Human- and Xeno-Transplantation Research and Ethics

Due to a dire shortage of donated human organs clinicians have turned to research animal-to-human transplantation (xenotransplantation). This article discusses ethical issues common to human- and xeno-transplantation as well those specific to xenotransplantation.

Here I wish to expand on some ethical concerns that were raised in my previous article published in this Bulletin.[1.] It is relevant since submissions to a public consultation on xenotransplantation closes on 12 March.[2] Xenotransplantation has risks of inter-species infection and raises other health concerns, including the impact it may have on a person's identity. I will concentrate on ethical issues, leaving aside cultural dislikes of some for it.

Personal Identity

Human beings have an awareness of themselves as unique living subjects of inestimable worth and personal dignity, as male or female, and for whom others are likewise equally valuable as persons. We cherish in particular our ability to think, to relate and communicate with others, to reason things out, to solve problems, to plan for the future and to freely choose our activities. We are aware that we are morally bound to follow the dictates of our conscience and that we are morally responsible for our deeds. Our experience of loving relationships is a precious part of our lives, including family bonding with a genetic basis. Part and parcel of being human is to enjoy our experience of a wide variety of feelings, emotions and awareness of our personality. We are historical beings in that we have memories of what we have done and endured, including our early education and formative experiences at home with our parents and at school. Much of this belongs to the core of our self-identity as persons. In short, we know that all this is possible in virtue of our human nature which enables us to be subjects of rationally self-conscious and free acts, including bodily activities.

At another level we experience the perception of our self-image, including appearance. We are aware of the relative importance of the various parts of the body as well as the need for our organs and senses to function normally. The evaluation of the relative importance of such factors may vary from person to person.

Ethical Issues Common to Human– and Xeno-Transplantation

The capacity to perform rationally self-conscious, free and morally responsible acts is central to our personal identity. As such it is of fundamental importance and should be treated as morally inviolable. This capacity should not be put at risk by medical research or clinical trials since it could make a person either incapable of acting as a moral agent or permanently impair the integrity of this capacity. Hence Pope John Paul II quoted with approval the ethical principle given by Pope Pius XII for xenotransplantation to be licit: `the transplanted organ must not impair the integrity of the psychological or genetic identity of the person receiving it; and there must also be a proven biological possibility that the transplant will be successful and will not expose the recipient to inordinate risks.[3]

It would be unethical to transplant the human brain or significant parts of it, eg. the cerebral cortex, because their specific functions are closely related to the patient's unique personal identity, rationally self-conscious and free acts, memory and the normal functioning of one's

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emotional life. John Polkinghorne rightly insisted that since it would be unethical to risk 'personality transfer', only small fragments of human fetal neural tissue or neurones should be transplanted to a recipient.[4] The taking of risks of predictable and substantial harm to the subjectivity of recipients is unethical, eg altering patients' perception of their own personality, memories, relationships and friends. However, transplants that would only minimally affect the experience of feelings and emotions may be ethically performed if there are reasonable grounds to believe that they will save patients' lives or significantly improve their quality of life.

On account of the importance of the genetic basis of family bonding between parents, their children and the extended family, it would unethical to transplant gonads from one person to another. The reason is that if the recipient became a parent, the resulting children would be genetically related to the donor of the gonads. It would be criminal to transplant an animal's gonads or an animal's cerebrum or cortex to a human patient - not that I am suggesting any responsible clinician or scientist would contemplate doing this.
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All known risks and likely benefits must always be communicated clearly to a prospective competent transplant patient to enable a free and fully informed decision to be made. In transplants the risks may be high or low, and the likely harm may be serious or minor. These have to be assessed carefully as to the probability of the risk and the degree of harm. Risky procedures need to be assessed on a case-by-case basis. A one in a million risk is substantially different from one in a hundred. It would be unethical to take the risk of serious harm resulting from a transplant unless the risk was proportionate to the likely benefit. If scientists or transplant clinicians believe a risk is too high, the transplant should not be offered to the patient. If more time is required for research on an animal model, the time must be taken until it is sufficiently safe to proceed. Incompetent patients should not normally be given transplants because they are unable to give informed consent. In the case of minors in a life saving emergency, their parents or legal guardians may give the necessary informed consent.

Advances in Animal-to-Human Transplantation

Life-saving or life-enhancing transplants from humans-to-humans have been performed ethically with mixed results for some years. A shortage of human organs/tissues and increased demand led clinicians to use animals as a source of organs/ tissues for human transplantation. To reduce the risk of immune rejection, scientists engineered transgenic animals by inserting suitable human genes into pig (porcine) fertilised eggs which were then implanted into recipient sows. Transgenic pigs with some human genes were subsequently born and bred. It was found to be more economic and much quicker to clone transgenic

pigs by fusing transgenic porcine cells with enucleated porcine eggs and then to implant them in one or more sows. There is a lower risk of humans rejecting transgenic porcine cells after transplantation because the human immune system would be less likely to recognise them as foreign due to the presence of the human genes in them. An additional problem was the sugar coating of most animal cells called "αGal" which induces an acute immune response. Scientists have now engineered "gene knockout" pigs whose cells are not coated with "αGal". This further reduces the likelihood of immune rejection of transgenic porcine cells after transplantation. [5]

Clinical trials of transplanting human fetal neurons into the brain of patients with Parkinson's disease (PD) show that significant symptomatic improvement was found in patients < 60 years of age. However this was not the case for PD patients > 60 years, 15% of whom developed uncontrollable writhing. This resulted from unregulated and excessive production of dopamine.[6] Furthermore there was no reversal of the neurogenerative disorder.[7] Only time will tell if transplants of human fetal tissue will have therapeutic potential for other brain diseases and brain lesions.

One would surmise the risks would be higher if animal neurons tissue were transplanted into the brain. In fact, porcine fetal neurons have recently been transplanted into 12 PD patients. After 12 months, clinical improvement of 19% was observed in 10 PD patients and up to 30% in some other PD patients: 'No serious adverse events were related to the cell implantation or surgical procedure'.[8] Also 'there was no evidence of transmission of porcine-derived pathogens or a porcine-specific endogenous virus, and no serious adverse events directly related to the implantation of porcine fetal cells.[9] However, in the 12 patients with Huntington's disease whilst there was no loss of total functional capacity, 'there was no sustained improvement in symptoms in any patient after transplantation.'[10] In a similar trial no evidence was found of serious adverse events related to the implanted porcine cells leading the researchers to conclude that 'porcine cell implantation appears to have a favourable short-term safety profile.'[11]

Ethical Issues Specific to Xenotransplantation

Xenotransplant patients need to be able to evaluate all the risks and benefits, especially risks of cross species viral infections or of permanent psychological harm, eg a change in the perception of their self-image or their personality. Great caution is needed in the transplantation of animal neural tissue to the brain. Successful outcomes of transplants of animal neural cells for the treatment of brain disease without any negative consequences would provide some guidance for best practice in this delicate matter.
One of the most serious dangers of animal-to-human

transplantation is the risk of infection by viruses that are extremely harmful or lethal to humans but not to animals. Before passing to clinical trials of xenotransplants there would be a need of a guarantee that the risk to patients and public health was insignificant. We are sensitive to this sort of danger after the scourge of HIV/AIDS, SARS and now a new strain of lethal bird 'flu. If a major disaster resulted from a xenotransplant, this would put xenotransplantation back for years. Participants in xenotransplant trials and public health officials must be adequately informed of all the health risks.

A review article has warned that short term monitoring of xenotransplant patients for viral infection and/or toxicity is not enough.[12] Participants must agree to honour their commitment to be monitored for life, regardless of the transplants' outcome. Likewise, people should not become carers or close contacts of participants in clinical xenotransplantation trials unless they have been informed of their risks and they agree to honour their commitment to be monitored for life.

Participants should not enter xenotransplantation clinical trials unless there are good reasons to believe it will be beneficial for them, even though some risks may be reasonably accepted. Where there are good or more effective alternative therapies available without comparable risks, xenotransplantation trials should not proceed. For some patients, xenotransplantation may be their only option. However, the same review article noted that the use of therapies for PD based on stem cells or new drugs also offer hope.[13]

Proper care should be taken of animals involved in research, using no more than necessary and minimising risks of harm or distress to them. Transgenic animals should be monitored and not be released into the general environment for the sake of public health.

Transgenesis

I fully agree with the Pontifical Academy for Life that in principle it is ethically permissible to insert genes into an animal embryo for the purpose of reducing the risk of immune rejection of animal organs or tissue transplanted into human patients.[14] Likewise it is ethically permissible to insert human genes into fertilised porcine eggs for the purpose of reducing the likelihood of immune rejection. In the light of solid experimental evidence and success, scientists and doctors should be allowed to determine the right number and types of transgenes to insert to achieve a safe and efficacious therapeutic benefit. There would, however, be ethical concerns about inserting a whole human cell into a fertilised porcine egg since it contains the complete human genome. Out of respect for the human genome and to prevent the abuse of attempting to initiate the development of the human genome in an animal egg to form a cloned embryo, Australia's Commonwealth's Prohibition of Human Cloning Act 2002 prohibits:

- intentionally creating a human embryo clone or to place a human embryo clone in a human or animal body, regardless of whether the human embryo clone did not or could not survive (Section 20);

- intentionally creating a chimeric embryo, i.e. an embryo into which a cell, or any part of a cell of an animal, has been introduced (Section 20 (1);

- intentionally creating a hybrid embryo created by fertilising a human egg by an animal sperm, and vice versa; or created by insertion of the nucleus of an animal cell into a human egg and vice versa (Section 20 (2).

Monitoring

Patients should be monitored after transplants as long as necessary. In the case of xenotransplants, strict monitoring should ensure that any resulting infections would pose no risks to the public. Furthermore, it is well known that disturbances in a person's brain may, to a greater or less extent, interfere with normal brain functioning which could affect the subjective states of a xenotransplant recipient. The emotional responses or memory of people who have had a stroke or have a brain tumour are usually abnormal, eg, unexpected weeping or loss of memory. It cannot be assumed in principle that something similar could not occur following the transplantation of porcine neurons to cure a brain disease. Apart from an obvious increase in lack of coordination of limbs following such xenotransplants, qualified psychologists should be part of the monitoring team to conduct tests for a variety of undesirable changes in patients' personality, cognitive capacity, emotional functioning and the perception of their self-image. Monitoring could lead to giving appropriate therapies to affected patients as well as improving future procedures in transplantation medicine.

Conclusion

The allocation of resources for xenotransplantation research is justified in view of its promising benefits for patients, granted the serious lack of suitable alternative therapies.

ENDNOTES

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Privacy, Biometrics, Technology and Health

This is part 2 of a two part series about privacy in health care. Part one discussed general privacy issues and this article examines the impact of technology in regard to privacy and security in health care. As technology becomes 'normal' for everyday living, the idea of privacy as we know it has changed. It is suggested that the idea of privacy is 'a distinctly modern phenomenon and that contemporary understanding about the protection of privacy has evolved not despite new technologies, but because of them'.[1] In the near future biometric technology may become as commonplace as the use of PINs and ATMs are today.

What is Biometrics?

The term biometrics is derived from the Greek words bio and metric, meaning 'life measurement'[2] and is the science that involves the statistical analysis of biological characteristics, and the application of computational methods to biological features, especially with regard to the study of unique biological characteristics of humans.[3] Increasingly, biometrics is associated with identification and authentication technologies used to enhance security. Biometric technology is suggested to have implications for human rights in general, and privacy in particular, as its potential to exploit people or exert social control is unregulated.

Biometric technologies use characteristics such as appearance, (descriptions as used in passports), natural physiography (measurements as in retinal scans), biodynamics (as in manner of writing a signature), social behaviour (as in style of speech), and imposed physical characteristics (as in embedded micro-chips), to maintain privacy and security.[4] Traditionally, surveillance of individuals was characterised in terms of who they were or what they were doing, but now technology can track where they are, where they've been or where they are going.[5] Passwords and access codes are commonly used in health care. The ability to remain 'anonymous' is threatened.

Biometric use in securing privacy

Biometrics used for verification asks 'Am I who I say I am?' and works by comparing an individual's previously stored piece of biometric data against an actual physical biometric as read by a scanning device, functioning similarly as a PIN number, password or signature.[6] Such 'one-to-one' searches mean that there is no need to search or match to a central database.[7] Biometrics used for identification, eg forensic comparison of fingerprints from a crime scene against a collection of prints from persons previously convicted of serious criminal offences, asks 'Who am I?' This is a 'one-to-many' match wherein a biometric presented by a person is compared against all biometric samples stored in its database.[8] A match should only be possible if the data is already on file.

The primary objective of most biometric schemes is to heighten security. That is, tracking who is in a particular location at a particular time, who conducted a transaction, or provided data, and the authentication of the identity of those who perform, or seek to perform, a particular act, eg. gaining access to premises or gaining access to data.[9] Unfortunately there is potential for these systems to be abused, resulting in discrimination or exclusion. Actual collection of a biometric may involve bodily trespass. The system may falsely reject an individual, or wrongly identify them. These schemes may enhance security but at the same time incur some loss of privacy. How does one protect what is private and personal about oneself? Biometric data has a long history in health care but only recently has its use been extended as a means of maintaining security and privacy in health.

Biometric Technology Threats to Privacy

Identity theft is rising as a result of the way technology is used and how criminals exploit it for fraudulent purposes. Biometrics is proposed as a solution to combat these threats, yet they are not foolproof. We all thought passwords and PINs were safe yet we now know that they can be stolen. Passwords and pin numbers can be changed. When criminals find a way to duplicate or 'steal' fingerprints or retinal scans used for biometric security schemes and commit identity fraud, it will be impossible for the victim to change their iris or fingers!

Biometric Threats to Health

There are reports that organisations face opposition in implementing biometric technologies due to fear that they may pose a health risk, eg. concern that eyes can be damaged by iris scanners. The prospect of continuous monitoring is a possible cause of stress for some people. Some industries may need to know who is where and when, and risk engendering an atmosphere of forced captivity. Consent is implied in some schemes, but others are 'non-consenting' such as 'facial-recognition' technology proposed to be adopted in Australian airports to help prevent passport fraud, people smuggling and other transnational crimes.[10]

Biometric Technology and Health

The concern about using human tissue or fluid as a biometric, whilst remote at present, is technologically possible. How the tissue or fluid is processed is not so much a privacy concern, but how it is obtained is, and what eventually happens to 'stored data' or 'samples' is very problematic. Workers may be coerced into enrolling into such schemes fearing their jobs, entitlements, and prospects may be jeopardised if they do not. Unscrupulous employers may use such samples beyond their 'authentication' purposes and screen their employees for genetic diseases and discriminate on the basis of these results. This may seem extreme, yet genetic testing of employees without their knowledge or consent has been reported in the US.[11]

Biometric medical devices are commonly used for therapeutic reasons, not surveillance. These include implanted devices, such as cardiac pacemakers. There was a push to use biometric tracking devices in certain groups of people, eg. those with dementia, and children. Many consider this technology to violate privacy principles. Another point of view is that imposed physiographic identifiers treat a person in a manner similar to inanimate goods on a production line.[12] Others call it a form of restraint. Such technology is available and has been utilised, but with limited support.[13] In some countries newborn babies are being tagged with barcodes that alert security systems if tampered with, in an effort to reduce baby snatching from hospitals.[14]

A potential growth area for biometric technology in health care is in 'tiny technology' and 'smart pills' of tiny computerised drug delivery systems that can be implanted under the skin.[15] 'Capsule endoscopy' (pill cam) has been used to visualise the small intestine.[16] The ability to continuously or remotely monitor people's physiological status outside acute episodes of illness is a double-edged sword - useful to predict problems, but useless if the technology crashes. It's possible to track certain devices, though legislation prohibits this generally, eg. location tracking of mobile telephone users. Using implanted medical devices for surveillance purposes is clearly outside their original purpose, yet the potential to do so remains.

Health Workplace Surveillance

There is a tremendous push to computerise many aspects of health care. Many workers in health care now use the computer for much of their day to day work. There has been ongoing debate about the privacy of workers, in particular, their access to, and use of, e-mail and the Internet, with suggestions that employers have the right to monitor such activity. The World Wide Web has increased the traffic of information. Health workers can post questions about puzzling medical cases to appropriate discussion groups, or browse the net seeking information. Due to certain in-built mechanisms, it is possible to track and record which sites are visited, (through cookies). This information may be sold to direct marketers, without the user's knowledge or consent.[17]

Employees are a vulnerable population in terms of workplace monitoring. The vulnerability of employees in terms of being research participants has been recognised by the NHMRC Human Research Ethics Committee.[18] But most workers are not research participants, yet they may be subjected to constant surveillance, which may contribute to stress-related disease. Random drug testing in the workplace is proposed to reduce workplace accidents, though the fear of monitoring is suggested to be a contributing factor in the first place.[19] On the other hand, employers have a duty of care to protect their product as well as their employees. In health care, patients are owed a duty of care to be treated by competent health professionals.

'Function Creep'

How probable is the likelihood that physiological data will be used outside the parameter of health care diagnosis, treatment and research? Once captured, it could be speculated that physiological data about an individual could be used in discriminatory ways. Such issues have been raised about genetic privacy in Australia.[20] The ten-

dency to use something beyond its original intent is sometimes referred to as 'function creep'. There are controversies about the storage of human tissue and fluids obtained for health related purposes. We know that 'databases' can be bought and sold. Information from a range of sources can be used to identify someone. It would be a moral and legal outrage if stored data were used to discriminate against or exploit people in some way. Yet the potential to do so persists, and laws can be changed to allow this, despite the moral objections.

For example, a person may say they would never submit to having a genetic test. Yet their potential genetic information may already be stored somewhere, without their knowledge. Indeed the ownership of relinquished specimens has been debated. Another huge repository of potential information about people's individual and family DNA has been captured on Guthrie cards used for newborn screening. The storage and possible use of this data is contentious.[21] Permitting use of human tissue or fluids in the biometric context raises the same ongoing concerns about use beyond the initial imperative, as well as ownership and storage issues.

Saving Privacy

The spectre of 'Big Brother' always watching, as fictionalised by George Orwell[22] is becoming fact. Such a society should be anathema, yet aspects of privacy are eroded away without debate or discussion. Video or closed circuit TV surveillance is commonplace. Use of PIN numbers, access codes, individual swipe cards, passwords, Tax File Numbers, etc can be monitored. Mobile phones can be used as tracking devices. The list is long. The health care industry is looking towards technology to maintain privacy and security. Biometric technology used in non-therapeutic ways, such as for security, may violate aspects of our right to be left alone. The Biometrics Institute has begun public consultations on a proposed 'Privacy Code of Conduct' for the biometrics industry in Australia, which is currently unregulated.[23]

Can we, or should we turn back the clock? Is it imperative that we give something up, such as some privacy, to get something we desire, such as increased security? How secure is all this information about us? Technology has made a mockery of the word privacy, as more technology is rolled out to ensure our security in using technology in the first place. So we give away a fingerprint, a snippet of DNA, a certain way we walk. We allow this information to be stored in huge databanks on our behalf and for our benefit, to prove that we are who we claim to be. It is ironic how we engender such conditions of paranoia about protecting our privacy, that we feel compelled to expose more about ourselves to satisfy the conditions of maintaining our privacy in the first place.

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Medical Technology: Master or Tool?

The following article attempts to articulate the problems arising from, and possible solutions to, an overarching imperative to apply technology in Medicine today

In a symposium on medical technology held in 1980, it was proposed that there was a prevailing technological imperative:

'Medical technology has grown from being a tool to becoming a companion and, in some cases, the master of physicians.'[1]

Disturbingly, there is no indication that this issue has become less topical or that healthcare technology is applied in a wiser way today than it was in the past. On the contrary, it is argued that the application of technology has become rampant and that health professionals are obsessed with technology.[2] Technology can defy meaning but in the medical context includes powerful medications in addition to instruments and techniques that greatly extend a health professional's therapeutic scope. It is our power, really, that technology expands.

It is not suggested we turn the clock back and reject technology outright. No one would seriously want that. It has made lifesaving critical care possible and, importantly, accessible to most people in the developed world. Many technologies have revolutionised treatment, especially the replacement of old diagnostic procedures with new, far less invasive ones. The same can be said for many other technological interventions that have enabled the wholesale movement away from prolonged inpatient care to ambulatory service and home or outpatient care.[3] Technology has transformed our lives through facilitating and enhancing effective healthcare functioning, but it can also be a strain on resources and counterproductive. Leon Kass got it in a nutshell:

'Because it is essentially instrumental, technology is itself morally neutral, useable for both good, and ill. There are, of course, dangers of abuse and misuse of technology, but these appear to be problems not of technology but of its human users, to be addressed by morality in general.'[4]

It is incumbent on society to ensure technology is applied prudently so that we do not need to sacrifice its many precious fruits. What are the issues arising from this technological imperative, then, and how might we overcome them to get the most from technology and optimise health care?

Exponentially Rising Healthcare Costs

Technological growth is blamed for much of the increase in national healthcare expenditure.[5] New techniques and devices cost more, and many in the healthcare arena believe that technology-driven increases in spending do *not* result in higher quality care.[6] For example, a disposable device has recently been introduced that cools tissue, much like an ice pack, after surgery but at a much higher cost---$1,000. Other instances are given below. Such practices strain healthcare resources and are unethical when funds could be better spent. 'We need to seriously evaluate the benefits of individual new technologies before encouraging their use.'[7]

Unnecessary Interventions

Technology is pushing up health expenditure in another way. It is not simply because newer technologies have become more expensive: rather, there is an excessive and unnecessary application of existing technology. Good intentions to be thorough can lead to overly aggressive testing and unnecessary treatment. Diagnostic tests are now being applied far beyond their intended scope. For example, there is an increasing tendency to use Magnetic Resonance Imaging (MRI) scans instead of an X-ray to diagnose a sprained ankle, raising the cost from about $50 to $1,000.[8] Such use leads to higher societal healthcare costs in addition to that borne by the patient.

Monitoring devices and practices are also used when the costs outweigh the benefits.[9] A recent trial investigated the intensity of monitoring women at risk of preterm labor. More intensive surveillance had no effect on the important primary outcomes such as the incidence of births before 35 weeks or neonatal outcomes. However, increased monitoring did lead to significantly more unscheduled visits and greater use of unnecessary prophylactic drugs.[10] Another study examined the effects of routine follow-up after hospitalisation compared to more frequent follow-up visits. Again, the conclusion was clear: although intended to reduce morbidity and hospitalisation, the greater intensity of surveillance resulted in a 36% increase in readmission rates and a trend toward increased mortality.[11]

Demanding technological methods are used when they are futile or even detrimental.[12] A study compared risk-adjusted outcomes among two patient groups, from New York and Texas, receiving different treatment interventions for the same condition---myocardial infarction. Residents of both states were equally likely to have heart disease detected and treated, but Texans with mild disease were much more likely (50%) to undergo an angio-

gram and receive revascularisation. After 2 years of follow-up, although more aggressively treated, Texans had significantly lower exercise tolerance, more angina, and higher overall mortality.[13] These examples all illustrate a deleterious technological imperative in healthcare.

Unreasonable Expectations

A general optimistic belief in technology pervades society currently. Technology, partly because of its success, has become the overarching symbol of progress for both clinicians and public alike. When patients consult doctors they often feel contented when referred for such advanced testing as Computer Tomography (CT), positron emission tomography (PET) or MRI scans but unsatisfied if the clinician refuses to take lab tests and worse, baulk at suggestions about lifestyle changes[14] (diet and exercise come readily to mind). There seems to be a general clamouring for technology which can result in understating the adverse side effects while over estimating the potential benefits.

Unwarranted pressure is brought to bear on clinicians. The theme espoused is increasingly 'that which is possible to do must be attempted.' Since we are now able to sustain life by means of Artificial Nutrition and Hydration, we ought to do so regardless and without limit. A cycle of well intentioned commitment can trump the immediate and individual needs of a patient. And so a technological imperative is born. This assumption is problematic, as it implies that something done is better than nothing, and that in medicine more choice is better than less. Apart from not being in the patient's best interests, healthcare professionals are routinely expected to try every possible avenue and in this way are held hostage to the latest technology.[15]

Death and old age are increasingly being regarded as preventable conditions.[16] Indeed, the bad things in life, such as old age, death, and pain are thrust on doctors often to keep families and society from facing them. Some of them are an integral part of medicine, and accepted as such. 'But there is a boundary beyond which medicine has only a small role. When doctors are forced to go beyond that role they do not gain power or control: they suffer.'[17] This is not only unrealistic but unethical. Both the public and the medical profession ought to remember that doctors are not infallible and medicine does not produce magic.

Novelty

'And, besides abuse and misuse, there is the genuine problem of technology itself: the unintended consequences arising from its proper use.'[18] Technology can have an almost autonomous growth. Both clinicians and patients can be taken in by novel, sophisticated treatment options. The latest technology on offer is often assumed to be the best. This should not be taken for granted as the example of statins show. Statins have been aggressively marketed for lowering risk of cardiovascular attack (CVA). The trial of pravastatin for primary cardiovascular prevention by the West of Scotland coronary prevention study indicates that of 10,000 CVA risk-patients treated with a statin for five years, 9755 would receive no benefit.[19] Although many may argue that treatment with a statin is best practice, for a health system, the cost of achieving these benefits among a minority of patients is staggering, and the resources consumed may be better used elsewhere.

Further Concerns

There is an unmistakable appeal in technology's capacity to remove ambiguity in diagnosis. Because clinical judgement is often complex, doctors strive for hard facts and certainty. Technology is ideal in these situations as it generates immediate and clear results. While this is understandable, such 'tunnel vision' can endanger health. Technology is a work in progress: it is only as good as the information on which it's based. Furthermore, while striving for a definitive answer clinicians may well overlook aspects and fail to see the patient in her entirety. For better or worse, we are physiologically complex and good healthcare ought to acknowledge this.

There also seems to be a premature acceptance of technology which is exacerbated by inadequate assessment. It is sometimes applied before it has been proven to be safe or effective, utilising novel tools that do not prevent, control, or cure disease.[20] An outstanding example is much of the current technology employed in the field of IVF. Variations and clever techniques continually emerge, yet none have overcome the primary problem of human infertility. IVF technology must be applied to achieve another pregnancy each time the couple presents; the underlying condition of infertility remains. Furthermore, society can be inclined to ignore its negative side effects, such as the increase in prenatal complications and childhood morbidity. Even with the rise of evidence-based medicine, it appears to be difficult to make the healthcare system implement the results of technology assessment. The lure of technology encourages implementation despite evidence against a particular intervention.[21]

Diagnostic testing is now so advanced it can detect differences that fall well below the established threshold for disease. For example, a quarter of young, asymptomatic adults screened in the US were found to have knee abnormalities by MRI[22], and half had a lumbar disk bulge, despite having no back pain.[23] The conclusion reached was that these so-called 'abnormalities' were coincidental and not necessarily useful indicators of future conditions. Such examples not only demonstrate the arbitrary nature of technology, but indicate we may be getting to the point

of diagnosing pseudo-diseases. This is not in the public interest.

Solutions

In all these cases, technology is not the problem---it is *our* perception of it that is problematic. Although value-less by itself, because the nature of technology is not well understood it is often blamed for the problems created by its use. The root of the problem really resides in the people using it and clamouring for it. The general public loves technology, doctors are often keen despite its limitations and national healthcare programs can disproportionately support its proliferation.

Assessment

Perhaps technology should be regarded with a more critical eye. In promoting the need for more evaluation, Dr. Clancy, director of the Agency for Healthcare Research and Quality (USA), said "We know very little of the benefits and potential harms of some of these technologies. There is a need for practical clinical trials that answer such questions as, 'Is this worth paying for?' and 'What are the expected benefits?' "[24]

Long-term effects or carefully evaluated adverse responses to specific forms of technology are usually a long time in coming, because the reporting systems on rarely used technical interventions are insufficient unless the intervention results in serious complications or death. The harm also may be under reported because it is indirect, such as creating sleeplessness or immobility of the patient. Good system design and vigilance on the part of clinicians are required to discontinue unnecessary studies and treatments as soon as they have outlived their usefulness.[25]

Clinical Wisdom

It takes good clinical judgment to decide when technology is useful, and when sophistication becomes overburdensome and unwarranted. Clinical methods and scientific tools influence decisions as much and sometimes more than theories and scientific evidence based on realistic outcomes. Even in ancient times, to exceed the reasonable limits of the means available to medicine was hubris:

'For in cases where we may have the mastery......there we may be craftsmen, but nowhere else. Whenever therefore a man suffers from an ill which is too strong for the means at the disposal of medicine, he surely must not even expect that it can be overcome by medicine'[26] 'Hippocratic clinicians recognized that appropriate applications of technology required a searching analysis of its capabilities,'[27] with both right and wrong ways to apply it.

Conclusion

Thus, the role of medical technology is a mixed one, and, while there is a technological imperative today, to conclude that it can not be appropriately modified with time seems a defeatist position. Surely the problems of technology can be dealt with so that we can continue to reap its benefits. Firstly, and perhaps most importantly, there needs to be broad societal acknowledgment of technology's limitations. Education could disabuse the public and clinicians alike of magical, unrealistic notions about technology. Secondly, stringent technological assessment and careful regulation should help to minimise inappropriate use. Thirdly, clinical diligence and respect for human dignity should prevent unnecessary or overly burdensome interventions. And finally, we could all bear in mind the common foibles in human nature that can mislead us at the expense of the primary aim of medicine---treating the patient well.

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Michael Herbert

Health Industry hit by 'Violence' Epidemic

Violence is no longer something that happens to other people, or only occurs in other countries. Everyday we are bombarded with news about violence in our own backyard. Violence is even violating our workplaces. This article discusses the growing evidence that workplace violence, particularly in the health care industries, is becoming an epidemic, which needs to be contained .

According to a 1999 Australian Institute of Criminology report, the health industry ranked highest in major workcover claims related to workplace violence. This report suggests that there is evidence that workplace violence within the health care sector has increased significantly.[1] Workplace violence affects the dignity of millions of people worldwide as well as being a major source of inequality, discrimination, stigmatisation and conflict in the workplace. It is becoming a central human rights issue.[2]

Workplace Violence or Bullying?

Workplace violence can be defined as incidents where staff are abused, threatened or assaulted in circumstances related to their work, including commuting to and from work, involving an explicit or implicit challenge to their safety, well-being or health.[3] Workplace violence can be a single opportunistic incident, or ongoing, random, persistent and premeditated. Workplace bullying generally involves internal conflicts between employees, including managers and supervisors. Workcover Victoria describes workplace bullying as 'repeated, unreasonable behaviour directed toward an employee, or group of employees, that creates a risk to health and safety'.[4]

Harassment and stalking do not necessarily fit so comfortably within the range of behaviours described as bullying or violence, yet both cause distress to the victim. The Australian Public Service Commission describes workplace harassment as 'behaviour that is unwelcome, unsolicited, usually unreciprocated and usually (but not always) repeated.'[5] Stalking refers to a constellation of behaviours encompassing repeated and persistent attempts to impose unwanted communications or contact upon another.[6] Stalking is an offence under the Crimes Act 1958.

Violence against clients can also be perpetrated by health care professionals. This includes premeditated harm such as murder.[7] Staff abuse of elderly residents is thought to be under reported. Why staff abuse clients in their care is multifactorial but includes frustration with staffing shortages, wanting to exert 'control' over the vulnerable, or just having a sadistic nature.[8] Violence can also erupt between patients, particularly residents in extended care facilities.[9]

Violence and the Law

The employer's Duty of Care and common law obligations under the Occupational Health and Safety (Commonwealth employment) Act 1991 states an employer must take 'all reasonably practicable steps to protect the health and safety at work of the employer's employees'.[10] In Victoria the relevant laws that protects employees against workplace bullying and occupational violence, are the Occupational Health and Safety Act 1985, the Crimes Act 1958 (Vic), the Summary Offences Act 1966 (Vic), the Equal Opportunity Act 1995 (Vic), the Sex Discrimination Act 1984 (Com) and Racial Discrimination Act 1975 (Com).[11] Only NSW has legislated to grant workers immunity from civil and criminal liability if they need to use reasonable force to protect themselves from a physical attack in the workplace.[12]

The laws seek to prevent injury and disease but are also a means to be compensated should an injury be incurred in the course of an employee's work. Despite the legislation, legal action is seldom pursued, and hospitals rarely call the police after a violent incident. This reflects a belief that compensation is difficult to get because legal professionals do not consider that violence against health workers is important. Where a nurse does not report a violent incident or has not actually sustained physical damage, the incident will probably not be recorded as an episode of workplace violence.[13]

Why are Health Care Places Violent

Workplace violence is not an isolated individual problem but a structural, strategic problem rooted in social, economic, organisational and cultural factors.[14] When people are injured or ill there is some loss of control, which may escalate to violence. Failures in communication may trigger some violent behaviours. Organisational characteristics, such as not rewarding worker loyalty may fuel internal situations. Environmental factors, such as poorly designed waiting areas may also contribute. Research has shown that increased waiting times and frustration, increasing use of weapons, inadequate security, a culture of silence, inadequate support for emergent mental health needs, lack of reporting, lack of institutional concern and systems of support are factors which escalate workplace violence.[15]

Victorian Nurses are being assaulted, stalked and threatened on the job. Drugs, alcohol, language barriers, waiting times and psychiatric disorders often trigger this violence. Threats and assaults in hospitals were once 'limited and spasmodic', but were now commonplace.[16] There may be historical reasons for this change. The growing inequality in terms of wealth, rising costs, and denying the limitations of medical technology. The de-institutionalisation of many psychiatric services may also be a contributing factor. Perhaps the violence is a consequence of encouraging an 'open-door' access to everyone, but without the infrastructure or staffing to support this.

The 'Cost' of Violence

The experience of violence is subjective. The long-term negative effects of workplace violence on staff may manifest in episodes of illness, not wanting to come to work, thinking about leaving, and feeling vulnerable. There are also effects on patients and their visitors.[17] Health care professionals are increasingly suffering from symptoms of Post Traumatic Stress Disorder (PTSD) which is a syndrome that occurs as a belated or prolonged response to a stressful event, such as violence. Exposure to violence may lead to PTSD, and some of the symptoms of PTSD are violent behaviour and aggression.[18] The long-term consequences of violence may be immeasurable, impacting not only on the victim, but their family, friends, colleagues and wider community.

Assaults by violent patients against health workers is said to have cost taxpayers $8 million in the past three years.[19] Nurses have higher levels of 'workers compensation' claims involving violence than those of police and prison officers.[20] Costs are not always monetary. Occupational violence is also a factor in skilled workers, such as nurses, leaving a health care sector already racked with funding and staff shortages, which ultimately effects patient care and perpetuates the problem.

Prevention or Control

Guidelines for the prevention of violence among health care and community service workers have emphasised repeatedly that a mix of risk control measures will usually be most effective.[21]

The personal histories or traits of employees, such as violent reaction to discipline, may signal the existence or the escalation of violence at the workplace.[22] Situational prevention techniques include increasing the effort required by potential offenders, increasing the chances of their apprehension, reducing or eliminating potential rewards from robberies, and raising people's awareness. These techniques are generally achieved through physical measures such as protective screens, closed-circuit television, and duress alarms.[23] Improving communication skills and learning techniques to manage challenging behaviours and de-escalate potentially violent situations should be mandatory for all personnel working in health care industries.

The Australian Nursing Federation (Victoria) suggest that all workplaces establish a zero tolerance approach to occupational violence and bullying based on a system/ risk management approach.[24] It is also suggested that it is unlikely that health care professions will achieve a zero-tolerance for occupational violence in the near future because of the aggressive nature of human beings and increasing trends towards violence in society.[25]

Is Our Society Becoming More Violent?

The concern that Western society is becoming more violent seems pervasive but others suggest that the trend towards violence is not a new phenomenon. Historically similar effects can be catalogued during periods of societal change, such as the Industrial Revolution. At that time people flocked to cities to find work. The cities consequently became crowded. There was competition for work. Crime and violence proliferated to ensure survival in an era where there was marked inequality in terms of wealth and power.[26] Sounds familiar?

Occupational violence cannot be measured in an objective way. People have varying tolerances to and about violence. Can a safe limit be imposed, as with blood alcohol levels and driving - either it is within the law or it is unlawful. Is it acceptable to be slapped on the face by someone stealing drugs, someone distraught with grief when a loved one has died unexpectedly, or by a person with dementia? The physical effects from the slap may be identical. When does a slap become a criminal assault? Some violence can be prevented or managed by adapting organisational practices and restructuring physical environments. Attitudes about violence, however, seem resistant to change.

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