GUEST EDITORIAL – Cameron Stewart and Ian Kerridge

Umbilical cord blood banking and the next generation of human tissue regulation: An agenda for research

The transformation of umbilical cord blood from being a waste product to being a valuable source of stem cells has led to the emergence of significant legal, ethical and social issues. This editorial proposes an agenda for research into the regulation of umbilical cord blood banking which focuses on issues of characterisation, consent, the interplay of public and private services, and the importance of applying property concepts. It concludes by stressing the need for reform to be based on well-informed public debate.

LEGAL ISSUES – Joanna Manning

Withdrawal of life-sustaining treatment from a patient in a minimally conscious state

This column reports on a recent decision, the first in England in which a court was asked to authorise the withdrawal of artificial nutrition and hydration from a patient in a “minimally conscious state”. Since the seminal decision in 1993 in Airedale NHS Trust v Bland [1993] AC 789, in which the House of Lords authorised withdrawal of artificial nutrition and hydration from a patient in a persistent vegetative state, the relatively new diagnosis of a “minimally conscious state” has been recognised. In deciding whether it was in the patient’s best interests that artificial nutrition and hydration be withdrawn and withheld, the court made a key legal determination, with precedential effect, as to whether the so-called “balance sheet” approach to determining a patient’s best interests, as opposed to the (discredited) “futility” principle, applies to a patient in a minimally conscious state. The merit of the former approach is that it forces explicit consideration of quality-of-life assessments in favour of and against withdrawing life-sustaining treatment. A significant pitfall of the English position, as it is currently developing, is the premium it places on accurate diagnosis, whether of vegetative state or minimally conscious state. These issues will have to be faced sooner or later by Australasian courts.

MEDICAL ISSUES – Mike O’Connor

Responsiveness to the chlorhexidine epidural tragedy: A mental block?

Paralysis following an epidural anaesthetic is a rare event. The mechanism usually involves accidental injection of skin antiseptic instead of local anaesthetic. Two recent cases, one involving paralysis, the other a “near-miss”, are described. The first case resulted in an extensive root cause analysis and an admission of liability by the hospital. The response of the anaesthetic community and the New South Wales Department of Health was swift but failed to produce uniform protocols across the region. Furthermore, the requirement of medical staff to double check medications with a second person before their administration was not addressed. Abandoning a more effective but neurotoxic antiseptic solution in favour of a solution with weaker antiseptic properties, as had previously occurred in one Sydney hospital, could incur higher risks of epidural infection. Defensive medical practice can lead to unwanted negative consequences.
Teaching medical ethics and law

The teaching of medical ethics is not yet characterised by recognised, standard requirements for formal qualifications, training and experience; this is not surprising as the field is still relatively young and maturing. Under the broad issue of the requirements for teaching medical ethics are numerous more specific questions, one of which concerns whether medical ethics can be taught in isolation from considerations of the law, and vice versa. Ethics and law are cognate, though distinguishable, disciplines. In a practical, professional enterprise such as medicine, they cannot and should not be taught as separate subjects. One way of introducing students to the links and tensions between medical ethics and law is to consider the history of law via its natural and positive traditions. This encourages understanding of how medical practice is placed within the contexts of ethics and law in the pluralist societies in which most students will practise. Four examples of topics from medical ethics teaching are described to support this claim. Australasian medical ethics teachers have paid less attention to the role of law in their curricula than their United Kingdom counterparts. Questions like the one addressed here will help inform future deliberations concerning minimal requirements for teaching medical ethics.  

Death by homoeopathy: Issues for civil, criminal and coronial law and for health service policy

Homoeopathy has a significant clinical history, tracing its roots back to Hippocrates and in the recent era to Dr Christian Hahnemann. In the last 30 years it has ridden a wave of resurgent interest and practice associated with disillusionment with orthodox medicine and the emergence of complementary therapies. However, recent years have seen a series of meta-analyses that have suggested that the therapeutic claims of homoeopathy lack scientific justification. A 2010 report of the Science and Technology Committee of the United Kingdom House of Commons recommended that it cease to be a beneficiary of NHS funding because of its lack of scientific credibility. In Australia the National Health and Medical Research Council is expected to publish a statement on the ethics of health practitioners’ use of homoeopathy in 2013. In India, England, New South Wales and Western Australia civil, criminal and coronial decisions have reached deeply troubling conclusions about homoeopaths and the risk that they pose for counter-therapeutic outcomes, including the causing of deaths. The legal decisions, in conjunction with the recent analyses of homoeopathy’s claims, are such as to raise confronting health care and legal issues relating to matters as diverse as consumer protection and criminal liability. They suggest that the profession is not suitable for formal registration and regulation lest such a status lend to it a legitimacy that it does not warrant.


Re Edwards (2011) 4 ASTLR 392; [2011] NSWSC 478 adds to the small line of cases to have considered whether a woman can not only require medical staff to remove sperm from her dead male partner, but whether she is justified in terms of law and international human rights to use it to create children. In this case a Justice of the New South Wales Supreme Court framed the issue as “what right does a woman have to take sperm from the body of her deceased partner so that she may conceive a child?” He did so, despite the manifest ambiguity and difficulty in characterising the legislative rights in this case, without referring to substantive human rights obligations under international Conventions.
to which Australia is a ratifying party (particularly Art 10 of the United Nations International Covenant on Economic, Social and Cultural Rights and Art 23 of the United Nations International Covenant on Civil and Political Rights. Technological advances such as those creating the possibility of capturing a dead person’s sperm by electro-ejaculation and creating children by subjecting it to intracytoplasmic sperm injection in connection with in vitro fertilisation have altered the balance of individual and social interests in deciding who should be regarded as owning a dead man’s sperm and how that relates to basic common law rights of bodily inviolability without free consent. It is to be regretted that in jurisdictions lacking relevant constitutional human rights, or legislation requiring coherence with international human rights, judges do not avail themselves in cases of statutory ambiguity of interpretative insights to be gained from legally binding human rights treaties to which Australia is a party.

**ARTICLES**

**Development of stem cells from umbilical cord blood and blood banking: “Non-controversial” and “free of political and ethical debate”? – Loane Skene**

Opponents of human embryo research have understandably welcomed pluripotent stem cells being derived from body cells including cells from umbilical cords after childbirth. The cord would otherwise be discarded and embryos are not destroyed. However, there are other ethical, legal and political issues in cord blood collection, whether for the child’s future use, or a public blood bank. Information and consent procedures may be misleading. Some parents have false hopes about potential outcomes. The right of access to stored blood and other benefits is sometimes uncertain for children and their families. Private stem cell repositories may compete with public ones. People may want to impose conditions on donation. Quality control may be an issue.

**Religious perspectives on umbilical cord blood banking – Christopher FC Jordens, Michelle AC O’Connor, Ian H Kerridge, Cameron Stewart, Andrew Cameron, Damien Keown, Rabbi Jeremy Lawrence, Andrew McGarrity, Abdalaziz Sachedina and Bernadette Tobin**

Umbilical cord blood is a valuable source of haematopoietic stem cells. There is little information about whether religious affiliations have any bearing on attitudes to and decisions about its collection, donation and storage. The authors provided information about umbilical cord blood banking to expert commentators from six major world religions (Catholicism, Anglicanism, Islam, Judaism, Hinduism and Buddhism) and asked them to address a specific set of questions in a commentary. The commentaries suggest there is considerable support for umbilical cord blood banking in these religions. Four commentaries provide moral grounds for favouring public donation over private storage. None attach any particular religious significance to the umbilical cord or to the blood within it, nor place restrictions on the ethnicity or religion of donors and recipients. Views on ownership of umbilical cord blood vary. The authors offer a series of general points for those who seek a better understanding of religious perspectives on umbilical cord blood banking.

**Umbilical cord blood banking: Beyond the public-private divide – Michelle AC O’Connor, Gabrielle Samuel, Christopher FC Jordens and Ian H Kerridge**

Umbilical cord blood is a source of haematopoietic progenitor cells, which are used to treat a range of malignant, genetic, metabolic and immune disorders. Until recently, cord blood was either collected through donations to publicly funded cord blood banks for use in allogeneic transplantation, or stored in commercial cord blood banks for use in autologous transplantation. The line between public and private cord blood banking is
being blurred by the emergence of “hybrid” models that combine aspects of both the public and private systems. The authors describe these hybrid models and argue that their emergence is explained by both market forces and public sector policy. They propose that the future of the sector will depend heavily on several key developments that will differentially affect public, private and hybrid banking models.

Racially conditional donation: The example of umbilical cord blood – Paul A Komesaroff, Ian H Kerridge, Cameron Stewart, Gabrielle Samuel, Wendy Lipworth and Christopher FC Jordens

While direction of donated tissue to family members has long been accepted, direction to members of specific racial groups has been opposed, on the basis that it is discriminatory and contrary to the ethos the institution of organ donation seeks to promote. It has, however, recently been proposed that racially conditional donation may provide a useful – and ethically acceptable – way to address the social inequalities and injustices experienced by certain cultural groups. This article examines the ethical, legal and cultural arguments for and against racially conditional donation, concluding that the practice is more likely to undermine the values of equity and justice than to promote them and that it may also lead to other unfavourable personal and social outcomes.

The ethical, legal and social implications of umbilical cord blood banking: Learning important lessons from the protection of human genetic information – David Weisbrot

Internationally networked umbilical cord blood banks hold great promise for better clinical outcomes, but also raise a host of potential ethical and legal concerns. There is now significant accumulated experience in Australia and overseas with regard to the establishment of human genetic research databases and tissue collections, popularly known as “biobanks”. For example, clear lessons emerge from the controversies that surrounded, stalled or derailed the establishment of some early biobanks, such as Iceland’s deCODE, Autogen’s Tonga database, a proposed biobank in Newfoundland, Canada, and the proposed Taiwan biobank. More recent efforts in the United Kingdom, Japan, Quebec and Tasmania have been relatively more successful in generating public support, recognising the critical need for openness and transparency, and ample public education and debate, in order to build community acceptance and legitimacy. Strong attention must be paid to ensuring that other concerns – about privacy, discrimination, informed consent, governance, security, commercial fairness and financial probity – are addressed in structural terms and monitored thereafter, in order to maintain public confidence and avoid a backlash that inevitably would imperil such research. Once lost, credibility is very difficult to restore.

Pandemic planning as risk management: How fared the Australian federation? – Terry Carney, Richard Bailey and Belinda Bennett

The role of law in managing public health challenges such as influenza pandemics poses special challenges. This article reviews Australian plans in the context of the H1N1 09 experience to assess whether risk management was facilitated or inhibited by the “number” of levels or phases of management, the degree of prescriptive detail for particular phases, the number of plans, the clarity of the relationship between them, and the role of the media. Despite differences in the content and form of the plans at the time of the H1N1 09 emerging pandemic, the article argues that in practice, the plans proved to be responsive and robust bases for managing pandemic risks. It is suggested that this was because the plans proved to be frameworks for coordination rather than prescriptive straitjackets, to be only one component of the regulatory response, and to offer the varied tool box of possible responses, as called for by the theory of responsive regulation.
Consistent with the principle of subsidiarity, it is argued that the plans did not inhibit localised responses such as selective school closures or rapid responses to selected populations such as cruise ship passengers.

Executive impunity and parallel justice? The United Kingdom debate on secret inquests and inquiries – Rebecca Scott Bray

At the beginning of 2008, the United Kingdom Government rolled into the Counter-Terrorism Bill some controversial proposals to reform coronial inquest processes, namely clauses that would provide for “secret inquests”. The provisions were heavily criticised both inside and outside Parliament, and took a rocky passage through both the House of Commons and the House of Lords before eventually being abandoned by the government.

In 2009 the government again tried to introduce “secret inquests” with the Coroners and Justice Bill, instead ultimately succeeding in establishing what critics have termed a “parallel” system of justice through provisions around “secret inquiries”. This move has been seen as subverting the principles of transparency and open justice in the investigation of contentious deaths. This article examines the government’s efforts to introduce “secret inquests” and thereafter “secret inquiries” in the context of the United Kingdom’s coronial law and purpose, human rights obligations and the ongoing issues around sensitive intelligence, and examines the clash of laws that gave rise to the controversial proposals.

Reinforcing historic distinctions between mental and physical injury: The impact of the civil liability reforms – Christine Forster and Jeni Engel

Mental injury has been differentiated from physical injury since its entry into Australian tort law, with mental injury consistently subject to the most onerous regime. In 2002 in its Review of the Law of Negligence, the Ipp Panel supported the historic distinction between physical and mental injury and recommended further (restrictive) changes to the common law rules in relation to mental injury. This article considers and evaluates the reforms which were introduced into six Australian jurisdictions in relation to mental injury in the tort of negligence in response to the Ipp Panel’s recommendations arguing that the rationale for differentiating pure mental injury from physical injury and consequential mental injury is nebulous. It argues that the reforms operate to reinforce and magnify historic distinctions between physical and mental harm despite increasing recognition in the medical literature of the interrelationship between physical and psychiatric injury; despite the recognition of the professional ability of psychiatrists and psychologists to accurately pinpoint and diagnose mental injury; despite extensive documentation of the far-reaching and devastating impact that psychiatric injury has on victims, families and the community; and despite evidence that early and adequate treatment of mental injury can prevent a raft of damaging and costly personal and societal consequences.

Euthanasia: A reply to Bartels and Otlowski – Jeremy Prichard

This article counters arguments made by Bartels and Otlowski in 2010 regarding euthanasia. It suggests that the authors over-emphasised the importance of individual autonomy in its bearing on the euthanasia debate. Drawing on literature concerning elder abuse as well as the “mercy-killing” cases reviewed by Bartels and Otlowski, the article contends that legalising euthanasia may increase the risk that some patients are pressured, inadvertently or deliberately, to request access. Safeguards to detect and deter pressure may be of limited effectiveness against such pressure. Regarding slippery slope arguments, the article discusses the potential for an Australian euthanasia system to eventually be extended in scope to encompass mental suffering. The article encourages consideration of long-term potentialities, including changes in macro-economic conditions.
BOOK REVIEW

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