From the bedside to the bench, and back again : clinical care and medical research

The extraordinary march of scientific research makes it vital to revisit regularly and if necessary recast the insights and assumptions implicit in the body of knowledge generated. And as the relationship between medical research and clinical practice becomes closer and more complex, the ethical guidelines applying to both disciplines also need to be reviewed.

The 2001 CHA C*ode of Ethical Standards for Catholic Health and Aged Care Services in Australia* proposes a sharp distinction between medical research and clinical care:

> Research differs from clinical practice in that the primary purpose of research is to gain knowledge, whereas the primary purpose of clinical practice is to benefit the patient, whether by diagnosis, cure, stabilisation or palliation, etc.[1]

Such a clear differentiation of primary purposes allows the Code to treat each discipline discretely, but it can also mask their symbiotic interrelationship. It is a truism that medical research finds its ultimate rationale in better clinical practice; what is perhaps not so well recognised is the research imperative inherent in clinical practice. Every human research ethics committee (HREC) has an interest in identifying and developing this relationship of mutuality to which, more often than not in my view, ethical codes and guidelines pay insufficient attention.

For example, when a researcher is also the treating clinician, an HREC typically asks questions about the potential for duality of interest in the patient/participant's relationship with the clinician/researcher; pays particular attention to disclosures in the Patient Information and Consent Form (PICF); and may sometimes require consent to be obtained by an independent third party. In this way the HREC seeks to address ethical issues which it believes may arise from the unequal and dependent relationship between the patient/participant and the clinician/researcher.

Implicit in this concern is a quite individualistic model of health care. Clinical care is conceived solely in terms of care for this particular patient, and so overwhelming priority is given to questions of this particular patient's consent, privacy and right to confidentiality. The same applies to medical research: the NHMRC *National Statement on Ethical Conduct in Human Research (2007)*[2] (National Statement) in Section 2.1 describes research risk only in terms of risks to the individual; likewise a proposed revision to Section 3.4 of the National Statement (entitled "Human Biospecimens") seems to overlook entirely any consideration of population risks, such as the risk to future clinical options for the whole community if a particular research project does not proceed.[3] The concept of the human person implicit in this view seems to me overly individualistic, reflecting a version of autonomy which ignores important aspects of our essentially relational nature.[4] I have described this stance elsewhere as 'flat-earth ethics'.[5]

Biobanks hold the potential to bring great benefit to both the individual and the whole population. Tissue obtained either specifically for research purposes or in routine clinical procedures (eg by surgical resection) can be stored and studied over time, yielding vital information about diseases at the cellular and sub-cellular levels, which can lead to better clinical outcomes for all health consumers. In biobanks the symbiotic relationship of clinical practice and medical research is very obvious: tissue obtained in the clinical treatment of a particular patient may provide important information for the future clinical care of that patient, and of many others, precisely because it contributes to a growing body of population-level research knowledge.

The NHMRC's proposed revision of Section 3.4 suggests that biobank research often merits special ethical consideration because of

> the way biospecimens are obtained; the information they may carry and the implications of that information for the individual and blood relatives; and the significance that may be attached to the biospecimens by individuals and/or communities.[6]

The proposed revision of Section 3.4 suggests that while some biobank tissue may have been collected without explicit consent for use in research (eg as a 'by-product' of clinical procedures), it can in fact be used for research purposes if an

HREC is satisfied that its use meets existing criteria for waiving consent.[7] HRECs are familiar with this retrospective process. They annually receive increasing numbers of applications to access pathology tissue without obtaining consent from the 'donors' under exemptions listed in Section 95A of the *Privacy Act 1988*.[8]

What is not so clear in the proposed Section 3.4 revision are the needs (i) to rethink consent processes for *prospective* use of biobank material generated through normal clinical care, and (ii) to explore conceptual bases for a less individualistic model of those processes. Practical questions relating to prospective consent can be managed quite easily: simply include consent for research use of retrieved tissue when obtaining patient consent for clinical procedures. One creative way is to stamp each clinical form with a research addendum, accompanied by a general explanatory brochure stating the patient's rights, including the right not to donate tissue for research purposes.[9] This approach achieves a balance between the 'community' interest in biobank research and the 'individualist' account of patient autonomy noted earlier.

It is legitimate to ask, however, whether assumptions underlying the current consent regime are accurate, and whether there might not be more 'relational' or 'community' based accounts of autonomy which could cast a patient's participation in medical research in a different ethical light.

The current assumption is that patients are interested not to expose their clinically-obtained tissue to research use without consent because they are concerned about issues of personal privacy, confidentiality and the potential commercialisation of research using their tissue. But has this assumption been tested? There are at least anecdotal indications that patients requiring surgical resection and pathology testing of tissue are actually far less concerned about these issues and far more concerned about getting the best possible clinical outcomes for themselves. This need not be cast as evidence of an overly individualist view, but rather as a legitimate concern for one's survival and healing at a time of often intense personal turmoil.

A more 'relational' or 'community' based account of autonomy could be grounded in Australia's system of universal health cover. If it is reasonable that everyone in this country should expect to benefit personally from our excellent health system, it is surely equally reasonable to expect everyone to contribute personally to those processes which promote better public and community health - including medical research. This opens up what is for now, at least, only an intriguing possibility. Based on a more holistic vision of the human person and a more 'relational' account of human autonomy, biobank research participation could become more or less automatic if patients were to understand that, unless they opt otherwise, whenever they give consent to surgical intervention they also consent to the use of clinically retrieved tissue for medical research purposes.

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[1] Catholic Health Australia (2001), C*ode of Ethical Standards for Catholic Health and Aged Care Services in Australia.* 6.2.

[2] National Health and Medical Research Council (2007), *National Statement on Ethical Conduct in Human Research.* Updated 2009. Online at http://www.nhmrc.gov.au/_files_nhmrc/publications/attachments/e72.pdf

[3] NHMRC, *Proposed Revisions to the National Statement on Ethical Conduct in Human Research 2007*. September 2012. Online at http://consultations.nhmrc.gov.au/files/consultations/drafts/consultationnationalstatement ethicalconduct120904.pdf

[4] Second Ecumenical Vatican Council (1965), *Pastoral Constitution* Gaudium et spes *On the Church in the Modern World,* 12: "*For by his innermost nature man is a social being; and if he does not enter into relations with others he can neither live nor develop his gifts*."

[5] J Parkinson (2009), *Over the Edge: Individual Autonomy and Flat-earth Ethics.* Annual Ethics Lecture, Curtin University of Technology. Online at http://www.bioethicsperth.org.au/Upload/Curtin%20University%20Annual%20Ethics%20Lecture%2018%20November%202009.pdf

[6] NHMRC, *Proposed Revisions*, Introduction. 'Communities' here appears to mean ethnic or other genetic communities to which the particular tissue donor belongs, rather than the general community as a whole.

[7] NHMRC, *Proposed Revisions*, 3.4.11

[8] Guidelines relating to S95A are online at http://www.nhmrc.gov.au/_files_nhmrc/publications/attachments/e43.pdf

[9] This solution has been operating very successfully in a biobank managed at St John of God Hospital Subiaco WA, which is housed with pathology in the Bendat Family Comprehensive Cancer Centre.