



Ms Kate Doherty
Coroner's Registrar
Coroner's Court of Victoria
Level 11
222 Exhibition Street
MELBOURNE 3000



Dear Ms Doherty

Court Reference: COR 2007 000067
COR 2007 000125
COR 2007 000126
COR 2007 000149

Investigation into the death of CARMELINA (LINA) R SIRANNI, KAREN WILKINSON, GURPAL SANDHU AND JOVO VRANJESEVIC.

The Organ and Tissue Authority (OTA) refers to the below recommendation made by Coroner Jamieson on 7 May 2013.

Recommendation 1: Inter and intra hospital communication post transplant

- a) To improve on intra and inter hospital communication and minimise the risk of adverse outcomes, **I recommend** that DonateLife be authorised by the hospitals performing transplant surgery to extend their liaison role in the post transplant period to accept responsibility for intra and inter hospital communication regarding the progress and/or usual/unusual symptoms and/or complications of donor organ recipients in circumstances where there are more than one recipient of organs from one donor.
- b) AND having regard to the evidence of Mr Michele who stated:
...the average length of stay would be seven days, that if there are significant issues about a week after transplant, that (sic) we should be sure to communicate with the other teams.
I recommend that DonateLife Commence this liaison with the transplant teams seven days post operatively and continue with this intra and inter hospital communication every 48 hours thereafter until the discharge of the recipients.
- c) AND to facilitate this intra and inter hospital liaison and communication in circumstances where the sage physician is consider more appropriate than the transplant coordinator, **I recommend** that on the occasion of each recipient organ transplant procedure the hospital nominate who is to be the designated contact person for DonateLife to communicate/liaise with.

Due to the inter-jurisdictional nature of donation and transplantation activities, the OTA is responding to the coroner as the Australian Government statutory body that coordinates the national reform agenda to implement a World's Best Practice Approach to Organ and Tissue Donation for Transplantation. As part of this role, the OTA provides oversight for an Australia-wide network of organ and tissue donation agencies, including DonateLife Victoria.

In considering the recommendation by the coroner and preparing this response the OTA has consulted with senior clinicians and managers from the donation and transplant



sectors as well as with senior jurisdictional health representatives and the state based agencies including DonateLife Victoria. There have been significant developments in the area of organ donation and transplantation since 2007 that have lead, or are leading, to improvements in inter and intra hospital communications.

The following information outlines national developments that support the recommendation by the coroner.

In 2008 the Council of Australian Governments endorsed the Australian Government's national reform agenda to implement a World's Best Practice Approach to Organ and Tissue Donation for Transplantation. The *Australian Organ and Tissue Donation and Transplantation Authority Act 2008* led to the establishment of the OTA in 2009. The OTA works with states and territories, clinicians and the community sector to deliver a nationally coordinated approach to organ and tissue donation processes.

Funding provided by the OTA to states and territories includes funding to employ hospital-based clinical specialists and organ and tissue donation agency staff. At the end of 2012 there were 275 DonateLife staff employed across 74 hospitals and 8 agencies throughout Australia. The DonateLife Network is made up of experienced medical and nursing staff who are accountable for key performance outcomes in their respective jurisdictions including liaison with transplant teams, and other allied health staff. A State Medical Director is employed in all jurisdictions across Australia and is responsible for overseeing organ and tissue donation processes and ensuring consistency of practice within the jurisdiction. State Medical Directors meet four times a year to consider matters that are relevant across jurisdictions with the aim to promote consistent nationwide practice.

One of the measures supported by the OTA and the DonateLife Network is the promotion of safe, equitable and transparent national transplantation processes. In 2012 the Transplant Liaison Reference Group (TLRG) was established to facilitate communication within the field of organ transplantation and between the donation and transplant sectors. The role of the TLRG is to inform the OTA on new and emerging issues pertinent to the area of transplantation that may also impact the donation sector. The TLRG together with the DonateLife Network plays a critical role in the ongoing development and assessment of communication strategies that support improved inter- and intra-hospital communication. These relationships are integral to the success of programs that are currently in development by the OTA to minimise the risk of adverse outcomes for organ recipients.

Development of a vigilance and surveillance framework has commenced to support the investigation of outcomes following donation and transplantation. It is expected that the framework will provide the governance structure to support the identification of factors that may be associated with the occurrence of serious adverse events and provide for timely alerts to medical and treating staff within the relevant sectors. This would include monitoring and reporting of adverse outcomes following donation and transplantation in the short and long term.

The overall objective of the vigilance and surveillance system is to provide a central point for detecting and reporting serious adverse events in organ donation and transplantation. The system will be developed by the OTA, with expert advice from leaders in this field, and will complement the current jurisdictional systems for clinical incident reporting. A primary outcome of the framework will be the ability to trace serious adverse events,

occurring in more than one transplant recipient, to a single donor and action any reported serious adverse event in a timely manner.

The OTA has invited nominees to be part of a working group of representative and individual experts to advise on the development of a national vigilance and surveillance framework for organ donation and transplantation. It is anticipated that the first meeting of the working group will be in September 2013. A copy of the Terms of Reference for the group is attached.

Concurrently, the OTA are developing an Electronic Donor Record (EDR) that will support the capture of donor referral data, medical-social history and family consent and provide a real-time system for the offer, acceptance and allocation of organs and tissue. The EDR will replace the current paper based Confidential Donor Referral Form (CDRF) and dispersed organ donation and transplantation liaison processes and will facilitate rapid identification of organ recipients from a single donor (rather than needing to access paper files). The reduced response time, combined with the national vigilance and surveillance system, will lead to improvements in communication and increased safety measures in organ donation and transplantation. It is anticipated that the EDR system will be operational from late 2013 and will provide a potential web-based platform for recording and sharing information on donor-related complications or adverse events.

Ensuring effective communication within and between hospitals post-transplantation is a considerable undertaking and, as highlighted by the coroner, is a critical component in ensuring the wellbeing of transplant recipients. Organs are regularly transferred between jurisdictions for transplantation and any strategies to further improve communication processes need to be supported and systematically implemented by all relevant stakeholders. Together, each of the initiatives detailed above contribute to a national process for improved communication within and between hospitals with the aim to quickly identify and minimise the risk of adverse outcomes.

Please contact me on 02 6198 9898 or yael.cass@donatelife.gov.au should you wish to discuss this response in more detail.

Yours sincerely



Yael Cass
Chief Executive Officer
Organ and Tissue Authority

2 August 2013

Enc: Vigilance and Surveillance Working Group – Terms of Reference



Australian Government
Organ and Tissue Authority

Vigilance and Surveillance Working Group

Terms of Reference

1. Title

The title of this group is the Vigilance and Surveillance Working Group (VSWG).

2. Purpose

To establish a time limited working group to scope and develop a national vigilance and surveillance framework in Australia for organ donation and transplantation.

The Vigilance and Surveillance Framework will include the following elements:

- Governance structure;
- System requirements identifying anticipated capability, functionality, and expected outcomes, and monitoring including early warning systems and response capacity;
- Scoping of current practice in each jurisdiction;
- Data validation, collation and analysis methodology;
- Online reporting; and
- International Vigilance and Surveillance link.

The overall objective of the vigilance and surveillance system will be to provide a central point for detecting and reporting of serious adverse events in organ donation and transplantation. The system will be developed to facilitate review and analysis of data resulting in annual public reporting to inform clinical practice.

3. Membership

3.1 The working group shall comprise:

- a member of the Organ and Tissue Authority Executive (Chair);
- an expert with experience in establishing a system of a similar nature;
- a person with expertise in domestic or international vigilance and surveillance systems in the health sector;
- a State Medical Director (SMD);
- two (2) Jurisdictional representatives;
- a Donor Coordinator;
- a Clinical/Operational Manager with experience in systems of a similar nature;
- a representative of the Transplantation Society of Australia and New Zealand, the Australasian Transplant Coordinators Association, the Transplant Nurses Association, and the Therapeutic Goods Administration respectively; and
- a representative from the Australian Commission on Safety and Quality in Health Care.

3.2 A quorum of members must be present before a meeting can proceed. A minimum of 50% of members must be present before a meeting can proceed.

3.3 At the request of the Chair, other relevant individuals or groups may be consulted on the project to provide advice and expertise where necessary.

- 3.4 Members will cease to be a member of the VSWG if they:
- resign from the working group;
 - resign from their employment; or
 - breach confidentiality.

4. Reporting

4.1 The VSWG is established by and reports to the Clinical Governance Committee (CGC) and the Jurisdictional Advisory Group (JAG) respectively of the Organ and Tissue Authority (OTA). The CEO will consider advice and recommendations from the VSWG, and will seek further consultation with the JAG and/or Clinical Governance Committee (CGC) as required.

4.2 Recommendations of the VSWG will be made by member consensus.

5. Proxies

Where a member is unable to attend a meeting, proxies will be allowed at the discretion of the Chair.

6. Secretariat

The Secretariat shall be an employee of the OTA and will be responsible for:

- scheduling meetings and notifying working group members;
- agenda drafting, seeking clearance by Chair and distribution to members;
- minute recording, drafting, seeking clearance and distribution to the working group; and
- inviting relevant specialists to attend meetings when required by the working group.

7. Confidentiality

Working group members may, on occasion, be provided with confidential material and may be required to sign a confidentiality agreement. Members are not to disclose this material to anyone outside the working group and are to treat this material with the utmost care and discretion and in accordance with terms of their confidentiality agreement.

8. Conflict of Interest

8.1 Conflict of interest is defined as any instance where a working group member, partner or close family friend has a direct financial or other interest in matters under consideration or proposed matters for consideration by the working group.

8.2 A member must disclose to the Chair any situation that may give rise to a conflict of interest or a potential conflict of interest, and seek the Chair's agreement to retain the position giving rise to the conflict of interest. Where a member gains agreement to retain their position on the working group, the member must not be involved in any related discussion or decision making process.

8.3 A working group member is not to participate in working group business until the Deed of Confidentiality and Conflict of Interest form has been completed.

9. Meetings

Meetings will usually be held by teleconference and/or videoconferencing. Any face to face meetings will be held in Canberra at the OTA Office at 221 London Circuit, Canberra City.

10. VSWG review of membership

The VSWG membership will be reviewed by the CEO 12 months post establishment to determine the future duration, membership and functions of the working group.

