all other standards of scientific investigation will be met. Under these conditions the HREC may well approve Bezwoda's trial, especially as at this stage there is no reason to question his integrity, after all he is a university professor.

Would Bezwoda's trial have been discovered to be substandard and scientifically misleading or perhaps even completely false under the guidelines contained in the National Statement? Well, maybe! Each individual HREC can determine their own 'goals for monitoring' research.[10] Depending on the organisation and the probable lack of resources available to their HREC it is unlikely that there would be random inspections of research sites or consent forms. It appears that if all Bezwoda was required to do was report annually to the HREC on his research then it may well have occurred in Australia. It may even have been published in a reputable journal, given it had HREC approval and currently journals do not require any more than that of their prospective authors.

The incidence of scientific misconduct and/or protocol violation in Australia may not be anywhere near that of the USA, however, it appears it would be naive to suggest that scientific misconduct does not occur in Australia. Increased measures need to be taken to prevent such unethical trials from occurring here. Relying on the integrity of clinical investigators is not sufficient in an era where drug company dollars are driving a large portion of research, even the research that is occurring in universities and hospitals.

Harm caused by misconduct

Misconduct in scientific investigations can potentially harm the research subjects within those trials. However, publishing or reaching misleading conclusions, can pose far greater harm to a wider range of people. For example, many women with high risk breast cancer, faced with limited treatment options may have opted for high dose chemotherapy, even given its risks, on the basis that some positive results have been demonstrated in other studies. Many potential research subjects, and those faced with decisions between different experimental therapy options, use the findings of other research to help them reach their decisions about whether or not to join a trial. One misleading scientific investigation can potentially harm many more people than those directly enrolled in the trial. Such misconduct can also reduce public confidence in medical research in general, leading to an overall decline in the number of potential subjects.

Bezwoda has admitted scientific misconduct and misrepresentation

What would prevent scientific misconduct?

It would be extremely useful for the NHMRC or a similar body to conduct a randomised audit of all medical research to determine whether scientific misconduct is occurring in Australia. It is difficult to predict that outcome of such an audit, however, I think it is still valuable to explore ways of reducing any potential misconduct in the future. Systems may need to be introduced to deter and prevent scientists from risk of misconduct and the penalties for those found to be involved in scientific misconduct or in violation of approved research protocols need to be increased. Currently when investigators are found to be violating research protocols their research is suspended. Penalties for endangering people in this way should be greater.
I would also suggest several possible ways of limiting the risk of scientific fraud and misconduct and ensuring that all patients are adequately protected from this type of research. They are:

- The establishment of a Clinical Trial Registry, where all trials are registered by HRECs, Biosafety Committees and other interested organisations. The registry would provide transparency for trial applications and approvals. The registry could also maintain information about how the trial is proceeding whilst maintaining commercial-in-confidence considerations.
- The Clinical Trial Registry could liase with similar international bodies in order to ensure research is not unnecessarily repeated and that international researchers have had no violations recorded against them elsewhere.
- Research or data based on clinical trials should not be published unless it has been registered with the Clinical Trial Registry and meets the appropriate standards.
- The Registry should also be responsible for conducting random investigations of all clinical trials, whilst they are under way, to ensure that patients are protected before the trial is completed.
- Investigators, clinicians and organisations such as universities and hospitals, should be severely penalised if found to have contravened approved ethical guidelines or research protocols. Suspensions of all trials, involvement in clinical practice as well as hefty monetary fines should be considered.

This list of initiatives, aimed at eliminating scientific fraud and misconduct, is not exhaustive. More could be done. Australia must take steps to protect all patients and research subjects before we experience our own Bezwoda.

ENDNOTES

[1] WR Bezwoda, 'Randomised, controlled trial of high dose chemotherapy (HD-CNVp) versus standard dose (CAF) chemotherapy for high risk, surgically treated, primary breast cancer.' *Proceedings of American Society of Clinical Oncology* 18/2 (abstract 4) 1999.
[2] WR Bezwoda, 'Randomised controlled trial ....' *European Journal of Cancer* 35 (suppl4) 230 (abstract 902) 1999.
[3] WR Bezwoda, L Seymour and RD Dansey. 'High-dose chemotherapy with hematopoietic rescue as primary treatment for metastatic breast cancer: a randomised trial.' *Journal of Clinical Oncology* 13 (1995) 2483-89.
[4] RB Weiss et al., 'High-dose chemotherapy for high-risk primary breast cancer: an on-site review of the Bezwoda study.'

The Lancet 355 (March 2000) 999-1003.
[5] South African investigator Bezwoda admits falsifying data in high-dose chemo study. *Cancer Letters* 26 (2000) 1-4.
[6] Department of Health and Human Services, Office of Inspector General, FDA Oversight of Clinical Investigators, June Gibbs Brown (Inspector General) June 2000.
[7] Ibid, 10.
[8] Fred Charatan, 'Clinton seeks heavy fines for breaching research ethics', *British Medical Journal* 320 (3 June 2000) 1491.
[9] *National Statement on Ethical Conduct in Research Involving Humans*, 3.
[10] Ibid, 20.

Tracey Phelan

Restraint – Can it be Ethically Justified?

The use of restraint is most often discussed in regard to people residing in aged care facilities. It is an issue that is highly emotionally charged and the overwhelming consensus is to support 'no restraint' or 'minimal restraint' policies. However, restraining inpatients in an acute hospital raises other issues. The appropriate ethical response to restraint in both environments will be discussed in this article.

Restraint may be defined as any method either physical or chemical of restricting a person's freedom of movement, physical activity or normal access to their body. Physical or mechanical restraints can include bed rails, vests, straps, wrist ties, mitts, belts, splints, ties, casts, wheelchair bars and brakes, binders and bed sheets. Further differentiation may be made between restraints and devices used as protection from harm such as a walking frame for someone who has an unsteady gait and needs compensation for a specific physical deficit, and immobilisation devices which are used for a short time during a medical procedure to limit the person's normal activity and movements.[1] Chemical restraint will not be discussed in this article.

In a health care setting it is usually nurses who restrain patients. There are several reasons stated by nurses as to why they believe it is necessary to restrain patients. Firstly, restraints are used to protect people from harm, especially from falls that may occur either directly from a chair or bed or, as result of the patient wandering without supervision. Secondly, restraints are used to prevent patients or residents from interfering with treatment and thirdly, to protect staff or other patients from being harmed by them.

According to Moss and La Puma [2] there are several factors that put someone at risk of being restrained. While many restrained people are elderly other risk factors include — impaired cognitive functioning, dementia, an abnormal mental status examination, post-operative delirium, a psychiatric diagnosis, severity of illness, immobility and physical dependence.

The aged care setting

Australia's population is ageing. According to the Australian Bureau of Statistics by 2051 it is estimated that the number of people aged 65 years and older will grow to between 6 and 6.3 million and will account for between 24 and 26% of the Australian population.[3]

The risk of developing cognitive impairment such as dementia increases with age. Several of the symptoms and behavioural changes that can occur with a dementing illness such as disorientation, wandering, memory loss, personality changes, impaired comprehension and judgement, hallucinations and delusions, can mean that the person may become very challenging to care for, and can at times be perceived to be at risk of harming themselves if the appropriate safeguards are not put in place. Restraints are often used as safeguards in order to 'protect' the person. In a study conducted in Victoria of over 10,000 nursing home residents it was found that bed rails and restraining belts were the most commonly used types of physical restraints and prevention of falls was the main reason cited as to why these restraints were used.[4]

Consequences of restraint

There are many documented physical and psychological consequences of physically restraining older persons and these include — 'decreased muscle strength, orthostatic hypotension, urinary incontinence, faecal incontinence, impaired balance, increased susceptibility to falls, accidental strangulation, reduced communication skills, increased confusion, loss of self confidence and loss of autonomy.'[5] Restraint can also lead to pressure sores, agitation, contractures, depression and anxiety. Research undertaken by Miles and Irvine in 1992 reported that 122 deaths of the people in their study were caused by strangulation and could be identified as being due to vest and strap restraints. They concluded that physical restraints directly caused 1 of every 1000 nursing home deaths in the United States.[6]

There is a mistaken belief that restraints prevent falls when in actual fact they have been known to create a higher incidence of falls. A study by Arbesman and Wright found that elderly hospitalised patients who had been restrained had approximately twice the risk of falling as patients who had not been restrained.[7]
Restraining a person can actually in-

crease the amount of nursing time involved in caring for them as there needs to be frequent and methodical monitoring and assessment which includes regular release from the restraint and toileting. It would appear that restraining patients might not be an efficient use of nursing time.

Ethical problems with restraint in aged care

A recent Victorian report that researched the issue of abuse of older people with dementia and their carers, found that restraints were used inappropriately. In particular, this report concluded that restraint use to prevent wandering, was an inappropriate response to dementia behaviours.[8]

Apart from the very obvious detrimental consequences of restraint mentioned above, there is also the complete restriction of liberty, the lack of respect for the patient's autonomy and the total affront on their personal sense of dignity. A person may have lost the capacity to be responsible for their financial affairs or to make complex decisions about their medical treatment but this does not mean that they are unable to make any choices or to express preferences. Restraint needs to be examined in the context of care and the responsibilities that carers have for those they are looking after. It would seem that restraints are an attempt to *control* behaviour rather than an attempt to *respond* to behaviour in an adequate manner. Restraining people is a generic response to 'undesired' behaviour rather than an individual approach to a particular person's needs in the context of their life.

A fractured femur from a fall may be considered a harm and one which carers feel they have a duty to protect their patients or residents from, but it must be balanced against the harms that long term physical restraint may cause. There needs to be a balance between concerns for the patient's safety, respect for their autonomy and the responsibility that carers have to ensure an optimal good quality of life for those in their care.

The use of restraint in aged care could be seen as an example of the practice of 'defensive medicine'. The priority is not the best interests of the person being restrained, but protection against legal liability. Such rationale cannot be used as ethical justification for the use of restraints.

Alternatives to restraint in aged care

Alternatives to restraint in a long-term care facility might include: restructuring of the environment, investigation into the cause of the behaviour or disorientation, changes in lighting, increased staff involvement and, implementation of an individualised care plan that takes into account the needs of the specific patient or resident. The families of residents of aged care facilities should be involved in developing care plans for their relative. It is often the family, fearful of their relative falling, who suggest some form of restraint without acknowledging the consequences or how infringement of liberty may severely diminish their relative's quality of life.

Restraint and the acute care setting

The goals of treatment and care in an acute hospital are different from those in an aged care facility. Aged care facilities, for the most part, are the homes of those who reside in them. Hospitals on the other hand, apart from when someone is in the dying stages of their life, are a temporary environment. Apart from palliative care, the aim of admission to an acute hospital care is to cure, restore or at least stabilise chronic conditions. In acute care the patients are sick, have illnesses for which a variety of therapies may be necessary, have a great heterogeneity of needs and their length of stay is usually shorter than that of people living in aged care facilities. People admitted to hospital are also likely to be undergoing life-sustaining treatments which are, of themselves, restricting and restraining.

The rationale for using restraint in the acute care setting is the fear that without it the patient will disrupt therapy. The use of physical restraints is justified so as to maintain technologically complex therapies such as endotracheal tubes, central venous lines or dialysis. The treatments are life sustaining and deemed medically necessary, and it is considered that there is a high probability of serious harm if the therapy is abruptly withdrawn or interfered with. There are many issues raised here not the least being that informed consent, apart from being legally necessary, is ethically appropriate before treatment can be undertaken. This is, however, problematic. The treatment may have been instigated in an emergency and as the patient's condition improves they may regain consciousness and not understand the purpose for the various tubes and lines. Alternatively, a patient may

they have been known to create a higher incidence of falls

have given fully informed consent prior to an operation or procedure, thinking that they would be able to comply with any treatment necessary afterwards. They may, however, not always be competent after surgery to understand the importance of the dialysis, the nasogastric tube or the central venous catheter. They may therefore attempt, and in some instances succeed, in pulling out or removing the 'medically necessary' tubes and lines. In such cases restraint is seen as the only solution. It can be quite distressing for nurses to have to restrain usually competent people in order to maintain 'medically necessary' therapy.

Interestingly, bed rails which are certainly deemed a common form of restraint in the aged care setting, are viewed differently in acute hospitals. *The Victorian Mental Health Act* 1996 Section 81 1A states that bed rails or 'beds with cot sides and chairs with tables fitted on their arm that restricts the person's capacity to get off the furniture' are not included in the definition as mechanical restraint. Many hospitals advocate the use of bed rails as mandatory when

patients have received premedication, are unconscious, have had ophthalmic surgery or are confused, disorientated or heavily sedated. Bed rails are also used routinely when transporting patients around the hospital in a bed and at night they are often used in the case of elderly patients.

If restraint has to be used in aged or acute care…

Before a judgement is made about applying a restraint the following questions should be asked — what is the behaviour, condition or reason that requires the use of restraint? is the cognitive ability of the individual impaired? what is the desired outcome? and, have any alternatives to restraint been used?

If restraint is the final course of action and all other alternatives have been investigated the least restrictive restraint should be used and there must be regular periodic assessment and review. The use of the restraint should be clearly documented and all staff should have up to date knowledge about the proper application of the restraint. The policies and guidelines of the institution should be strictly followed.

If restraints are used they must be consistent with the overall goals of care and therapy. 'If the goal of therapy is to prolong life, to restore a patient with an acute or chronic illness to health, or to improve decision-making capacity, using restraints to prevent interference with life-sustaining is consistent with treatment goals.'[9] However, if a person is nearing the end of their life where comfort and the relief of pain and suffering are the goals of treatment or, they are living in an aged care facility, restraint is inconsistent with the goals of care.

According to Moss and La Puma [10] because physical restraints pose known medical risk and 'there is insufficient validation of both their safety and efficacy, their use in clinical practice should be understood as an application of an investigational or nonvalidated therapy. The use of restraints limits personal freedom in a way that we would usually think is reprehensible, so the onus must be on those who advocate the use of restraints to establish the justifiability of their use.[11]

Informed consent is necessary for any sort of therapy but in the case of an unproven treatment the standard should be higher. Patients with full decision making capacities should understand all potential benefits and risks of restraints together with therapeutic goals before such treatment is instigated. Those patients who do not have decision making capabilities should have proxies such as an agent with enduring power of attorney (medical) or a guardian who can consent to or refuse the use of restraints based on an understanding of the nature of the treatment.

Conclusion

The reasons for applying restraint should be considered in relation to the objectives and quality of care in each situation. In the aged care setting the use of restraint may be seen as protecting residents' safety. It must be acknowledged however that it is a form of behavioural control and a potential infringement of the person's rights. Given that an aged care facility is a person's home, their autonomy, so far as they can exercise it, should be respected so that their quality of life can be maximised. In the acute hospital, however, where medical treatment is administered in order to cure or stabilise ill health conditions or to prolong life and where patients are usually admitted temporarily, the use of restraint may be ethically justified in order to achieve these goals.

ENDNOTES

[1] As described in PA Winston et al., 'Improving Patient Care through Implementation of Nurse-Driven Restraint Protocols', *Journal of Nursing Care Quality* 13/6 (August 1999) 33.
[2] RJ Moss and J La Puma, 'The Ethics of Mechanical Restraints', *Hastings Center Report* (Jan/Feb 1991) 22–25.
[3] Australian Bureau of Statistics (ABS) *Australian Demographic Statistics*, June Quarter 1999.
[4] Andrew Retsas, 'Survey findings describing the use of physical restraints in nursing homes in Victoria, Australia', *International Journal of Nursing Studies* 35 (1998) 184–191.
[5] Susan Koch, 'Restraining nursing home residents', *The Australian Journal of Advanced Nursing* 11/2 (December 1993 - February 1994) 10.
[6] SH Miles and P Irvine, 'Deaths caused by physical restraints', *Gerontologist* 3/2 (1992) 762–766.
[7] M Arbesman and C Wright, 'Mechanical Restraints, Rehabilitation Therapies, and Staffing Adequacies as Risk Factors for Falls in an Elderly Hospitalized Population', *Rehabilitation Nursing* 24/3 (May/June 1999) 122.
[8] Alzheimer's Association Victoria and LaTrobe University, *Overcoming Abuse of Older People with Dementia and Their Carers: A Discussion Paper*. September 2000, 34.
[9] Moss and La Puma, 'The Ethics..' 24.
[10] Moss and La Puma, 'The Ethics.' 23.
[11] S Dodds, 'Exercising restraint: autonomy, welfare and elderly patients' *Journal of Medical Ethics* 22 (1996) 161. ✣

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