Children's Health Ireland at Temple Street Spinal Surgery Programme for Patients with Spina Bifida

External Quality Review and Programme Assessment

Prepared by a Multidisciplinary Team from
Boston Children's Hospital under the direction of
Children's Health Ireland
July 7th, 2023

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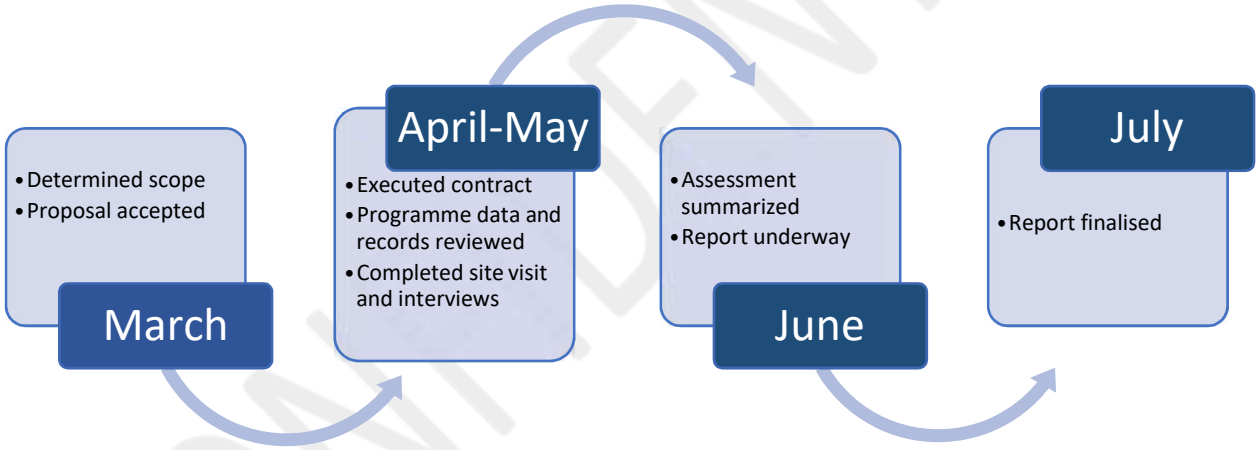
Objective and Scope

Objective: The objective of this engagement was to conduct an external review and programme assessment of the CHI at Temple Street Spinal Surgery Programme for patients with Spina Bifida and provide observations and recommendations, as per the agreed upon scope of work.

Project Scope: The scope of work focused on reviewing key materials, quality indicators, and conducting meetings with representatives and leaders from CHI and CHI at Temple Street to address certain aspects of CHI at Temple Street's spine surgery programme, including: (1) clinical review of the Spinal Surgery Programme to identify any immediate patient safety concerns based on care provided during the Review Period (October 1st, 2019 to October 31st, 2022); (2) review of CHI at Temple Street's clinical processes related to the Spinal Surgery Programme, including current capabilities and Spinal Surgery Programme gaps; (3) Spinal Surgery Programme structure; and (4) reporting on the quality and outcomes of the Spinal Surgery Programme. The external review did not include an assessment of CHI at Temple Street's facilities, physical space, equipment, instruments, sterile processes or other specific conditions or aspects present in the operating theatre.



Background on High Spina Bifida Population and Backlog of Spinal Surgery

There are over 1.2 million children in Ireland under the age of 18 years (23.6% of the total population) and approximately 1 million under the age of 15 years. Ireland has one of the highest incidences of spina

bifida in the world, with an overall incidence of about 1 in 1000 live births[1,2]. It is estimated that there are currently at least 500 children (0-18 years) with spina bifida in Ireland.

Demands for quality paediatric health care and spinal surgery for patients with spina bifida are higher in Ireland compared to other countries. As a result, in 2022, the Minister of Health allocated €19 million for children who are in need of orthopedic surgery to assist with these high demands[3].

In addition to the sheer volume of patients, the Irish healthcare system has been further stressed by the cancellation of elective surgeries during the COVID public health emergency, a recent cyberattack on the health care system and the lack of postoperative beds this past winter due to the high number of respiratory infections in children requiring inpatient stays.

Summary of Review

The team consisting of clinicians with specialties in orthopedic surgery, spinal surgery, complex care, anesthesia, and nursing completed this review by assessing the following:

- **In-depth Interviews:** Conducted over 30 individual or small group interviews with representatives in the areas including but not limited to:
    - Anesthesia
    - Dietetics
    - Hospital leadership
    - Infectious disease
    - Inpatient nursing
    - Intensive Care Unit
    - Microbiology
    - Neurodisability
    - Neurosurgery
    - Occupational Therapy (OT)
    - Orthopedic surgery
    - Physical Therapy (PT)
    - Plastic surgery
    - Psychology
    - Social Work
    - Theatre nursing
- **Observation**: Orthopedic case presentations were observed and tours were conducted of CHI at Temple Street, CHI at Crumlin, and the new children's hospital scheduled to open in the future.
- **Medical Record Review:** The medical records of 16 patients who received care by the Spina Bifida Multidisciplinary Team (MDT) and underwent spinal surgery during the review period

[1] EUROCAT 1991. Working Group. Prevalence of neural tube defects in 20 regions of Europe and the impact of prenatal diagnosis, 1980–1986. Journal of Epidemiology Community Health, 45, 52–8.
[2] McDonnell R, Delany V, O'Mahony MT, Turner MJ. An Audit of Neural Tube Defects in the Republic Of Ireland for 2012-2015. Irish Medical Journal. 2018 Mar 14; 111(3):712-23.
[3] Condon, D. February 18, 2022. Plans to target paediatric orthopaedic waiting lists: Extra €19 in funding made available. Irish health pro. Available at: https://www.irishhealthpro.com/content/articles/print/name/plans-to-target-paediatric-orthopaedic-waiting-lists

commencing October 1, 2019 and ending October 31, 2022[4] were reviewed. The medical record review was conducted along with review of radiographs, microbiology lab results, data from the Paediatric Intensive Care (ICCA system), data from the Theatre management system (ORMIS), blood bank transfusion records from the Hematology department and CHI at Temple Street's Internal Spines Clinical Review Report from April 2023.

Key Themes

Below are key themes and findings from the review of CHI at Temple Street's Spinal Surgery programme for patients with Spina Bifida.

- **Supporting a sustainable, high quality Spinal Surgery Programme/MDT for patients with Spina Bifida is important.** Members of the MDT and leadership are committed and motivated to provide safe, effective, patient-centered, timely, and efficient care in order to optimize clinical outcomes. If CHI at Temple Street decides to continue to offer spinal surgery for this patient population, it is important for the hospital to continue to provide leadership, training, support, quality metrics, and motivation to existing staff to maintain a culture of safety.
- **Given the high incidence of spina bifida in Ireland, and the increased risk of neuromuscular scoliosis with spina bifida, careful consideration must be taken when addressing the high demand for spinal surgery.** CHI at Temple Street's waiting time for surgery did not appear to have a negative impact on the increased rate of post-operative complications. However, high complexity surgery requires significant resources and therefore if these surgeries are going to continue to be done at CHI at Temple Street these resources need to be available. Alternatively, CHI leadership may want to consider and assess the opportunity to offer some or all these surgeries at another CHI facility.
- **There were concerns raised regarding the outcomes of paediatric spinal surgical in children with spina bifida.** To address these types of concerns, programme metrics designed to evaluate outcomes should be established and reviewed regularly. CHI at Temple Street should continue to provide oversight and increased training for staff caring for medically complex patients undergoing spine surgery.
- **A unified programme structure/governance around care for children with spina bifida is important.** Leadership, engagement, and accountability between surgeons and other clinicians are cultural mainstays. Solid governance structure with clinical leadership, enhanced interdisciplinary forums, and a quality improvement programme will support care planning and allow for benchmarking of programme performance.
- **As CHI at Temple Street cares deeply about the quality of care, more attention is needed to create a culture where all members of the care team are encouraged and comfortable sharing safety questions and concerns.** To truly create a highly reliable safety culture, CHI at Temple

[4] Although the review period was requested during this time period stated above, the 16 patients underwent surgeries from in 2018-2022.

Street should look at other high reliability paediatric institutions that have successfully developed environments focused on patient safety and quality. Leadership should carefully be proactive in addressing any and all concerns whether raised by clinical or other staff, families, regulators or others.

Understanding the Current Environment and Fundamental Challenges

There are key opportunities identified in both the internal and external environments at CHI at Temple Street. CHI at Temple Street has already begun to explore some of these best practices.

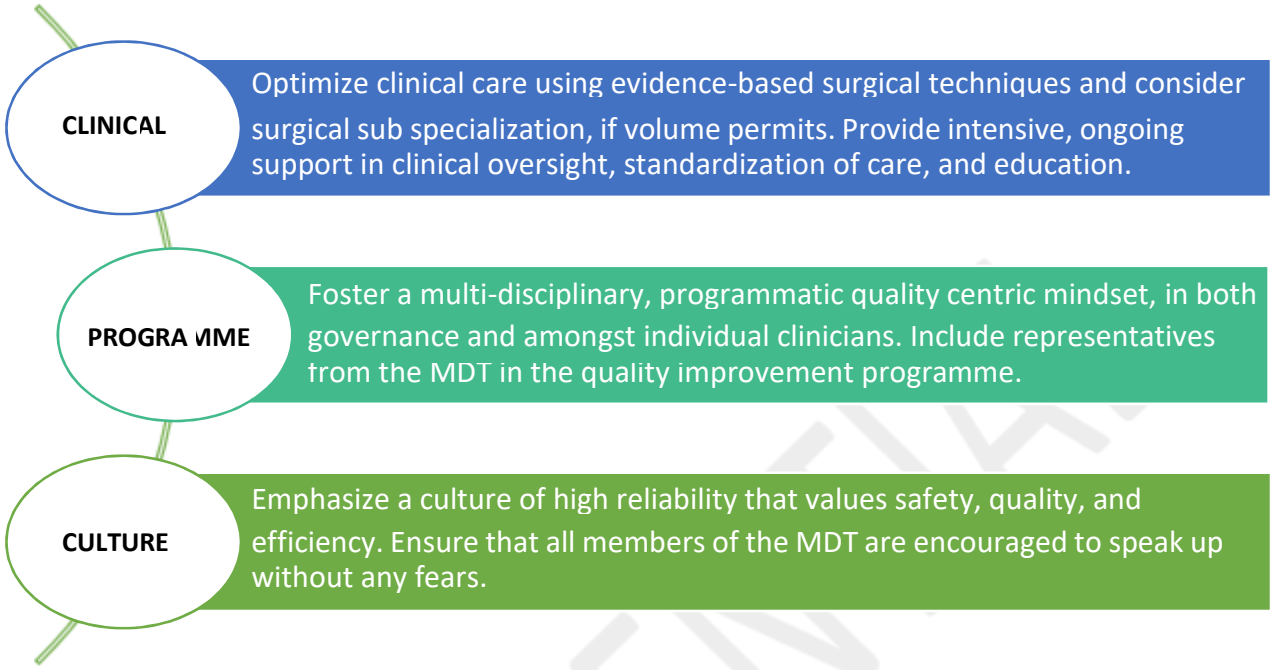
Internal Environment

- **Leadership:** Transparent clinician accountability and standards, role clarity across clinicians, and a defined governance structure are critical to the future success of the programme. Deficiencies in these areas can lead to discord for health care programmes.
- **Culture:** A robust quality improvement programme and meaningful opportunities to speak up for safety, which are taken seriously and addressed, are foundational to the provision of high quality care. Inadequacies, as well as inconsistent attendance and participation at clinical team meetings, can create challenges.
- **Stakeholder Alignment:** A shared vision and open communication are fundamental to success. Having all clinicians engaged as early as possible in pre-operative planning is likely to optimize patient outcomes.

External Environment

- **Patient Volume:** Ireland has one of the highest rates of spina bifida and incidence rates remain stable. CHI continues to have a backlog of patients waiting for spine surgery. If CHI at Temple Street plans to increase surgical volume, a thoughtful strategic plan with involvement of all stakeholders may help implement that initiative in a safe and effective way.
- **Physical infrastructure:** The physical infrastructure at CHI at Temple Street limits the number of spine surgeries that can be completed (4 operating rooms). A state of art paediatric hospital will open in 2025 which should help to alleviate the long wait times and provide updated infrastructure and physical facilities.

It is critical for CHI at Temple Street to continue to leverage its strengths and internal capabilities as well as implement change with focus and intent in the following key areas:



High-Value Actions That Enable Programme Success

Outlined below are high-value actions that enable a successful programme. These opportunities continue to be grouped in the following three areas:

1. Clinical
2. Programmatic
3. Culture and Patient Safety

Clinical Care

- Optimize outcomes using evidence based surgical techniques/processes including but not limited to incorporating the latest knowledge from high quality research studies and collaboration with other paediatric spine centers where clinicians care for high numbers of patients with spina bifida. This should include:
    - Utilization of standard length constructs for corrections of spinal curvature, including kyphosis.

- Tables, instruments and radiographic equipment to allow for intra-operative imaging of all surgical implants in multiple planes, including implants going to the pelvis.

- Collaborate with other surgical specialists and transparently define processes for involvement of plastic surgery for wound closures and neurosurgery for dissections and nerve decompressions.
- Enlarge the dedicated group of orthopedic surgeons with the technical expertise to operate on children with complex spinal deformities including those with spina bifida.
- Develop a specialized spine team in the theatre comprised of anesthetists, nurses, orthopedic surgeons, and other surgeons when applicable (neuro and plastic) in order to improve team cohesion and ultimately improve patient outcomes, prevent medical errors, improve efficiency and decrease complications.
- Implement mentoring/coaching programme for the orthopedic surgeons.
- Encourage other surgeons on the spine team to serve as the second surgeon in complex cases or assist with other surgeons' cases in their absence (i.e. patient requiring urgent/emergent surgery). This will increase peer responsibility for excellent outcomes.
- Develop pre- and post-operative standardized, evidence based clinical guidelines and checklists, as well as order sets to improve the clinical efficacy, care efficiency, and patient safety.
- Develop a formalized informed consent/shared decision making process to optimize communication of the risks and benefits of surgery including the potential complications and need for additional surgeries.
- Encourage the MDT to increase the caloric nutrition of spina bifida patients in order to minimize the occurrence of wound breakdown/infection.
- Provide ongoing advanced training for all clinicians involved in caring for medically complex patients including the prevention/management of complications.

Programmatic

- Appoint a Clinical Speciality Lead for Orthopaedics who has the responsibility and power to make changes and to advocate for staff both professionally and academically.
- Develop and implement an effective orthopedic department-wide, data-driven quality assessment and performance improvement programme designed to collect metrics on clinical outcomes, complication rates, ICU admissions, and post-discharge resource utilization. Benchmark to professional organization metrics.

- Improve orthopedic case conference effectiveness by ensuring that all members of the team are invited/able to participate.
- Implement monthly structured Orthopedic Morbidity and Mortality (M & M) rounds with MDT using a high reliability structure including adverse event reporting system incorporating formal documentation of unprofessional behavior.
- Routinely use quality tools (e.g., root cause analyses, failure mode and effects analyses [FMEA]).
- Establish procedural mechanisms for initiating full team 'difficult case' reviews prior to initiating the perioperative surgical trajectory.
- Create structures that promote collaboration and clearly define roles of the orthopedic surgeons and neurodisability clinicians (e.g. audit responsiveness to communications and core professional duties).
- Encourage full participation of all team members in case conferences, MDT meetings and peer review to ensure clear communication.
- Support educational engagement including attending national and international educational meetings.
- Consider interventions such as simulation to improve team functioning/dynamics.

Culture and Patient Safety

- Encourage a culture of high reliability that demonstrates consistent excellence in quality and safety across the MDT that is continually evaluated and refined over time.
- Support a culture of psychological safety in which clinicians are encouraged to express their ideas and concerns, to speak up with questions, and to admit mistakes — all without fear of negative consequences.
- Establish a formal governance structure especially for the Operating Theatre and within the orthopedic department to ensure safety and compliance, measure quality and performance, optimize the workforce and hold clinicians accountable for clinical care that falls short of standards.
- Consider a patient-centric model where the entire team fully participates in the patient care. Everyone must clearly communicate and reach consensus regarding the plan of care.
- Engage the MDT as early as possible in pre-operative planning.

- Reinforce that there will be no tolerance for unprofessional behavior; that all members of care team need to be listened to and respected.
- Strengthen relationships among all staff involved in the care of patients with spina bifida. Consider addressing team morale by developing mutual respect, trust and open communication.

Summary of Best Practices

In conclusion, below is a summary of some best practices that should be considered when supporting a high quality spinal surgery programme.

Governance

- Identify and support Clinical Speciality Lead for Orthopaedics.
- Establish an Operating Theatre Governance Committee (Surgeon, Anesthesia, Nursing).

Hospital Reporting/Quality and Patient Safety

- Develop a quality improvement team that includes a surgeon, nurse and quality improvement director.
- Strengthen a quality improvement programme that routinely collects and tracks metrics (unplanned reoperations, infection, neuro deficits, death).
- Implement a structured Monthly Surgical Morbidity and Mortality (M & M) Rounds.
- Increase utilization of the formal adverse event reporting system.
- Establish a culture of high reliability that demonstrates consistent excellence in quality and safety across the MDT.

MDT Process

- Encourage full team MDT participation in decision making and case conferences with the lead being a neurodisability physician.
- Consistently follow processes for all patients with Spina Bifida requiring spine surgery.
- Develop pre- and post-operative standardized, evidence based clinical guidelines and checklists.

Evidence Based Surgical Techniques / Processes

- Expand clinical team to assist in cases (neurosurgery for dissections and nerve decompressions, plastic surgery for wound closures).

- Incorporate the latest knowledge from high quality research studies and collaborate with other paediatric spine centers where clinicians care for high numbers of patients with spina bifida. This should include:
    - Utilization of standard length constructs for corrections of spinal curvature, including kyphosis.
    - Intra-operative imaging of all surgical implants in multiple planes, including implants going to the pelvis.

Review/Triage of Waiting List

- Closely monitor the patient list and continue to prioritize children based on acuity.

Data and Outcomes

Demographics

The team reviewed medical records and radiographic images of 16 children with spinal bifida who underwent spinal surgery during the review period commencing October 1st, 2019 and ending October 31, 2022 with surgeries ranging from 2018-2022.

The team also reviewed the Internal Review "Spines Clinical Review Report" provided by CHI at Temple Street in May 2023.

Of note, there were no major discrepancies between the 2 sources of data. Below is a summary of the key demographics from the patients reviewed.

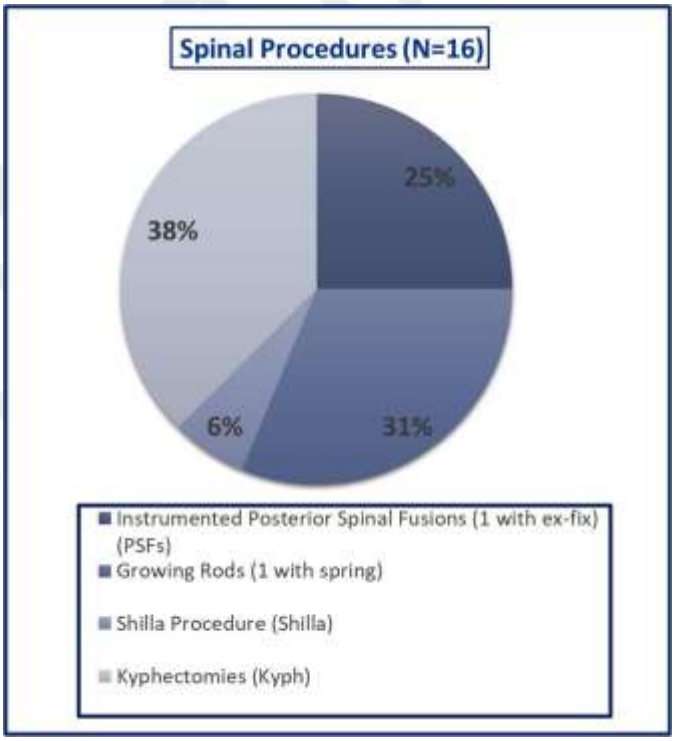
Child Characteristics	**N = 16**
Age at time of Index Surgery	M= 7 years, Range = 5-17 years
Sex	
Male	5 (31.3%)
Female	11 (68.7)
Co-Morbidities	
Arnold Chiari II Malformation	16 (100%)
Hydrocephalus	15 (93.8%)
Nutritional Concern/low wt.	6 (37.5%)
Neurogenic Bowel	16 (100 %)
Seizure Disorder	5 (31.3%)
Sleep Apnea	4 (25%)

Previous Surgeries	
G-tube	1 (6.3 %)
VP Shunt	15 (93.8%)
Tracheostomy	1 (6.3 %)
Decompression	5 (31.3%)

Type of Spinal Procedure

Procedures (N=16)

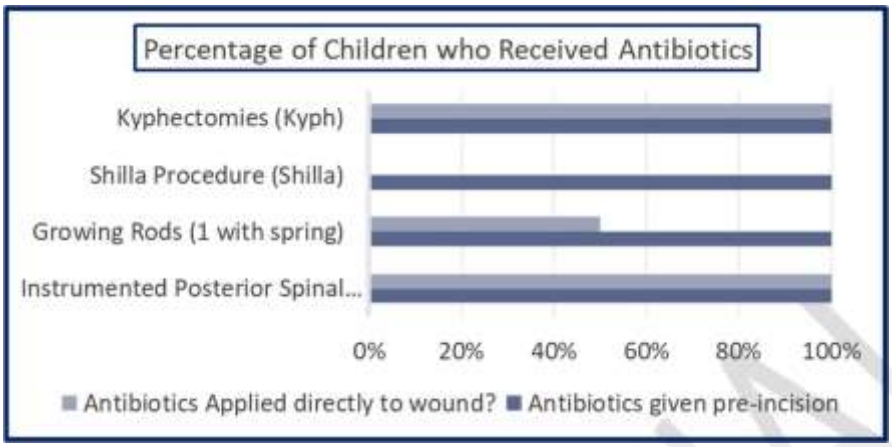
- Instrumented Spinal Fusion (n=4, 25%)
- Growing Rods (n=5, 31%)
- Shilla Procedure (n=1, 6%)
- Kyphectomies (n=6, 38%)



Peri-Operative Antibiotics

Intra-Operative Antibiotics

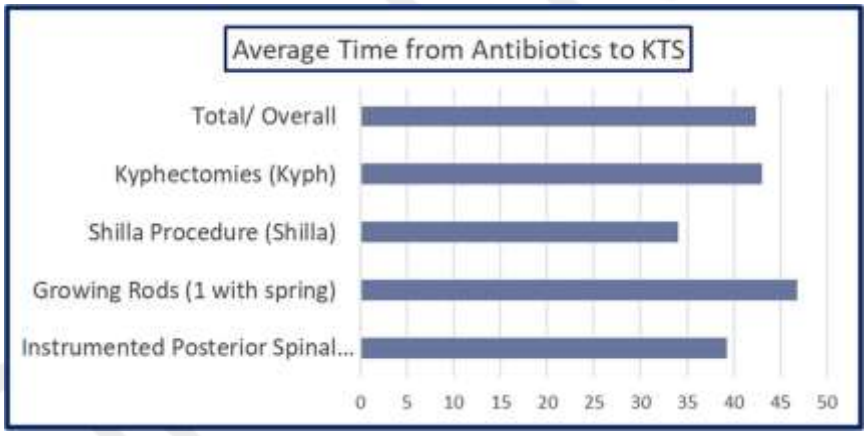
- 100% of patients received antibiotics pre-incision.
- 80% of patients received antibiotics directly into the wound.



Time from Antibiotics to KTS (Incision)

- The average time from antibiotics to KTS was 42 minutes with the longest time being 150 minutes (2.5 hours).

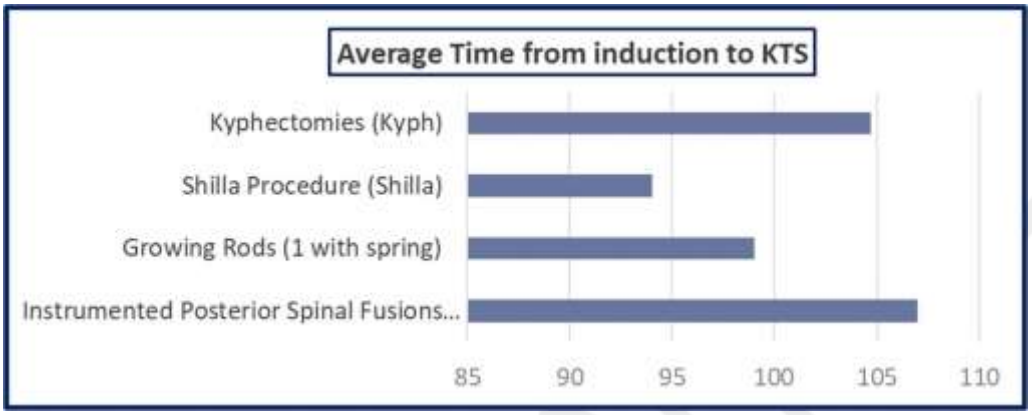
Note: 4 patients received antibiotics greater than 1 hour prior to incision.



Theatre Times

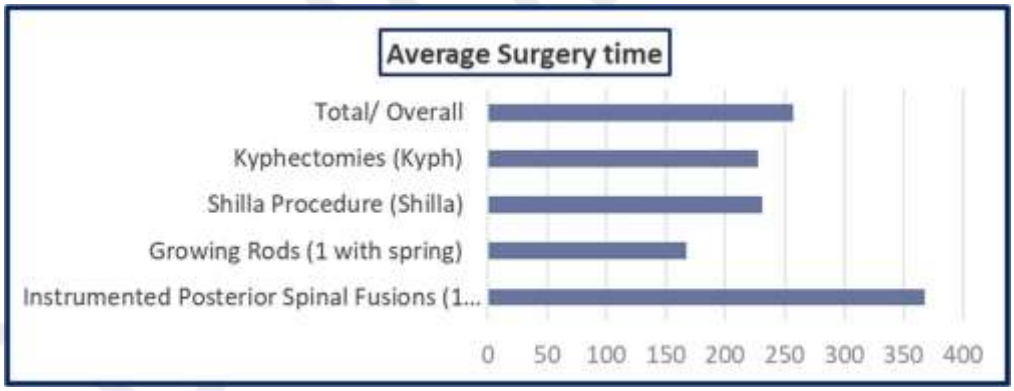
Time from Induction to KTS (Incision)

- Mean time from induction to KTS was 102 minutes (1.7 hours) with the longest time of 149 minutes (2.5 hours).



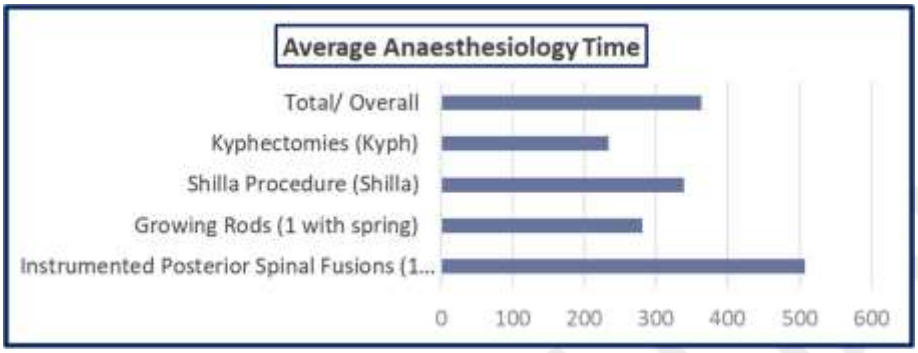
Time of Index Surgery

- Mean time of surgery was 257 minutes (4.3 hours) with the longest time being 523 minutes (8.7 hours).



Time of Index Anesthesia

- Mean time for anesthesia was 362 minutes (6.0 hours) with the longest anesthesia time of 650 (10.8 hours).



Transfusions

Transfusions: Packed Red Cell (PRC) and Related Transfusions

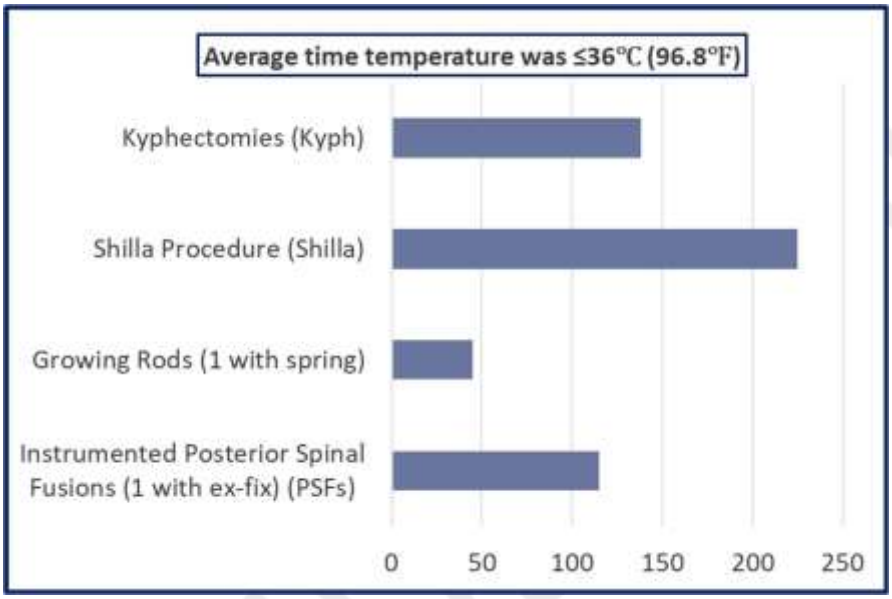
- 13/16 patients (81.25%) required a PRC transfusion
- The mean number of PRC transfusions was 6.9 units

Criteria	Instrumented Posterior Spinal Fusions (1 with ex-fix) (PSFs) (n=4)	Growing Rods (1 with spring) (n=5)	Shilla Procedure (Shilla) (n=1)	Kyphectomies (Kyph) (N=6)	Total/ Overall (n=16)
Blood Transfusion	**4/4 patients required a PRC transfusion** PRCs: Mean = 13.7 Greatest = 20 Octaplex: Mean =10 Fibrinogen: Mean = 3g Platelets: Mean = 6	**3/5 patients required a PRC transfusion** PRCs: Mean = 2.7 Greatest = 4 Riastap: Mean = 2	**0/1 patient required a PRC transfusion** No blood transfusions	**6/6 patients required a PRC transfusion** PRCs: Mean = 5.5 Greatest = 16 Plasma: Mean = 15 Platelets: Mean = 2 pool Pedipacks: Mean = 2	**13/16 patients required a PRC transfusion** PRCs: Mean = 6.9 Greatest = 20 Octaplex: Mean = 10 Fibrinogen: Mean = 3g Pool Platelets: Mean = 4 Riastap: Mean = 1 Pedipacks: Mean = 2 Plasma: Mean = 15

Intra-Operative Hypothermia

Under 36 degrees Celsius

- Mean time temperature was ≤36℃ (96.8℉) was 106 minutes (1.7 hours) with the longest time ≤ 36℃ (96.8℉) was 300 minutes (5 hours).



Under 35 degrees Celsius

- 3/16 patients (18.75%) recorded a temperature ≤35℃ (95℉).
- Mean time temperature was ≤35℃ (95℉) was 180 minutes (3 hours).

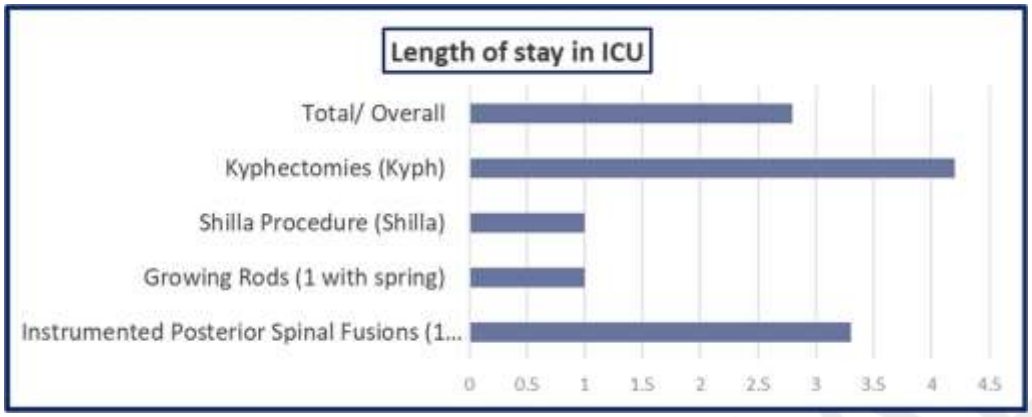
- **Note:** Data were skewed by longest time of 360 minutes (6 hours) with a temperature ≤35℃ (95℉) in a single case.

Length of Stay: ICU and Inpatient Ward

Length of Stay in ICU

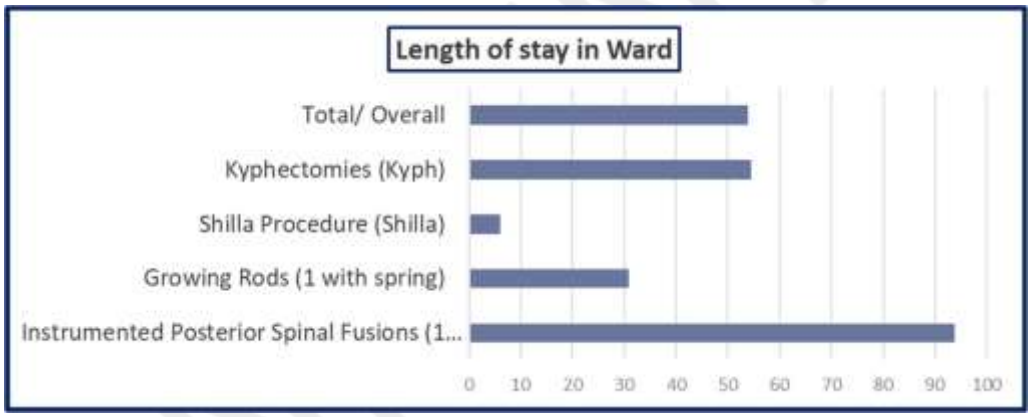
- Mean length of stay for all surgeries was 2.8 days.
- Longest length of stay was 11 days.

- **Note:** Data includes readmission days for the 7 patients who had >1 admission.



Length of Stay in Inpatient Ward

- Mean length of stay was 53.8 days.
- Longest length of stay was 233 days.



Complications: SSI/Wound Infection

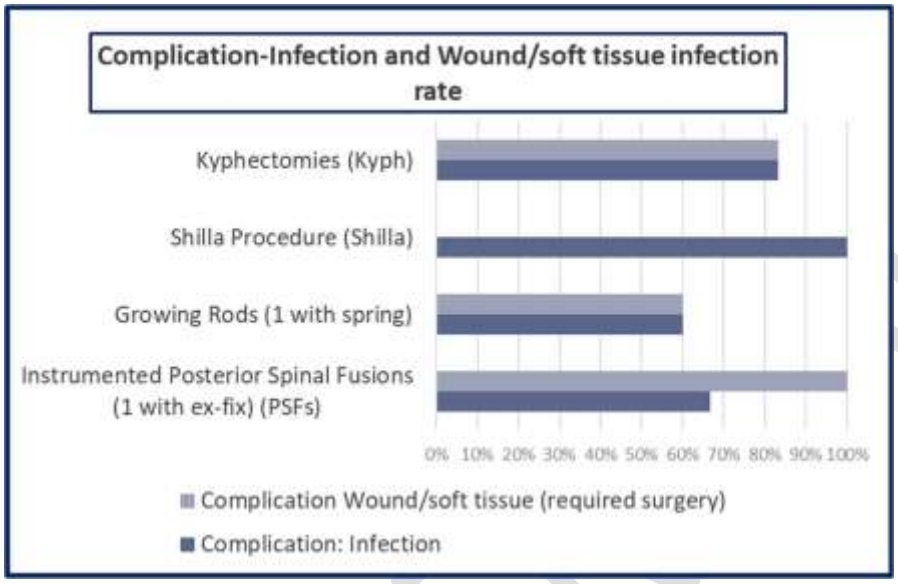
Surgical Site Infection

- 11/15 patients (73.4%) developed a SSI based on microbiology and clinical findings.

- **Note:** No information was available for one patient related to infection and was excluded from analysis.

Wound Complications

- 12/16 patients (75%) developed a wound infection requiring additional surgery.



	Instrumented Posterior Spinal Fusion (1 with ex-fix)	Growing Rod (1 rod with spring)	Shilla Procedure	Kyphectomies	Total/Overall
Complication: Infection	66.7 % (2 out of 3 patients got infection) No information available for one pt., excluded from the calculation.	60 % (3 out of 5 patients got infection)	100 % (1 out of 1 patient got infection)	83.4 % (5 out of 6 patients got infection)	73.4 % (11 out of 15 patients got infection)
Complication Wound/soft tissue (required surgery)	100% (4 out of 4 patients - wound/soft tissue complication)	60 % (3 out of 5 patients - wound/soft tissue complication)	0 % 0 out of 1 patient	83.4 % (5 out of 6 patients)	75 % (12 out of 16 patients got infection)

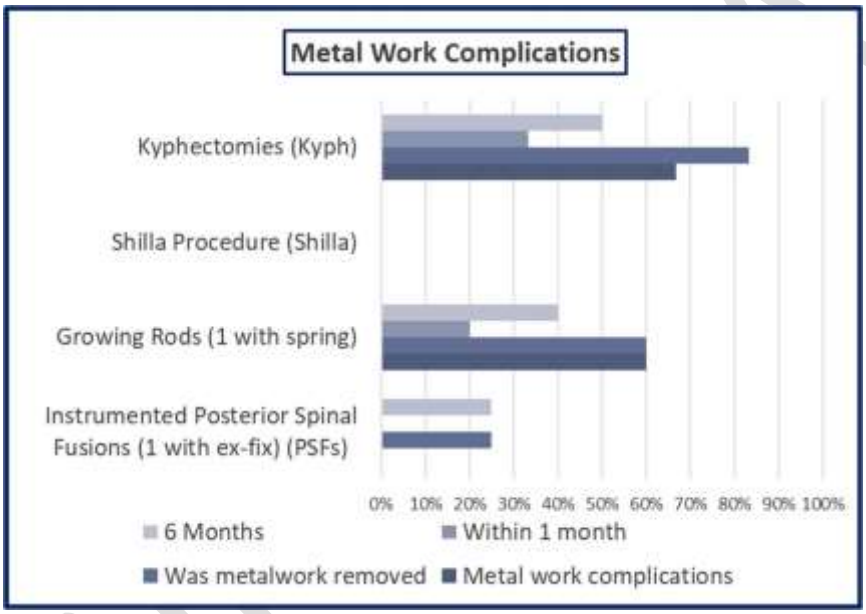
Complications: Metal Work/Hardware Failure

Metal Work/Hardware Failure

- Non-infective metal work complications were identified in 7/16 (44%) of the patients.

Metal Work/Hardware Removal

- Removal of metal work was required in 9/16 patients (56%).
  - 18% within 18 months of the index procedure.
  - 37% within six months of the index procedure.



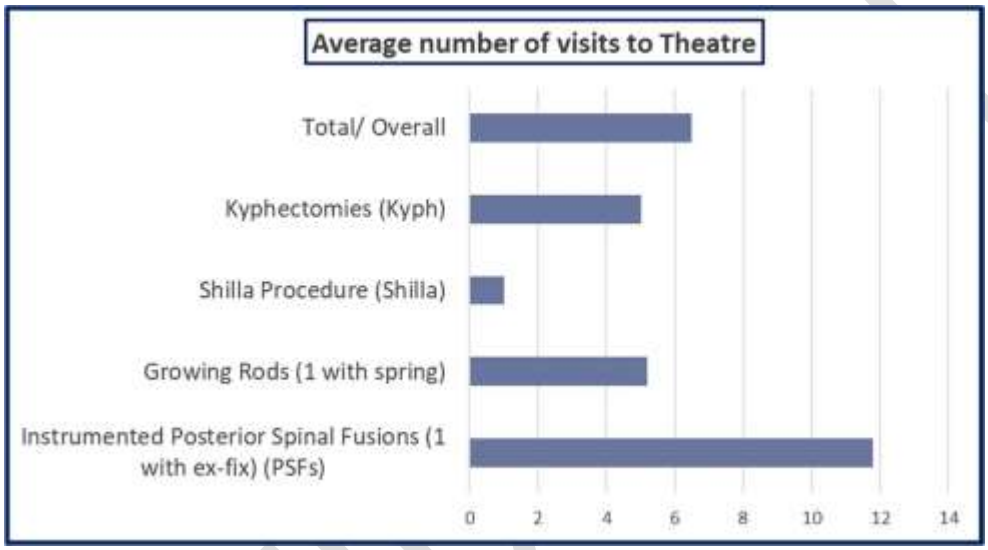
	Instrumented Posterior Spinal Fusion (1 with ex-fix)	Growing Rod (1 rod with spring)	Shilla Procedure	Kyphectomies	Total/Overall
Metal Work Failure complications	0 % 0 out of 4 patients	60% 3 out of 5 patients	0 % 0 out of 1 patient	66.7% 4 out of 6 patients	43.8 % 7 out of 16 patients
Was metalwork removed	25 % 1 out of 4 patients	60 % 3 out of 5 patients	0 % 0 out of 1 patient	83.4 % 5 out of 6 patients	56.2 % 9 out of 16 patients

Complications: Return to Theatre

Returns to the Theatre

- 13/16 patients (81.2%) required additional surgery due to a post-operative complication.
- Mean total number of visits to the theatre was 6.5 times with the highest number of visits of 34.

- **Note**: These averages include the index procedure.



	Instrumented Posterior Spinal Fusion (1 with ex-fix)	Growing Rod (1 rod with spring)	Shilla Procedure	Kyphectomies	Total/Overall
Total number of visit to Theatre	Highest: 34 Mean: 11.8	Highest: 8 Mean: 5.2	Highest: 1 Mean: 1	Highest: 7 Mean: 5	Highest: 34 Mean: 6.5
Number of returns to Theatre	Highest: 33 Mean: 11	Highest: 7 Mean: 4.2	Highest: 0 Mean: 0	Highest: 6 Mean: 4	Highest: 33 Mean: 5.5

Summary of Complications

Surgical Site Infection

- 11/15 (73.4%) developed a surgical site infection.
- Data was missing on 1 patient and was removed from analysis.

Wound Complications

- 12/16 (75%) developed a wound infection requiring additional surgery.

Metal Work/Hardware Failure

- 7/16 (44%) developed a non-infective metal work complication.
- 9/16 (56%) required removal of metal work.

Returns to the Theatre

- 13/16 (81.2%) of the patients required additional surgery due to a post-operative complication.

Mortality

- 1/16 (6.25%) patients died.
- Mortality at 30 day (n=0).
- Mortality at 1 year (n=1, 6.25%).

Resources

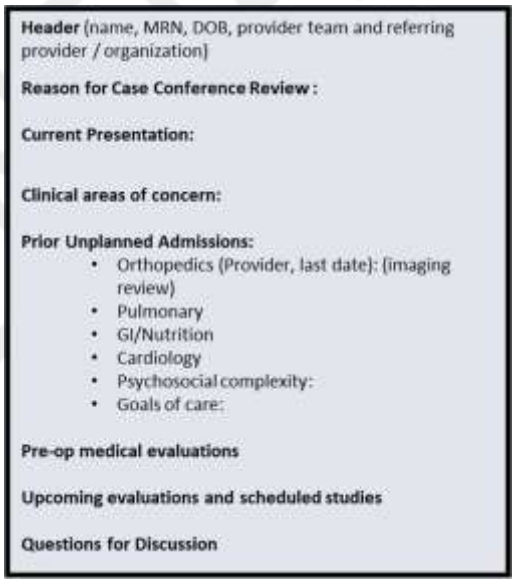
Case Conference Structure Template

Develop a standardized Case Conference packet; sample templates include:

Sample Summary Table:

	DOB	Age	MRN	Type of Surgery Scheduled	Surgeon	Cardiologist	Page # of Packet
Patient #1							
Surgery Date & Time							
Patient #2							
Surgery Date & Time							

Sample Case Summary Template



Case Summaries should circulated prior to conference – content to include:

- Header with key patient demographics.
- Current presentation / anatomy & case summary/ XRAY, MRI.
- Clinical areas of concern.
- Prior unplanned admissions.
- Pre-operative medical evaluations.
- Upcoming evaluations and scheduled studies.
- Questions for discussion.

Presentation Best Practices

- Identify a clinical resource to prepare case conference materials each week.
- Send case packet to all conference participants in advance of the conference.
- Assign a clinician to present the patient history and an imager to present each diagnostic study.
- Encourage clear and open dialogue regarding case planning, next steps and follow-up questions (led by surgeon & primary paediatrician).

M&M Review Structure Template

M&M considers and is inclusive of all **three phases of care**: pre-operative, intra-operative, and post-operative.

Consider including all contributory factors in M&M summary:

- Patient (Risk factors).
- Work environment (staffing, skills, workload, shift, equipment).
- Team (communication, leadership, structure, availability of help).
- Task (use of protocols, test results, decision making).
- Organizational Management and Institutional Context Factors (structure, policy, safety culture, priorities).

Sample Case Summary Template

- Instructions and Reasons for Review:

Instructions:

- Criteria for Morbidity and Mortality (M&M) form completion:
  - Any unanticipated deaths; unanticipated catastrophic or major events; cardiac or respiratory arrest (unless reasonably expected given underlying condition)
  - Select cases or events involving a substantial review/discussion during M&M such as:
    - Near misses, systems issues, serious complications, diagnosis or treatment errors
- Please complete one form per case reviewed at M&M. (Do not include routine reviews of common, known complications)
- This form is not intended to capture *all* discussion during the M&M conference or to be M&M meeting minutes. It can be downloaded and included as a part of meeting minutes for the identified cases or events.

The M&M form is confidential and peer review protected.

Reason for M&M Review:

Select one review method and follow the instructions below:

☐ Morbidity/Mortality (go to Morbidity & Mortality section 1)

☐ Educational (go to Education section on page 3 section 1)

☐ No cases for review this month (form complete)

Morbidity & Mortality

Section 1: Overview

Date of M&M: Click here to enter text.

Event Date: Click here to enter text.

Department/Division: Click here to enter text.

Other departments/services that involved/participated in M&M: Click here to enter text.

Person completing M&M form: Click here to enter text.

MRN: Click here to enter text.

Section 2:Case Details

SERS File ID (if known): Click here to enter text.

1. Case/Event Summary: (Can copy brief factual description from SERS)

Click here to enter text.

Section 3:Case Evaluation

2. Was the event/case:

☐ **A.** Expected/anticipated (Was the event/complication/death associated with the natural progression of the underlying disease process and its appropriate treatment?) *Go to question 4*

☐ **B.** Unexpected/unanticipated (Was the event/complication/death considered an unintended consequence associated with management of the underlying disease process?)

3. If unexpected, was the event/case considered to be: Check all that apply

☐ **A.** System-related (may involve multiple individuals and/or departments)

☐ **B.** Patient-related (expected sequela of a disease state or related to patient characteristics beyond the control of provider(s)

☐ **C.** Provider-related (substantially due to provider-related provision of care)

4. Contributing Factor(s): List here: (for example process, policy, technology etc.)

1.

2.

5. Final Severity:

☐ Level 0 – Near Miss
☐ Level 1 – No Harm
☐ Level 2 – Minor
☐ Level 3 – Moderate
☐ Level 4 – Major
☐ Level 5 – Catastrophic (Mortality)

If Level 5 - Catastrophic, please answer question 7.

6. Final Preventability:

☐ Preventable
☐ Possible Preventable
☐ Not Preventable

7. Was an autopsy:

☐ Requested
☐ Refused
☐ Completed
☐ Unknown

Additional information (if needed):

Section 4: Summary of Learnings & Opportunity for Improvement

8. Summary of learning points/opportunity for improvement:

(**Opportunity for improvement:** Modification in structures and/or processes of care to reduce the incidence of real or potential adverse events or improve outcome. If the same patient were to walk through the door today, would we do anything differently?)

9. Are follow up action items needed?

☐ **A.** Yes (add follow up action plan to question 10)

☐ **B.** No (No additional action required)

10. Follow up action plan:

Description of follow up action:	Expected Completion Date:	Follow up with: