Submission on TGA consultation: Proposed standards for human blood and blood components, human tissues and human cellular therapy products

Organisation: Sydney Centre for Cell and Gene Therapy
Including:
Sydney Cellular Therapy Laboratory – Westmead Hospital
Gene and Cell Medicine Facility – Kids Research Institute at Westmead

Thank you for providing your comments using the template below.

- Rows may be added or deleted as required. Tables may be left blank or deleted if no comments are to be made on other documents.
- 'Reference' indicates the specific section/ subsection/ paragraph where relevant, e.g. In the infectious disease Order, 8(1)(b) would be used to reference requirements for donor interview timeframe in Part 3, Section 8, Subsection (1), paragraph (b).
- 'Issue' invites a short statement to summarise the comment.
- 'Comments' may include a position including justification or an alternative position.
- Additional general comments are also invited on the impact of these standards, as indicated below each table.

Standards for minimising infectious disease transmission via therapeutic goods that are human blood and blood components, human tissues and human cellular therapy products

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Reference	Issue	Comment
Part 1 4(2) and Part 3 8(1)(a) and	Definition of 'Trained Interviewer'	**We request that the definition of 'trained interviewer' be further clarified**. Is there any associated certification, qualification for this role? What kind of evidence is required to demonstrate that the interviewer is trained? Who is deemed adequately qualified to perform this training?
Part 3 9 (2) a)	Blood sampling of a donor must take place no more than 7 days prior to or 7 days after collection of blood, blood components, cells and tissue.	A number of our collections are received by through the Westmead Bone Marrow Transplant Service which is NATA accredited and soon will be FACT accredited. The timeframe stipulated in the TGO does not align with the serology testing requirements to be met by the service which are specified in in following documents i.e. tested within 30 days before collection: • B6.6 Foundation for Accreditation of Cellular Therapy (FACT) International Standards for Cellular Therapy Product Collection, Processing and Administration (4th Edition) • S2.4 Requirements for Procedures Related to the Collection, Processing, Storage and Issue of Human Haemopoietic Progenitor Cells (Third Edition 2009) **We request that the TGA review the timeframe for collection to align with these recognised national and international standards.**
Part 3 8 (1) b)	The interview must occur no more than 7 days prior to or 30 days after collection	The timeframe of 7 days does not allow for another eligible donor to be found if the donor is ineligible. This is important as the recipient would have usually commenced conditioning prior to this timeframe and must proceed with an infusion. **We request that that the donor interview occur within 30 days prior of**

		collection to reflect the current industry practice.
Part 3 8 (10) a)	A product must not be manufactured from a donor who is known to have a disease or condition…..	This presents difficulty in patients receiving an autologous cellular therapy who have received radiation therapy or high dose chemotherapy e.g. patients who develop EBV driven tumours as a result of poor immune function induced by the therapy they have received. These patients should not be excluded as there limited risk in receiving their own cells. **We propose an additional clause (c) be included exempting cells to be used in an autologous setting.**
Part 3 10 (4) a)	All donors must be tested in accordance with and must comply with the following requirements: (a) all donors must be tested by serology at the time of collection, and (b) NAT testing for HIV, HCV and HBV must be performed at the time of collection to exclude a window period infection; or	The move to NAT testing for HIV, HCV and HBV will have large cost implications on a sector facing a number of new cost requirements with licencing etc. **We request scientific and literature evidence detailing the risk with current serology testing practices and need to also perform NAT testing?** **We also request that the TGA ensure that laboratories performing NAT testing for blood from donors that have been mobilised have their procedures validated for blood with high white cell counts.**
Part 3 8 (4) Table 1	Table 1 sections (d) to (s). This list is overly restrictive for islet allotransplantation.	Given that the donor pool is already small, adherence to this protocol which is based on blood donation will eliminate highly desirable donors without any real reduction in risk. Donor pancreases for islet transplantation should adhere to the same criteria as whole organ donors. Given that these donors have been in ICU it is often not possible to wait until they are infection free. Most will have had a blood transfusion during ICU and many have lived in the UK or a Malaria prone

		area. Experience with organ donors has shown that the risk to the recipient of disease transmission is minimal in these circumstances. Even when including recent tattoos and past drug behaviour. Especially when compared to the substantial risks involved with immunosuppression and the transplant procedure itself. **We propose the donor pancreases for islet transplantation conform to the same infectious disease standards as other solid organs**.
Part 3 10 Table 3.	Serology testing for autologous use following islet auto transplantation.	Islet autotransplantation is undertaken when a patient undergoes a total pancreatectomy for severe recurrent pancreatitis. The islets are isolated from the excised pancreas and transplanted into the liver of the patient in a single procedure i.e. whilst the patient is anaesthetised for the pancreatectomy. There is no second chance. There is no rationale for undertaking NAT testing or infectious disease testing in a TGA approved lab rather than the NATA accredited hospital laboratory. There are no additional risks to the patient as the tissue is autologous. The timing of the surgery is a medical decision and NOT a regulatory one and the rules in Table one should not apply. **Islet autotransplantation should be exempt from the regulatory requirements. It is a low volume (<5 patients per year) medical procedure under the control of a single medical team. There is no additional infectious disease risks to the patient especially as they are already having major abdominal surgery outside the regulatory process.**

What is the perceived impact, if any, of implementing these requirements in your organisation?

- Additional cost implications associated with NAT testing of donations.
- In the Islet Cell Transplantation setting the infectious disease restrictions outlined will severely and adversely affect access to organ donors and hence will adversely impact on patient outcomes. It means that the delays it causes will have unnecessary patient risk especially when waiting for a second or third islet transplant. Patients will have the added risk of immunosuppression without the benefit of a full function transplant.

Other general comments:

General requirements for the labelling of biologicals

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What is the perceived impact, if any, of implementing these requirements in your organisation?

Other general comments:

The TGO appears satisfactory.