POLICY POL201/4

Response to signals arising from audit of solid organ retrieval and transplantation outcomes

This Policy replaces POL201/3	**Copy Number**
	Effective **03/08/15**

Summary of Significant Changes

Addition of paragraph 4 re publication of outcomes after solid organ transplantation

Policy

1. Introduction

1.1 NHS Blood and Transplant (NHSBT) is responsible for ensuring that all donated organs are retrieved as safely as possible and that there is appropriate monitoring of outcomes after solid organ transplantation in the UK.

1.2 There are many individuals and organisations that share a responsibility for ensuring that donated organs are safely retrieved and that outcomes after solid organ transplantation are as good as possible and there is no inequality of outcomes. Interested parties include the patients and donors, transplant health care professionals, their employing Hospital Trusts/Boards, Commissioners, regulators and national Departments of Health.

1.3 If monitoring suggests that outcomes may be less than optimal, there needs to be a process in place to ensure that adverse trends are detected early and causes identified, rectified and audits take place to ensure that there has been an appropriate change in practice. Appropriate monitoring also allows identification of those centres with above average outcomes and so encourages sharing of best practice.

1.4 It must be recognised that the response to a signal must be appropriate and the trigger set at an appropriate level. If the threshold for a signal is set too low, then there will be a number of false alarms. Reacting to these will not only waste time and resource, but will also have an adverse impact on the confidence of the stakeholders in the system, and potentially encourage risk averse behaviour. However, a threshold for a signal that is set too high will possibly allow poor practice to continue unchecked and uncorrected. A signal is a trigger for investigation to determine whether there is a cause for concern or not.

1.5 In NHSBT, Statistics and Clinical Studies is responsible for monitoring outcomes, using data supplied by centres to the UK Transplant Registry. Data used for monitoring organ retrieval damage rates are reported by receiving transplant centres. It must be acknowledged that assessment of damage is subjective and it may be difficult to differentiate between intrinsic, acquired and surgical damage.

2. Purpose of paper

2.1 The aim of this paper is to outline the response when deterioration in performance or divergent outcomes have been identified and require investigation.

3. Response to a signal

3.1. In the response to a signal a nominated representative from NHS England (subsequently referred to as 'the nominated representative') will act not only on behalf of NHS England but also the Commissioners in the other three UK nations and all four national Departments of Health and will be responsible for ensuring that all these interested parties are kept informed as necessary where relevant.

3.2. When a monitoring report has been produced, the Associate Medical Director (AMD) for Organ Donation and Transplantation (ODT), and the Associate Director for Statistics and Clinical Studies will be notified of any signals.

3.3. Following a signal, the AMD will inform the nominated representative and the Chair of the relevant Organ Advisory Group or National Retrieval Group (or nominated deputy if there is an actual or potential conflict of interest), and a timely response requested from the Head of the centre involved. If a response is not received within an agreed time frame (usually 4 weeks), a reminder will be sent and if no response is received, then the issue will be escalated within the relevant hospital Trust/Board.

3.3.1 If it is agreed by the AMD, nominated representative and Chair of the Advisory Group (or deputy) or National Retrieval Group that the signal represents inherent variation and that there is no underlying cause for concern:

- The reasons for considering that the signal does not indicate a possible cause for concern will be documented.
- The AMD will be responsible for informing all relevant interested parties and ODT Clinical Audit, Risk and Effectiveness (ODT CARE) Group and, for signals relating to organ retrieval, informing the National Retrieval Group, of the reasons for the decision not to investigate further. This will be recorded in the minutes of the ODT CARE meeting or, in the case of signals relating to organ retrieval, in the minutes of the National Retrieval Group.

3.3.2 In all other circumstances:

3.3.2.1 For signals relating to outcomes after transplantation:

- The nominated representative will be responsible for liaising with the appropriate commissioner of the service to ensure that there is appropriate investigation and, where indicated, that remedial action has been identified and taken.
- Any investigation will be led by the appropriate commissioner of that service. NHSBT will support any such investigation as requested.
- The monitoring process for that centre may subsequently be rendered more sensitive so that if a problem persists, this will be detected more quickly.

3.3.2.2 For signals relating to organ retrieval damage

- NHSBT commissions the National Organ Retrieval Service so will lead the appropriate investigation.
- The investigation will be led by the National Clinical Lead for Organ Retrieval (or deputy if appropriate) with support from the Assistant Director for Commissioning and will co-opt one other independent expert.

3.3.2.3 The nominated representative will be responsible for ensuring that all relevant interested parties, including the clinicians, the transplant centres, the Trust/Board, the Commissioners (where relevant), the Departments of Health, Regulators and NHSBT are kept informed as to the running and outcomes of any investigation and will make a formal report to the AMD of ODT within 6 months of the signal occurring.

3.3.3 Where specified by the relevant Commissioners, the 'interested parties' will include those Commissioners of transplant services for patients who travel to another UK nation for transplant.

3.3.4 NHSBT Statistics and Clinical Studies Directorate will work with the nominated representative to provide any additional data that are required, but the nominated representative may seek additional data from any directorate of NHSBT.

4.0 Publication of outcomes after solid organ transplantation

4.1 NHSBT is committed to ensuring rapid and accurate publication of outcome data after solid organ transplantation. The outcomes after transplantation for each organ type by centre are published annually on the web-site and in organ-specific reports.

4.2 NHSBT will publish patient and graft outcomes both graphically using Funnel plots and in tabular form on an annual basis

4.3 NHSBT will not publish the individual CUSUM analyses for each organ and centre since any associated signals are based on non-verified data, may not be fully risk adjusted and are set at a level where normal practice will result in a significant number of signals.

4.3.1 NHSBT Statistics and Clinical Studies will submit to each meeting of each Solid Organ Advisory Group a summary report of signals that have been generated in the previous six months, together with outcomes of the investigation and actions taken, if appropriate. These reports will be published on the web-site with the other papers of that Advisory Group meeting.