Original Summary

Surgery/Procedure Event (2) - 11-22-2024

Board of Registration in Medicine

File State: New

Owner: Erin Long - QPSD Quality Analyst

Entered Date: 11-22-2024

Fields labeled with an asterisk(*) are required.

Quality and Patient Safety Division

THE MASSACHUSETTS BOARD OF REGISTRATION IN MEDICINE (BORIM), THROUGH ITS PATIENT CARE ASSESSMENT (PCA) REGULATIONS, (243 CMR 3.00-3.14), IS RESPONSIBLE FOR ENSURING THAT ALL MASSACHUSETTS HOSPITALS AND AMBULATORY CLINICS, AS A CONDITION OF DEPARTMENT OF PUBLIC HEALTH (DPH) LICENSURE, HAVE QUALIFIED PCA PROGRAMS. THE REGULATIONS REQUIRE THAT HOSPITALS SUBMIT REPORTS OF QUALITY ASSURANCE ACTIVITIES (243 CMR 3.07) AND REPORTS OF UNEXPECTED PATIENT OUTCOMES KNOWN AS SAFETY AND QUALITY REVIEW (SQR) REPORTS (243 CMR 3.08). THROUGH THE SUBMISSION OF THESE REPORTS, HOSPITALS AND AMBULATORY CLINICS DEMONSTRATE TO THE BORIM THAT THEY HAVE ROBUST SYSTEMS AND PROCESSES IN PLACE TO IDENTIFY ADVERSE EVENTS, CONDUCT INTERNAL REVIEWS, AND IMPLEMENT CORRECTIVE MEASURES TO PREVENT A RECURRENCE AND TO IMPROVE PATIENT CARE.

Date and Facility Site

EVENT DATE AND HCF SITE

Date Event Occured	04-22-2021
File Owner	Erin Long - QPSD Quality Analyst
Site	[redacted]
Facility Type	Acute Care Hospital
Cohort Teams	Acute 600-1000 beds

Patient Involved in Event

PATIENT DETAILS

Date of Birth	05-26-2008
Age	12 years
Gender	Female
Race	White or Caucasian
Ethnicity	American
Admission Date	04-22-2021

Type of Patient Affected	Outpatient
Admitting Diagnosis	L radius/ulna fracture

Surgery/Procedure

GENERAL INFORMATION ABOUT THE SURGERY / PROCEDURE EVENT

Surgery Event Type	Foreign Object Retained

Safety and Quality Review

SAFETY AND QUALITY REVIEW FORM

Type of Report	Complete Report

A preliminary report should only be chosen if the investigation and/or report is NOT complete and additional information will be added in the future

Type of Event	Type 4

Type 1- Maternal Death related to delivery Type 2- Death in the course of, or resulting from, elective ambulatory procedure Type 3- An invasive diagnostic procedure or surgical intervention performed on the wrong organ, extremity, or body part Type 4- Death or major or permanent impairment of bodily function that was not ordinarily expected as a result of the patient's condition on presentation

Harm Level	Temporary harm
NQF Serious Reportable Event (SRE)?	Yes
What type of Serious Reportable Event?	1D. Surgical or invasive procedure events - Unintended retention of foreign object

Was this patient transferred to another facility

- ○ Yes
- ◉ No
- ○ Not applicable
- ○ Unknown/Unsure

Was there any consideration to transfer the patient to a higher level of care, but an inability to do so?

- ○ Yes
- ◉ No
- ○ Not applicable
- ○ Unknown/Unsure

Facility Staff Involved in Event

Credentialed Health Care Provider Involved

- Anesthesiologist
- Orthopedic Surgeon

Non-Credentialed Health Care Provider Involved

- Registered Nurse (RN)
- Surgical Tech

Narrative of the Event

14-year-old white female who was brought to the OR on 4/22/22 for an ORIF of her communicated L radius/ulna fracture. Pt with a past medical history of atopic dermatitis and allergic rhinitis. Pt had been jumping on a trampoline when she jumped into a handstand and sustained a fracture to the left arm. Pt was sedated, a left brachial plexus block was administered by anesthesia followed by induction of general anesthesia. The ORIF was lengthy and complicated by muscle tissue found between

the fracture sites and a complicated re-alignment with intramedullary nail placement. At the conclusion of the surgery, the skin was sutured, and a cast was being placed as the surgical count occurred. During count it was noted that part of a scalpel blade was missing.
Timeline of events:
0800 Pt brought to the OR
0810 Left brachial plexus block administered
0815 Induction of anesthesia
0818 ORIF began
0945 Skin closure
1000 Cast placed
1010 Xray of L radius/ulna
1000-1015 OR team completing counts and checklists recognize that part of the scalpel blade is missing and bring this to the attention of the surgeon.
1015 Surgeon views post-op film. Notes that there is a small metal object noted in the tissue at one of the four incision sites
1020 Cast cutter obtained, cast removed, incision opened, site explored. A small metal fragment was retrieved. Object was found to be the missing scalpel blade. Patient re-casted. Surgeon left the OR immediately after the case.
1045 Patient to recovery room. Disclosure was made to the child's mother with f/u planned for 1 week.

Internal Review

INTERNAL REVIEW DETAILS

Event Reviewed by	Individual Reviewers • Vice President Quality • Chief Medical Officer • Chief Nursing Officer • Chief Quality Officer • Quality Director • Risk Manager/Director • Pharmacy Director • Nurse Manager • Nurse Director
Internal Review Findings	• Communication • Credentialed Provider Skill/Judgement • Equipment related
If other, please list	
Description of Results of Internal Review	A RCA was completed with the OR Chief of Staff, the surgeon, nurses, OR tech and anesthesia. The findings were as follows: • It was felt that the patient was appropriately prepped, and anesthesia was given in a timely manner. The skin was opened using a #10 scalpel. While the sharp was thought to have been intact, a piece of the scalpel was later found to have broken off. • Due to the nature of the fracture and difficulty with rod placement, there were several people assisting in the surgery, holding the arm while the rods were being placed and the metal object was not noticed. Additionally, the child was starting to wake up at the end of the case and required more sedation. This was thought to be a distractor.

• During count it was noted that part of the scalpel blade was missing. This was brought to the attention of the surgeon who did not respond. The surgeon was felt to be rushed and dismissive to staff. The surgeon was behind due to the complicated surgery and was getting ready to go into the next case. The staff reported that they were hesitant to approach the physician with concerns as he was "curt and dismissive to the staff".
• When the post-op films were completed and the object was noted on the film, the staff reported that the surgeon "appeared angry and his manner of speech hostile". The surgeon removed the cast, opened the incision, located, and removed the object and then reclosed the wound. The surgeon then re-applied the cast and left the OR.
• Anesthesia reviewed the case for concerns of the child waking up towards the end of surgery. Dosing was reviewed with pharmacy and was appropriate for age/weight. Timing of dosing appropriate. No additional recommendations or findings.

Quality Improvement Measures or Corrective Actions

Safety and Quality Improvement Measures

- Clinician related measure- Credentialed provider action
- Moderate action- Enhanced surveillance and auditing
- Weaker action- Education
- Weaker action- Policy/Protocol implementation, revision

If other, please list

Description of Quality Improvement Measures or Corrective Action

Several issues were identified from this case.
• It was found that the scalpel was not inspected for integrity after use. The post-surgery OR count policy was revised with specific wording to address inspection of instruments and sharps post use. Education was completed on updated policy.
• TeamSTEPPS training will be initiated in the OR as this is known to be a high-risk setting and teamwork and communication is key to patient safety. Training to start 8/1/22.
• Support was provided to staff members who were involved in this incident. This support is ongoing for staff members involved in events with poor outcomes and/or patient safety events that occur.
• Policy developed: Stop the Line for Patient Safety including the manner in which to escalate events when staff do not feel they are being heard. Policy education completed and policy in effect 5/30/22.

Credentialed Health Care Provider(s) Data and Findings

WHEN APPLICABLE, PLEASE PROVIDE DE-IDENTIFIED PERFORMANCE DATA AND ANALYSIS FOR INVOLVED CREDENTIALED HEALTH CARE PROVIDERS.

Credentialed Health Care Provider Data and Findings

• The surgeon in this case has a higher percentage of complications and deaths compared to internal and external peer groups. The surgeon has a higher surgical site infection (SSI) rate compared to their peers which is trending downward. There is plan in place to address this metric. The surgeon is being supported by Infection Prevention and Control and the Chief of Surgery. SSI rate has decreased from 3.5 in Q1 2022 to 1.9 in Q4 of 2022. • A trend was identified regarding the provider. It was noted that there were two previous complaints of inappropriate behavior from the OR staff in a two-year period. The surgeon was placed on a focused professional practice evaluation (FPPE) for the behavioral concerns and peer support was offered and accepted.

Attachments

ATTACHMENTS

FileName	Category	Description
Picture1.png		

Follow-Up on File

HEALTHCARE FACILITY- USE THIS SECTION TO ADD FOLLOW-UP ONLY AFTER A SUBMISSION HAS BEEN MADE. QPSD WILL ADD FOLLOW-UP TO A SUBMISSION ONCE THE REVIEW IS COMPLETE.

Follow-Up Actions
Not Specified

End of Form

Vendor Comparison Q1 2020-Q 4 2022

	Number of Cases	% With Complications	% Deaths Observed	% Deaths Expected
Provider	**52**	**16.5**	**1.99**	**1.26**
Hospital Peer Group	1208	10.9	6.03	6.49
Vendor Peer Group excluding this provider	250,602	10.4	7.01	6.89