To:	**Trust Board**
From:	**Deputy Chief Executive / Chief Nurse**
Date:	**31 January 2013**
CQC regulation:	Outcome 16

Title:	**Update on Never Events**

Author/Responsible Director: Director of Safety and Risk

Purpose of the Report:

To provide Trust Board Members with an update on actions and progress relating to two Never Events, and to provide assurance that the new Department of Health Never Events Policy Framework document is being followed.

The Report is provided to the Board for:

Decision		Discussion	X
Assurance	X	Endorsement	

Summary / Key Points:

- Both Never Events have been reported and are being investigated in line with UHL and Department of Health Never Events Policy Framework.
- Appropriate action is being taken in line with Human Resources policy regarding staff involved.
- Actions to strengthen clinical processes have been implemented.
- These Never Events have been shared internally and externally.
- Monitoring of the action plan will continue through appropriate committees.

Recommendations: Trust Board is invited to note:-

- That Never Event Case 1 has been fully investigated, the RCA reported, completed and that the action plan will be carefully monitored at appropriate committees;

- That the investigation of Never Event Case 2 continues in line with the Incident Reporting Policy and the Never Events Policy Framework.

- That appropriate and careful communication with the patient/family has taken place during these investigations;

- That Commissioners have been properly notified of these cases, and;

➢ That lessons have been learnt and actions taken to minimise further incidents. ➢ That the Management of Surgical Swabs, Instruments and Accountable Items Policy has been updated.
Previously considered at another corporate UHL Committee? Never Events reported to:- ➢ Relevant Divisional Board ➢ Quality and Performance Management Group ➢ Quality Assurance Committee ➢ Updates to Executive Team

Strategic Risk Register:	**Performance KPIs year to date:** Red

Resource Implications (eg Financial, HR): Financial penalties may apply (with-holding of payment for associated period of treatment/procedure).
Assurance Implications: Monitored through Quality Contract/Clinical Quality Review Group Meeting.
Patient and Public Involvement (PPI) Implications: Being Open Policy correctly applied
Stakeholder Engagement Implications: Monthly discussions with Commissioners.
Equality Impact:
Information exempt from Disclosure: Patient details.
Requirement for further review? Update required at next Trust Board for Case 2

Trust Board Paper M

UNIVERSITY HOSPITALS OF LEICESTER NHS TRUST

REPORT TO: **TRUST BOARD**

DATE: **31ST JANUARY 2013**

REPORT BY: **DEPUTY CHIEF EXECUTIVE / CHIEF NURSE**

SUBJECT: **UPDATE ON NEVER EVENTS**

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1. INTRODUCTION

1.1 The purpose of this paper is to provide Trust Board Members with an update on two Never Events cases. The Trust works to the updated Never Events Policy Framework document published in October 2012. Within this Never Events Policy Framework is the requirement to report all Never Events to Trust Board. The Medical Director and Chief Nurse are appropriately engaged in the incident investigations, one of whom is required to sign off completed RCA reports.

2. CASE 1

Summary

2.1 In October 2012 a child underwent surgery at the Leicester Royal Infirmary. The surgery was uneventful. During wound closure, the suture needle broke and became disconnected from the thread. Searches were made but the needle was not located. The child was allowed to leave the theatre without being x-rayed and later returned to theatre where an x-ray confirmed that the needle was in the child. With consent from the mother, the child was re-anaesthetised and the needle located and removed from subcutaneous tissue. The child made a full and uneventful recover.

2.2 The incident was classified as a "Never Event" under Criteria 3 – 'retained foreign object post-operation'.

2.3 The incident was reported internally and externally as per Trust policy and a full Root Cause Analysis (RCA) investigation undertaken.

2.4 A key finding was that there had been a failure to adhere to the Trust's 'Management of Surgical Swabs, Instruments, Needles and other Accountable Items within the Operating Theatre' policy and procedures. The policy states that if something is missing, until proven otherwise, it must be assumed that the item is in the wound.

2.5 Lessons for learning and recommendations were made and an action plan developed (see Appendix **A**).

2.6 The National patient Safety Agency (NPSA) Incident Decision Tree (IDT) was utilised for all staff involved in this incident.

2.7 The findings of the IDT process have resulted in appropriate referral of the Consultant Surgeon to Trust Human Resources processes. This is being led by the Medical Director.

2.8 An apology was made to the mother and child at the time of the incident and she was informed of the investigation process, in line with the 'Being Open' policy.

2.9 The final RCA report is complete and has been signed off by the Divisional Director and the Medical Director. The RCA was completed within the required time frame and this has been sent to the Commissioners for closure. The associated action plan will be monitored by the Divisional Board, reviewed at Quality Assurance Committee and presented at the Learning from Experience Group.

2.10 Further contact has been made with the child's mother in order to share the report and its findings with her.

3. CASE 2

Summary

3.1 In November 2012 a patient underwent an elective lower segment Caesarean section (ELSCS). The baby was born in good condition. Following delivery, there was an increase in bleeding per vaginum and despite appropriate management for post-partum haemorrhage (PPH), bleeding continued. The patient was taken back to theatre where no obvious cause for the bleeding could be identified. A Bakri balloon was inserted in to the uterus to tamponade the placental site. As part of this procedure a vaginal pack was inserted to assist retention of the balloon. The patient's condition stabilised. The management plan was documented in the medical records, but there was no explicit instruction to remove the vaginal pack.

3.2 The Bakri balloon was deflated and removed as per instructions the following day, but the vaginal pack was not.

3.3 The day after this, the patient, whilst in the shower, began to spontaneously expulse the vaginal pack. An obstetrician was called to attend and the pack was carefully removed.

3.4 Following extensive discussions, review of the Never Events Policy Framework and regional thematic review, this incident was classified as a 'Never Event under Criteria 3, 'retained foreign object post-operation'.

3.5 A full RCA investigation is being undertaken but is not yet complete.

3.6 The patient received an apology and has been informed of the investigation. The full report will be shared with her on completion.

3.7 Immediate action undertaken at the time of the incident escalation was to formally advise all relevant medical staff, via e-mail, outlining the background of this case and the requirements for clear documentation regarding the insertion and removal of a Bakri balloon.

3.8 The completion date for the final report is the 8th March 2013 and the Division do not anticipate difficulties in achieving this.

4. RECOMMENDATIONS

4.1 The Trust Board is invited to note the content of this report and to note:-

i That Never Event Case 1 has been fully investigated, the RCA reported, completed and that the action plan will be carefully monitored at appropriate committees;

ii That the investigation of Never Event Case 2 continues in line with the Incident Reporting Policy and the Never Events Policy Framework.

iii That appropriate and careful communication with the patient/family has taken place during these investigations;

iv That Commissioners have been properly notified of these cases, and;

v That lessons have been learnt and actions taken to minimise further incidents.

vi That the Management of Surgical Swabs, Instruments and Accountable Items Policy has been updated.

ACTION PLAN FOR 2012/26978

Root Cause/ Contributing Factor	Level of Risk	Agreed Action	*Level of Recommendation* Individual, Team, CBU, Division, Organisation	By Whom	By When	Resources Required	Evidence of Completion	Sign Off
The surgeons were confident that the needle was not in the patient's wound and the Consultant Surgeon said he would take full responsibility for this.	High	Implementation of Human Resources process in relation to the Consultant Surgeon involved in the incident.	Division	Dr Peter Rabey, Divisional Director	01/02/13		Email confirming process completed	
		Incident discussed at paediatric surgery morbidity and mortality meeting attended by all registrars.	CBU	Clinical Fellow involved in incident	03/12/12		Presentation	
No one in the operating theatre stated that the patient must not go to recovery prior to radiological investigation.	High	Staff to be reminded of the policy, with a particular focus on the need to keep the patient in theatre until a radiological examination takes place where a needle, swab or piece of equipment is missing. This will be through a variety of communication systems: • Disseminated to Team Leaders who will require staff members to sign to say they have read and understood the policy	Specialty	Jo Hollidge, Lead Nurse	28/02/13		Signed sheets	
		• Discussed at Clinical Support Division's Specialist Nurse and	CBU	Jo Hollidge, Lead	12/02/13		Meeting minutes	

		Matrons Meeting.		Nurse				
		• Disseminated to all Anaesthetists by email	Specialty	Laura Kelly, Quality and Safety Co-ordinator	30/01/13		Email	
		• TAPS CBU Quality and Safety Newsletter	CBU	Dr Tim Bourne, Consultant Anaesthetist	28/02/13		Quality and Safety Newsletter	
		• Paediatric Surgical Morbidity and Mortality Meeting	CBU	Lynn Randall, Quality and Safety Co-ordinator	31/03/13		Meeting papers	
		• Disseminated to surgical teams via Quality and Safety teams.	Organisation	Laura Kelly to send to other Quality and Safety Teams	18/02/13		Email	
		• Safety Matters Bulletin	Organisation	Laura Kelly to send to Jolyon Folkett, Senior	31/01/13		Safety Matters Bulletin	

				Health and Safety Manager				
		• There will be an agenda item at the Learning from Experience Group there will to discuss how to empower and make all staff responsible for challenging policy breaches by senior colleagues.	Organisation	Laura Kelly, Quality and Safety Co-ordinator /Helen Jones, Quality and Safety Manager			Agenda and minutes of meeting	
		• Staff to be reminded of Never Events list through desk-top message and news article on InSite (UHL intranet).	Organisation	Laura Kelly, Quality and Safety Co-ordinator			Screen shots	
	Moderate	An internal alert reminding staff of the need to retain equipment involved in incidents, including needles, has been circulated.	Organisation	Peter Cleaver, Risk and Assurance Manager	12/12/12		Internal alert	

	Moderate	An offer will also be made to share this investigation report with the patient's mother and the staff involved in the incident.	Division	Laura Kelly, Quality and Safety Co-ordinator	25/01/13		Letter to mother, emails to staff. Minutes of meeting with mother if applicable.	