

Board of Directors Meeting: Thursday 21 May 2009

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Subject	Briefing on action taken to improve patients' safety following the unexpected death of a child during surgery			
Purpose of paper	To review the action taken as a result of a serious untoward incident			
Board Lead(s)	Mrs Elaine Strachan-Hall, Director of Nursing and Clinical Leadership			
Background papers (if any)	SUI 366: Final Summary Report and Action Plan			
Action/decision required	To support the identified action, including the establishment of a working party to examine the management of surgical risk			
Key purpose	Strategy	<u>Assurance</u>	Policy	<u>Performance</u>
Strategic Goal(s)	SG1: To be Hospitals of Choice			
Strategic Objective(s)	SO2: To provide high quality, efficient and innovative care services SO6: To provide demonstrably excellent clinical outcomes and indicators of patient safety			
Links to: Board Assurance Framework/ Trust Key Risks/Annual Health Check element(s)	Standards for Better Health C1a: Patient safety and incidents C4b: Medical Devices acquisition and use C5b: Supervision and leadership of clinical and treatment C5d: Clinical audit and clinical reviews C7a and 7c: Governance and Risk			
Also considered by	Governance Committee			
Resource and financial impact	Limited costs of establishing the proposed working party.			
Consideration of risk legal/equality/diversity/engagement issues	This paper identifies strengthening processes to reduce risk in operative settings.			

Acronyms and abbreviations used	SUI: Serious Untoward Incident
Author	Mrs Elaine Strachan-Hall, Director of Nursing and Clinical Leadership

Briefing on action taken to improve patients' safety following the unexpected death of a child during surgery

1. Background summary

This report relates to the unexpected death on 27 July 2006 of a five year old girl. She had a hereditary condition causing enlargement of the spleen. To alleviate her symptoms, it was planned to remove her spleen, and on 26 July 2006, she was admitted to the John Radcliffe Hospital, in preparation for surgery the following day. It was planned that the surgery to detach the spleen would be performed laparoscopically which means that the spleen needs to be broken up before removal from the abdomen. On the evening before surgery, the surgeons decided that they would use a mechanical morcellator to break up the spleen.

Surgery commenced on 27 July 2006 at approximately 1.30pm. The operation appeared to be going well until 4.15pm, when the Consultant Anaesthetist noticed a deterioration. Immediately, the abdomen was opened. Upon identifying small tears to the aorta, these were repaired and although the child's condition stabilised for a period this was not sustained. At about 5.30pm, her condition deteriorated again. Attempts at resuscitation continued until 5:50pm, but were unsuccessful. Death was formally certified at 6.30pm.

A Coroner's Inquest was held in November 2007, at which it was concluded that damage to the aorta was due to surgical instrumentation but unlikely to be due to the use of the mechanical morcellator.

In March 2008, the associated legal claim was concluded.

2. Investigation

A Serious Untoward Incident (SUI) investigation was commenced to identify whether action could be taken which might prevent the recurrence of any similar tragedy, and improve patient safety for the future. A Final Summary Report was updated following the inquest and the action plan finalised.

The SUI investigation concluded that there were areas of practice that could be improved upon for future care, with regard to the following:

- i. Consent
- ii. Decision-making process regarding use of the morcellator
- iii. Transcribing patient's weight
- iv. Retaining equipment
- v. Recording blood loss

Following review of the SUI process of investigation, it was also concluded that a patient and/or family involved in a SUI should have ready access to a clearly designated appropriate individual within the Trust, who would have prime responsibility for ongoing liaison with the patient and/or family.

3. Action Plan

Implementation of the full action plan is in progress and is being monitored by the Governance Committee. In addition, the Trust intends that a Surgical Safety Working Party be established to complement the Trust's internally focussed Safety Action Group.

4. Working Party to examine the management of surgical risk

The Trust is one of Europe's leading teaching and research medical institutions, and a major provider of clinical services locally, regionally and nationally. For the benefit of its patients, it is committed to the early adoption of pioneering, innovative surgical techniques, whether developed in the United Kingdom or overseas, or by transposition from work in related disciplines.

The Board of Directors believes that, in order to support this ambition with strong governance arrangements, a protocol is needed to foster responsible innovation while safeguarding the safety of patients and the interests of practitioners. The Board intends that such a protocol should be regarded by other institutions, related bodies and agencies and the courts as a recognised standard against which the adequacy is judged of arrangements for the introduction and monitoring of surgical innovation.

Accordingly, the Board proposes to:

- 1.1 establish a working party to examine the management of surgical risk.
- 1.2 publish the conclusions of the working party.

5. Terms of reference of the working party

It is proposed that the working party will consider:

- 5.1 arrangements for the authorisation of the use of new surgical procedures in the Trust, including the use of an established technique but for a different indication, whether in a research or routine clinical setting;
- 5.2 the level of expertise that will be expected from any surgeon who is undertaking such a procedure, or who is undertaking any procedure for the first time;
- 5.3 the type and range of supervision that will be required in such situations;
- 5.4 the nature of medical records to be kept in such situations;
- 5.5 the type of review that is appropriate in each case, including circumstances in which procedures should only take place as part of a clinical trial;
- 5.6 more generally, the extent to which such arrangements differ from those that should be in place for all surgical procedures, and to define the point(s) at which a "new" intervention become routine;
- 5.7 how surgeons can best keep up-to-date with changing practice and technology, especially when new procedures are not in common use.

6. Membership of the working party

The Board will invite the participation of:

- 6.1 an independent, non-clinical chairman;
- 6.2 a scientist from another discipline in which the management of risk is central;
- 6.3 a surgeon of national standing;

- 6.4 a theatre nurse of national standing;
- 6.5 an expert in human factors safety;
- 6.6 a patient representative;
- 6.7 a clinician with expert training.

7. Timetable

The Board will ask the working party, once convened, to:

- 7.1 consult widely, and to examine best practice in both the United Kingdom and overseas;
- 7.2 to make its report available to the Board by 31 December 2009.