

**THERAPEUTIC GOODS ORDER: STANDARDS FOR MINIMISING INFECTIOUS
DISEASE TRANSMISSION VIA THERAPEUTIC GOODS THAT ARE HUMAN BLOOD
AND BLOOD COMPONENTS, HUMAN TISSUES AND HUMAN CELLULAR
THERAPIES
CONSULTATION SUBMISSION**

Barwon Health – Bone Bank

11/02/2010

Barwon Health, The Geelong Hospital, Geelong Victoria 3220

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Executive Summary

The Barwon Health Bone Bank is a small human tissue bank located at the Geelong Hospital in Victoria. We exclusively bank femoral heads from live donors having total hip replacement surgery. We provide these as non-irradiated bone for use in orthopaedic procedures, primarily in the Geelong region and occasionally to Bendigo and other areas.

We support the need to provide a safe and reliable tissue service for the Australian public, but we seek to challenge the Therapeutic Goods Committee to review these new regulatory documents with a view to developing a more blood, tissue and cellular therapy specific regulatory vision, rather than a set of manufacturing principles.

We argue, in this submission, that the current model is conceptually and practically flawed and propose a paradigm shift to regulation of blood and tissue banking as a service and not a manufacturing industry. Quality and safety standards should be maintained through “Good Tissue Practice” rather than “Good Manufacturing Practice.” At minimum, we believe a terminology shift to more appropriate language would be beneficial to the regulation and licensing assessment of the sector.

For the benefit of the Australian public, blood, blood components, human tissue and cellular therapy services must be encouraged to expand and develop with emerging technology, in a safe and controlled manner, with a reasonable balance of justified oversight, but without excessive or undue regulatory burden.

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Introduction

The Barwon Health – Bone Bank (formerly the Douglas Hocking Research Institute – Bone Bank) is a repository for Human Tissue, donated by public and private patients undergoing Total Hip Replacement (THR) surgery in the Geelong region. Although the Bone Bank is operated by Barwon Health – The Geelong Hospital, we rely on the cooperation and support of the local Orthopaedic Surgeons and the theatre staff of the two local private hospitals. The Orthopaedic surgeons and theatre staff are involved in the screening and consent of donors and collection of donations during Total Hip Replacement surgery. They receive no financial remuneration for their contributions to the bone bank, and there is no cost recovery for the institutions that they work for.

The Barwon Health – Bone Bank collects, stores and supplies fresh frozen (non-irradiated) femoral heads for bone graft in orthopaedic surgery. We aim to provide sufficient stock to meet the needs of our local surgeons and, when sufficient stock is available, we often supply bone to surgeons in Bendigo and other areas upon request. The bank is licensed to ‘manufacture’ this ‘product’ by the Therapeutic Goods Administration (TGA) under the current regulatory regime.

Our small bank is maintained by three core staff members who are employed in a part-time capacity for their bone bank duties. Quality control and medical director roles are fulfilled in a predominantly advisory capacity, which is funded directly by Barwon Health, as the approved ‘cost recovery’ rebate currently allowed through section B of the Prosthesis List is not sufficient to meet these costs.

We are one of only 2 or 3 small banks in the country who struggle to routinely supply this non-irradiated ‘product,’ which our local orthopaedic surgeons prefer over the irradiated alternatives produced by other, mostly larger, bone banks.

The Banks Review¹ discusses the need to reduce the “regulatory creep” that results in unintended and unnecessary, “pervasive effects” on small business. “Regulatory creep” in the human tissue sector gravely jeopardises the future of small, localised banks such as ours. We fear that “regulatory creep” will undoubtedly remove our valued, non irradiated tissue resource from the healthcare system. This is not because of any failure of our bank or the precious tissue we supply, which has been in common medical use for many decades, but because the banks that supply these tissue items will become non-viable under the regulatory and ‘cost recovery’ rebate systems. Obviously, this would be an unintended and unnecessary consequence of the “Therapeutic Goods Act.”²

Unfortunately, the current post release ‘cost recovery’ system does not effectively compensate or ensure the long term survival of any tissue bank and “regulatory creep” increases the burden on the tissue sector. Our own recent experience with the requirements for microbiological contamination testing stands as an example of the restrictive consequence of a regulatory burden that potentially threatens the survival of the entire sector.

Our contracted service laboratory ceased providing a TGA licensed microbiological contamination service to us in 2008. The Australian Code of Good Manufacturing Practice for Human Blood and Tissues³ mandates that this testing be performed in a TGA licensed facility,

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however, there is no other licensed facility in Victoria that is prepared to meet the regulatory requirements for introducing and validating the culture methods required for our sample types. It simply is not cost effective, particularly considering the relatively small number of samples to be cultured for us annually. Our microbiological samples could be reliably cultured using similar culture methods, within a couple of hours of collection, at a local pathology service, but the mandate for TGA licensed facilities has required us, at significant additional cost, to transport microbiological specimens from Geelong to Sydney, overnight, to a TGA licensed microbiology laboratory. The samples are ultimately cultured up to 24 hours after collection.

Even under validated transport conditions, the prolonged, interstate transport time clearly cannot enhance our sample or tissue “quality” in any way, yet has served to double our upfront costs. This is an inevitable consequence of the high regulatory burden that has been applied to the sector. There are currently very few microbiology testing laboratories prepared to undertake the onerous process of TGA licensure and it has been our recent experience that many of those that are not directly linked to a blood or tissue service are questioning the cost implications and rational for continuing to provide licensed services.

The additional impacts of this single regulatory requirement illustrate some examples of the very real financial consequences that threaten the existence of our tissue bank service:

- Although the significant additional cost of transport and the higher service fees for the testing were incurred in mid 2008, we were unable to recover these additional costs until our application for a rebate increase on Part B of the Prosthesis List was approved in February 2009 (Please note that that our approved rebate is at a lower rate than was justified in our application).

Consequently, our budget was stretched for more than 6 months, with additional costs incurred for transport and no guarantee that our rebate increase would be approved. This left our public hospital to absorb the additional costs while we waited for the February 2009 List. The alternative would be to close the bank for collections until the additional cost recovery could be guaranteed. Fortunately for orthopaedic patients in Geelong, our hospital’s Chief Executive Officer elected to support the bank financially rather than lose 6 months worth of potential donations.

- If not for the 180 day donor retesting requirement for live donors, which delays the release of tissue until follow-up serology screening is completed, we would never be able to recoup the additional cost of any tissue released before the February 2009 Prosthesis List was published. Although regulatory and ‘cost recovery’ issues are separate, one cannot be considered without consideration to the implications of the other. The impact of regulatory requirements on the financial viability of tissue banking in this country must be considered by the Therapeutic Goods Committee in the review of these draft documents.

There is no opportunity to recover the cost of discarded or non-conforming product, yet significant cost is still incurred.

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- The change control for this issue alone took more than 6 months for our part-time staff to complete to a standard that will satisfy the regulatory requirements of the TGA. The biggest issues were firstly, finding an appropriately licensed facility that was willing to take our work, then negotiating and validating a transport method to safely deliver the specimens interstate within defined time and temperature limits.
- In the transition period between service contracts, 10% of our donations (and consequently our income) for 2008 was lost, due to an inability to have the specimens cultured. This income loss and 6 months of staff time, diverted from regular duties, will never be recovered or compensated under the current rebate scheme. Thus leaving our local public hospital to absorb the cost.
- To meet transport service requirements for overnight delivery, our specimens must be dispatched by 15:00 hours each day. This prevents collection from surgical cases scheduled in the afternoon. As a result, our collection rate in 2009 has been decimated by 40% as compared to 2008. Therefore, on top of the staff time loss for 2008, our ability to generate income to support the service has also been reduced by 40%.

This is just one of the regulatory factors that have contributed a doubling in our Prosthesis List approved rebate from \$1,080 to \$2,113 on the February 2009 list. The cost of our service, to both public and private healthcare, has increased 5 fold since the introduction of regulation in 1996. Yet we still test, package, store and supply our bone donations in much the same way and there have been no adverse clinical outcomes reported from cases involving tissue from our bank in that time. In fact, our *“Audit of the Douglas Hocking Research Institute bone bank: ten years of non-irradiated bone graft”*⁴ published in 2009, documents that the incidence of deep infection in procedures using our non-irradiated bone, was no greater than the incidence of deep infection for all local joint replacement surgery.

Orthopaedic surgeons, theatre staff, and the healthcare services they work for, receive no compensation for the costs that they incur through their support of the bone bank. Our quality control and medical advisors are likewise unfunded. The true cost of providing human tissue for transplant is not nearly met by the ‘cost recovery’ model, but by the goodwill of healthcare providers who can ill afford the additional expense and individuals who choose to contribute their skills for the greater good of the community.

In this introduction, we have attempted to give the Therapeutic Goods Committee an insight into the real implications of the regulatory burden on this, mostly publicly funded, sector. Giving particular focus to the struggle of banks to provide quality tissue items for the community, within the constraints of a ‘not-for-profit,’ ‘cost recovery’ financial system.

We appreciate that the role of the Therapeutic Goods Committee and the Blood and Tissue reference group does not involve the financial considerations of the blood and tissue sector, however, one cannot be considered without the implications to the other. We implore the committee to carefully judge the implications of the additional regulatory requirements that are proposed in these draft documents and to weigh the conundrum of maintaining quality with the reality of continuing to provide a human tissue service.

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If the impact of more stringent regulatory standards ultimately reduces our ability to provide tissue services, then it is not the best outcome for the healthcare of Australian citizens?

General Comments

The introduction of this new draft of the code represents an opportunity to reconsider some of the manufacturing concepts used in relation to the provision of Blood and Blood components, Human tissues and cellular therapies.

We believe there is a fundamental legislative flaw in defining human tissue items as products. The use of terms such as ‘product’ and ‘manufacture’ consequently lock the human tissue banking sector into a regulatory paradigm developed for manufacturers of inanimate objects and pharmaceuticals. These regulations were never established with the complexities and unique properties of human tissue items or the potential of emerging cellular therapies in mind. Human tissue and cellular therapies do not fit well within the manufacturing framework. We have expressed this view in the current round of government reviews into areas that affect tissue banking and Health Technology Assessment⁵. We see this as a timely opportunity to reassess the definitions and regulation of human tissue items.

The greatest obstacle facing human tissue products in the current regulatory model is that they are not considered in their own context. They are consolidated within an existing system, designed for manufacture of pharmaceuticals and devices, a regulatory system in which they simply do not fit, nor belong. Human tissue items, by their very nature, are as unique and variable as the donor from which they come.

Human tissue ‘products’ are regulated as ‘manufactured’ medical devices, which they clearly are not. Many of the manufacturing principles simply don’t apply to something that is procured from a living being, rather than manufactured from defined and controllable raw materials. The simple fact is that human tissue items are neither ‘manufactured,’ nor are they ‘products’.

Our fear is that the spectre of this manufacturing style of regulation and “regulatory creep” will have negative implications in the future for organ transplant activities and will also stifle the development of cellular therapies from the research lab to clinical application in our “not-for-profit,” “cost recovery” legislated service industry.

If tissue and cellular therapies are to develop and proliferate in this country, then we feel there needs to be a reconsideration of the current regulatory model. The American Association of Tissue Banks in the United States has developed a Code of Good ‘Tissue’ Practice to apply to human tissue banking and presumably cellular therapies. If the principles are based on the provision of a tissue service, then this would seem to be a more enlightened approach to the regulation of human tissue and cellular therapies.

We recommend a brave leap to the use of more appropriate terminology and a refreshed code and standards that reflect the realities and unique nature of the provision of human blood and blood components, human tissues and cellular therapies.

Firstly, it is our view that the provision of human blood and blood components, human tissues and cellular therapies is a ‘service’ industry and not a ‘manufacturing’ industry. We collect

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altruistic ‘donations’ and ‘process’, not ‘manufacture,’ these as a ‘not-for-profit’ service to provide a therapeutic benefit.

We would like to recommend that the Therapeutic Goods Committee consider a change in the terminology of the code from “products” to “human blood and tissue items” and from “manufacture” to more appropriate term such as “processing” or “preparation”, where relevant.

As any additional requirements in these new draft documents will have significant implications for smaller banks such as us, we urge the Therapeutic Goods Committee to identify the additional requirements and to consider the “real” added quality value versus the potential additional cost of implementation. We hope the committee understands the fragility of the altruistic tissue services and appreciates that additional regulatory requirements directly increase the cost of providing human blood and tissue items, which will ultimately increase the cost of healthcare.

Specific Comments

We are concerned with the TGA’s recent communications, interpreting a mandate for NAAT testing of live tissue donors, in addition to 180 day repeat serology. Successful implementation of such an interpretation would have imposed significant additional cost to the sector despite the scientific position that there is no additional safety benefit of NAAT when 180 day repeat serology represents the safest and most appropriate screening regime for live donors.

The TGA has sensibly rescinded this interpretation, but we caution the Therapeutic Goods Committee to review these new regulatory instruments to specifically avoid the risk of unjustified, extraneous or inappropriate interpretation.

Clause	Page	Comment
		Schedule 2 POLICY
(1)	9	The intent of this clause can be achieved without the need to require a specific policy document in relation to mitigation of disease risk, especially as the content of this TGO is particularly detailed and specific. It should not be necessary for individual banks to document a policy that regurgitates the requirements of this TGO.
(1) (b)	9	This structure of this clause could be stated in a clearer manner. Again, it should not be necessary for individual banks to document a policy that regurgitates the requirements of this TGO. (i) We do not agree with mandating the exclusion of tissue donors based on an arbitrary 6 month period of possible exposure between the arbitrary dates that were set for vCJD risk for blood and blood components?

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(1) (b) (i)	9	We disagree with mandating the exclusion of tissue donors based on the arbitrary 6 month period of perceived exposure to vCJD in the United Kingdom between 1980 and 1996 as set for blood and blood components. Aside from the subjective dates and exposure period (i.e. 6 months) described, there remains no convincing clinical evidence of disease transfer through tissue. We recommend a thorough review of the medical evidence before approving this clause.
(3)		Again, the intent of this clause can be achieved in procedural documents, without the need to require a specific policy document.
		Schedule 3 MEDICAL & SOCIAL HISTORY
(2)	10	We, as do other tissue bankers, question the specific requirement for face-to-face Medical and Social History donor interviews.
(2) (a)	10	The real practicalities of surgery schedules, especially in the public sector with surgical waiting lists and rescheduling of cases dependent on emergency demands, means that a requirement to interview donors no more than 7 days prior to donation will be difficult to achieve. In our experience, it is not uncommon for surgical donors to attend a perioperative preadmission clinic 2-4 weeks prior to surgery. We actively protest the concept of obtaining medical history on the day of donation for surgical donors on the grounds that the donor may feel under duress immediately prior to surgery, thus impairing their ability to accurately recall specific information to complete a questionnaire or interview. Early surgical cases require very early admission times and donors may be prescribed a sedative or receive aesthetic premedications very early on the day of donation. We support the case for a 90day allowance for live donors, given the requirement for 180 day retesting.

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(2) (b)	10	We question the inconsistency of allowable timeframes between completion of Medical and Social History and donation for donors of different tissue types. In particular the 30 day window for HPC-A and HPC-M donors and allowance of 14 days post donation for confirmation of the history for umbilical cord donors. We question the justification for this discrepancy.
(2) (c)	10	Again, we question the inconsistency of allowable timeframes between completion of Medical and Social History and donation for donors of different tissue types. In particular the 30 day window for HPC-A and HPC-M donors and allowance of 14 days post donation for confirmation of the history for umbilical cord donors. With regard to written confirmation of current history on the day of donation, we question the ability and legal capacity of a woman during labour.
(2) (d)	10	We object to the impracticality of this new requirement for confirmation of medical history currency, no more than 7 days prior to donation for surgical donors. Refer to comments for (2)(a).
Table 2	10	We would encourage the Therapeutic Goods Committee to seek medical guidance on the content of Table 2, with the view to creating consistency in 6 month or 12 month deferral for selection criteria that represent a risk of recent exposure to infectious diseases. Especially in live donors who are repeat tested.
Table 2 (b)	10	This deferral criterion raises a few questions. Will this need to be followed-up and documented, or is the donor's assurance acceptable? Will investigation of currency of the practitioner licence or evidence of the use of sterile, non-reused needles be expected?
Table 2 (c)	11	Should this deferral criterion be interpreted to mean that no deferral is required if injury or contact is not high risk for HepC, HepB or HIV?
Table 2 (d)	11	We are concerned about the use of arbitrary hours for this criterion.

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Table 2 (k)	11	Should this deferral period be interpreted as requiring establishment of disease free status prior to donation, or can post donation (and 180 day retest for live donors) be considered evidence of disease free status?
Table 2 (o)	11	Must the disease free status for tuberculosis be established by testing or medical consultation or is the donor's assurance sufficient?
Table 2 (p)	12	Does this imply a level of active investigation or is the donor's assurance sufficient?
Table 2 (t)	12	Should this be interpreted to mean there is no requirement to defer for recipients of allogeneic blood, blood components or blood products that meet the requirements of this order?
		Schedule 4 SAMPLING, TEST KITS, TEST PROTOCOLS AND TEST MANAGEMENT
(2) (b)	14	Wording is unclear regarding 7 day requirement. Before or after donation?
(2) (c)	14	What is the justification for different blood sampling standards for different blood/tissue types? Sampling 7 days before or after donation is allowed for umbilical cord blood.
(2) (d)	14	What is the justification for different blood sampling standards for different blood/tissue types? Up to 30 days prior donation is allowed for HPC-A and HPC-M.
(4) (b)	14	Again, why the different standard for HPC-A & HPC-M. Up to 30 days prior.
(6) (a)	14	We are wary of the potential interpretation of the wording of this clause with regard to new or updated technologies, especially given the recently rescinded notification that NAAT testing should be required for live donors, even though 180 day serology is required and reducing the window period at collection provides no net benefit.
(10)	15	We question the justification for maintaining both a donation sample and a 180 day retest sample for archive? Surely the retest sample is sufficient to assess the donor's infective status. Further to this, the clause should allow for discard of any archive serum samples if the donation is not released for transplant.

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(11)	15	If a new, more sensitive, screening technology ever becomes available, this clause will effectively enforce a complete freeze on the release of all blood, tissue and cells in Australian banks until retrospective testing of stock is completed. Also, given Australia's 'cost recovery system' and the 6 month (minimum) delay in approval for rebate increases on the Prosthesis List, recovery of the cost of this retrospective testing cannot be claimed for any tissue released prior to the publication of the next Prosthesis List.
		Schedule 5 DONOR TESTING AND EXAMINATION
(1)	16	This clause specifically introduces a new requirement for mandatory physical examinations for live donors. We protest the logistics and additional cost to implement this requirement and question the rational for inclusion. The purpose of the "physical examination", as defined at the beginning of this TGO, is to seek evidence of injuries, treatments or behaviour that would otherwise be captured in a Medical and Social History questionnaire and interview. If the TGA is concerned that donors may not be truthful in completing a medical questionnaire, then we caution the reviewers that the introduction of this requirement will likely reduce donation rates because of difficulties with compliance and donor's reluctance to consent to unnecessary personal invasion. We suspect the consequent reduction in tissue donations would unnecessarily exceed the perceived risk of donor dishonesty in a voluntary and altruistic setting. We urge the reviewers to carefully consider the potential implications of this proposed requirement.

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(1)(c)	16	An inconsistency exists here. (1) Specifies donors of human blood and blood components, human tissues or human cellular therapies must be tested and examined for evidence of infectious disease, yet (c) specifically excludes reference to blood and blood components but (c) (i) again specifies blood. Is this an oversight in point (c) of this clause or is this recognition of the logistical burden and reduction in donations that would result from imposing a requirement for “physical examination” on whole blood and plasma donation? If the latter is true, then we strenuously protest the inconsistent application of a requirement for physical examination and advocate the removal of the requirement for tissue and cells.
(1)(c)	16	(ii) Why is a restriction of “5 days and no more than 7 days” so loosely recommended here? If this new requirement for “physical examination” is to be enforced, then the grace period should be consistent with the requirements for obtaining Medical and Social History, as stated in Section 3.
(2)	16	Although the intent of this clause seems to reflect our position that NAAT should not be required when 180 day repeat serology can be performed, we are concerned that the current wording of the clause is open to alternate interpretation. We recommend that the intent of the clause be stated more clearly and specifically with regard to testing requirements for live donors.

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(5)	17	Under the current code, it has been interpreted that there is no requirement for bioburden determination of tissue which is not treated for bioburden reduction. More specifically, we have not been required to establish the bioburden of our non-irradiated bone as donations are discarded if any microbe is detected by microbiological contamination sampling. We question the intent of this clause as stated and highlight the uncertainty, described in our general comments, associated with the use of manufacturing terms in the regulation of human blood and tissue. In the case of our bone stock, we release the femoral heads as received from collection in the operating theatre. The packaging is not opened and no processing or manipulation of the tissue occurs. Our tissue is not “manufactured,” yet we hold a Therapeutic Goods Licence to Manufacture. Hence the uncertainty with regard to this clause. Does this clause now require us to determine the bioburden of our non-irradiated bone, or does the use of the term manufacture relate only to tissue that is processed, modified or manipulated, thus introducing a risk of further contamination? We resist any requirement to determine the bioburden of our tissue as we discard for any microbiological growth and there is no net benefit of imposing the additional cost, which cannot be recovered. We request an appropriate amendment to the wording of this clause.

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Thank-you for the opportunity to express our views in this submission. Further information or confidential examples can be obtained by contacting us directly.

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1. *“Rethinking Regulation – Report of the Taskforce on Reducing Regulatory Burdens on Business, January 2006”* (the Banks Review)
2. *Therapeutic Goods Act, 1989*
3. *Australian Code of Good Manufacturing Practice - Human Blood and Tissues, August 2000.*
4. *“Audit of the Douglas Hocking Research Institute bone bank: ten years of non-irradiated bone graft”*. [Love D](#), [Pritchard M](#), [Burgess T](#), [Van Der Meer G](#), [Page R](#), [Williams S](#). *ANZ J Surg*. 2009 Jan-Feb;79(1-2):55-61.
5. *Review of Health Technology Assessment in Australia* (the HTA Review)