



SUBMISSION FORM

Submission Details:

TARGETED CONSULTATION: x

Submission Closes: 3 July 2015 – 5.00pm.

This submission reflects the views of:

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Submission:

(Please identify the section/paragraph of the draft Framework that your comments relate to) .

Kidney Health Australia welcomes the opportunity to comment on the 'Draft Australian Vigilance and Surveillance Framework for Organ Donation for Transplantation'. Kidney Health Australia is the peak body representing those affected by kidney disease, and as such brings a considered health consumer and patient perspective to the ongoing discussion and reform to the organ donation agenda. The submission outlined below represents the views of Kidney Health Australia with significant input from our national network of consumers.

1.1. Ensuring priorities and strategic direction are agreed, communicated and achieved

Good governance requires that goals, priorities and strategic direction for providing a quality vigilance and surveillance system are in place. These should provide a vision for vigilance and surveillance delivery over an agreed timeframe.

Response: The agreed time line of a corrective action should be explicitly linked to the severity of the risk to the patients. This should be standardised Australia-wide.

1.2. Defining roles and responsibilities

Key roles in the Serious Adverse Event or Reaction (SAER) reporting communication pathway are referenced in the Organ Donation and Transplantation National Serious Adverse Event or Reaction Reporting Communication Pathway (Appendix C).

Response: Appendix C demonstrates a great pathway for communication, but it does not contain timelines, and public notification (it is not clear if this means patients or general public) is a long way down the list.

2.2. Functionality

A paper based system has been implemented to support national SAER reporting.

Response: Paper based system can be slow - especially when it comes to notification and communication.

3.1. Identifying, sharing and supporting best practice

Data reporting and regular feedback from stakeholders will provide mechanisms for evaluating and improving the vigilance and surveillance system.

Response: An electronic database would be beneficial here.

4.5 Reporting

Analysis of data on SAERs in donation and transplantation will result in release of a public annual report. The report will be de-identified to minimise the risk of identification of events.

Response: It is important to ensure that this reporting is supported by adequate consumer information and education.

6. Australia's capacity to report serious adverse event data related to deceased organ donation and transplantation

States and Territories have a number of initiatives to improve the quality and safety of patients in Australia through vigilance and surveillance practices.

Response: Identification of best-practice and national standardisation based on this is preferable.