NHS England

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3 February 2015

Coroner ME Hassell
Senior Coroner
Inner North London
St Pancras Coroner's Court
Camley Street
London N1C 4PP

Dear Coroner

Regulation 28: Prevention of Future Deaths Report. Ref 368837

Thank you for your letter informing us of the findings of the Report to Prevent Future Deaths, which we received on 27 November 2014. This report reflected on the experience of four children, all of whom sadly died as a result of graft failure following stem cell transplantation at Great Ormond Street Hospital for Children NHS Foundation Trust (GOS).

The role of NHS England

As you identified, NHS England has a duty to respond in these matters as the commissioner for prescribed specialised services, which include blood and marrow transplants for children. NHS England directly commissions blood and marrow transplants for children. This includes a responsibility for specifying the detail of the services to be provided, including the standards to be met, and for monitoring delivery of these standards.

Under its mandate from the Department of Health, NHS England is legally bound to pursue the goal of continuous improvement in the quality of health services. NHS England works to commission evidence based, equitable services which improve outcomes and patient experience. This includes learning from reports such as yours, and ensuring that the lessons learned are shared across the NHS.

On receipt of your report, Simon Stevens, Chief Executive of NHS England, asked that appropriate colleagues across NHS England work to establish the actions necessary to reduce the risk of future deaths. I would like to assure you that NHS England has reviewed in detail the findings of the report, and has considered its implications for clinical practice, quality assurance and the commissioning of these services.

As National Clinical Director for Specialised Commissioning, I convened a review group of senior clinical and management staff to consider your report, and to make recommendations to me on its findings and the actions which should be taken in response. This has included working with a range of stakeholders to identify opportunities to further strengthen governance and to reduce the risk of future deaths. The work of the review group has informed this response to you.

Key themes from your report

As your report identifies, these tragic cases highlight a number of complex issues in relation to stem cell transplantation. For this response, I have addressed these points under two headings:

- Quality assurance of technical processes involved in transplantation
- Clinical governance (including peer review, audit and benchmarking of outcomes)

I will deal in turn with issues relating to each of these areas, and then set out the actions which NHS England is taking to address them and to reduce the risk of future deaths.

Quality assurance of technical processes involved in transplantation

Your report confirms that the procedure used for processing cells was the cause of the engraftment failure which unfortunately occurred in all of these children. However, we also note your conclusion that a more successful graft would not have changed the outcome for three of the children, and it remains unclear whether it would have changed the outcome in the case of the fourth child.

The deaths of these children were reported by GOS through the national incident reporting system in the NHS as a serious incident (an SI). In response, NHS England's London Regional Team worked with the Trust to review the cryopreservation serious incident. The investigation and action plan have provided assurance that procedures and protocols have changed as a result. The key points of learning from the incident have already been shared with other paediatric transplant providers by the British Society for Blood and Marrow Transplantation (BSBMT), and we will in February be issuing an NHS England Specialised Services Circular to all teams involved in commissioning specialised services to highlight the concerns raised and the actions being taken nationally, and required of Regional teams, to respond to your recommendations

With regard to the processing of cells, NHS England requires that transplant providers implement the regulatory and quality assurance systems that are a condition of Joint Committee-ISCT (Europe) & EBMT (JACIE) accreditation. As part of NHS England's contractual derogation processes, we agree timed action plans with providers who do not currently meet this standard and will suspend the commissioning, or decommission, providers where this is not rectified within the required timescale and we believe that this could present a significant issue concerning the safety and quality of care provided.

Your report focuses most attention on the clinical governance for transplants and the rest of our response focuses on this and the action NHS England, with its stakeholders, is taking to resolve this issue.

Clinical governance (including peer review, audit and benchmarking of outcomes)

Blood and Bone Marrow Transplantation (BMT) is a low volume, high risk procedure. In 2013, BSBMT recorded a UK total of 370 transplants in children and 83 of those were autologous transplant (where the donor and recipient are the same person). Relapse is the major cause of treatment failure in the autologous setting with 90% of paediatric deaths due to relapse.

The governance arrangements for paediatric BMT are set out in the following NHS England prescribed specialised service specifications:

Actions by NHS England in response to your report

1. **Guidance to commissioners and providers:** NHS England will issue to commissioning teams and providers in February a Specialised Services Circular restating the requirement that transplants should only take place and be funded in providers compliant with the BMT / Paediatric Oncology service specifications i.e.:

- With the appropriate JACIE clinical programme accreditation.
- Using JACIE accredited laboratories / collection and processing facilitates
- Compliant with the published policy for transplants which includes evidenced based indications for transplant.
- Reporting to the national registry
- Participating in the new expert group, MDT and audit arrangements.

2. **Review of service specifications:** NHS England will also be reviewing the service specifications relating to bone marrow transplants for children and making any changes in wording required to clarify and reinforce this requirement.

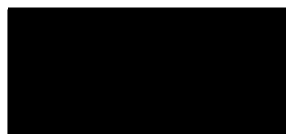
3. **Establishment of a new national expert group**: NHS England has agreed with the Paediatric Cancer Clinical Reference Group (CRG) and JACIE to establish a national oncology group of experts systematically reviewing research and cases to inform indications, protocols and benchmarking. We consider that this will enhance governance and reduce the risk of future deaths occurring. The Paediatric Cancer CRG is leading the establishment of this group, with the first meeting being planned for February 2015. This group will report on a review of the indications for autologous transplants for solid tumours and advise on any changes required to the clinical commissioning policy. The group will also review individual cases and act as the forum for audit and benchmarking. We expect this oncology group and the UK Paediatric BMT Group to forge strong links so that a full picture of transplant in children can be shared and understood.

4. **Improved reporting:** This expert oncology group will enhance the current reporting into the BSBMT registry to enhance the benchmarking through this route. This will in turn support the ongoing development and refinement of the NHS England Quality Dashboard, which we use as a key tool to compare outcomes and identify good practice.

5. **Assurance:** NHS England will commission its internal quality surveillance team to support and assure changes in governance are implemented.

In this response to your report, I have described the role of NHS England, summarised the key themes, and described the actions that NHS England is taking. I hope this provides you with the assurance that you are seeking about how NHS England is taking forward the lessons learned from the sad deaths of the children concerned.

With best wishes
Yours sincerely



National Clinical Director, Specialised Commissioning