



# **Children's Health Ireland Report on Spinal Surgery for Patients with Spina Bifida in Children's Health Ireland at Temple Street**

The purpose of this report by Children's Health Ireland (CHI) is to collate findings and recommendations from two clinical reviews into spinal surgery for patients with Spina Bifida in CHI at Temple Street. It also includes a summary of researched publications on post-operative spinal surgery complications. These are used to develop a CHI Spinal Surgery Programme Implementation Plan to improve spinal surgery services for patients with Spina Bifida. This Implementation Plan is iterative and updated accordingly.

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## Summary Overview and Background

### a) Summary Overview

The purpose of this report by Children's Health Ireland (CHI) is to:

- outline the rationale as to why clinical reviews were undertaken, including establishing if there were issues with existing spinal surgery services for patients with Spina Bifida in CHI at Temple Street;
- develop a single source to report, collate and detail the findings and recommendations from the three review sources undertaken and;
- to develop a CHI Spinal Surgery Programme Implementation Plan (see Appendix 1 for detailed plan) based on the review findings and recommendations, to improve spinal surgery services for patients with Spina Bifida.

There are two key reasons why CHI needed to undertake these clinical reviews. The first is because in July and September 2022, two serious post-operative surgical incidents in spinal surgery were reported in CHI at Temple Street. CHI commissioned serious incident investigations into these two incidents which are currently (as of August 2023) in progress. The second reason is that in September / October / November 2022, concerns about spinal surgery outcomes were also raised by members of the Spina Bifida Multi-Disciplinary Team (MDT) to their Clinical Director (CD) and the CHI Chief Medical Officer (CMO).

As a direct result of these two incidents and the concerns raised by the Spina Bifida MDT in CHI at Temple Street the following reviews were instigated:

1. An internal clinical review of surgical outcomes for spinal surgery in CHI at Temple Street commenced in November 2022 (completed May 2023) to look objectively at the frequency and severity of surgical complications, and gross indicators of outcomes in patients with Spina Bifida who have undergone complex spinal surgery at CHI at Temple Street between 2018 and 2022;
2. Given the technical and specialist nature of the surgery involved and to bring clinical independence to the matter, the CHI Executive decided on 28 November 2022 that an external clinical review be commissioned, undertaken by an independent international external review team. This would be of benefit in exploring the concerns being raised and identify any actions required to improve Spina Bifida spinal surgery services and outcomes. This external clinical review and Spinal Surgery Programme assessment commenced in March 2023. It was undertaken as a Protected Peer Review to directly inform CHI of the actions it needs to take to provide a Spinal Surgery Programme, ensuring patient safety and improving processes and clinical outcomes for patients with Spina Bifida. The findings and recommendations of the external peer review are fully incorporated into this **CHI Report into Spinal Surgery for Patients with Spina Bifida in CHI at Temple Street (August 2023)**; and

3. A review and summary of internationally published papers (see Appendix 2 for an overview of details and data) on post-operative surgical complications for a specific spinal surgery procedure, Kyphectomy, (see Appendix 3 for overview of the procedure) used to provide a comparative basis for the outcome data in CHI's internal clinical review of spinal surgery outcomes between 2018 and 2022.

This **CHI Report on Spinal Surgery for Patients with Spina Bifida in CHI at Temple Street (August 2023)** encapsulates the findings and recommendations of these three reviews in order to report in a single source and put the recommendations into a CHI Spinal Surgery Programme Implementation Plan that maps the actions required, timelines and responsible persons to:

- a) address the immediate patient and family clinical needs and engagement processes on the findings and recommendations, including open disclosure where required;
- b) improve spinal surgery services and outcomes for patients with Spina Bifida in CHI, comparable to best practice standards for this complex surgery patient cohort;
- c) address concerns raised by the Spina Bifida MDT; and to
- d) implement changes to spinal surgery services in CHI as outlined in the CHI Spinal Surgery Programme Implementation Plan. This plan is an iterative document and updated regularly.

#### **b) Background to the Provision of Spina Bifida Services by CHI**

There are over 1.22 million children in Ireland under the age of 18 years (23.6% of the total population). Ireland has one of the highest incidences of Spina Bifida in the world, with an overall incidence of approximately 1 in 1000 live births<sup>1,2</sup>. It is estimated that there are currently just under 500 children (0-18 years) with Spina Bifida in Ireland. Therefore, demands for quality paediatric healthcare and spinal surgery for patients with Spina Bifida are higher in Ireland compared to other countries.

Consolidation and development of Spinal Bifida services for children through a Spina Bifida MDT was planned in 2014 by the HSE and CHI at Temple Street. Commitment was given by the HSE in 2014 to commence funding a Spina Bifida MDT from 2015 and for all newborn babies and current paediatric patients requiring Spina Bifida services to be located at CHI at Temple Street. Resourcing this Spina Bifida MDT happened in 2015 and 2016. This included an additional orthopaedic surgeon with a special interest in complex spinal surgery for children, including for patients with Spina Bifida, in 2016 in CHI at Temple Street. A small number of patients with Spina Bifida chose to remain in CHI at Crumlin post 2014 for their care and treatment but all newly diagnosed babies born with Spina Bifida since 2015 are referred from the maternity hospitals to CHI at Temple Street for treatment

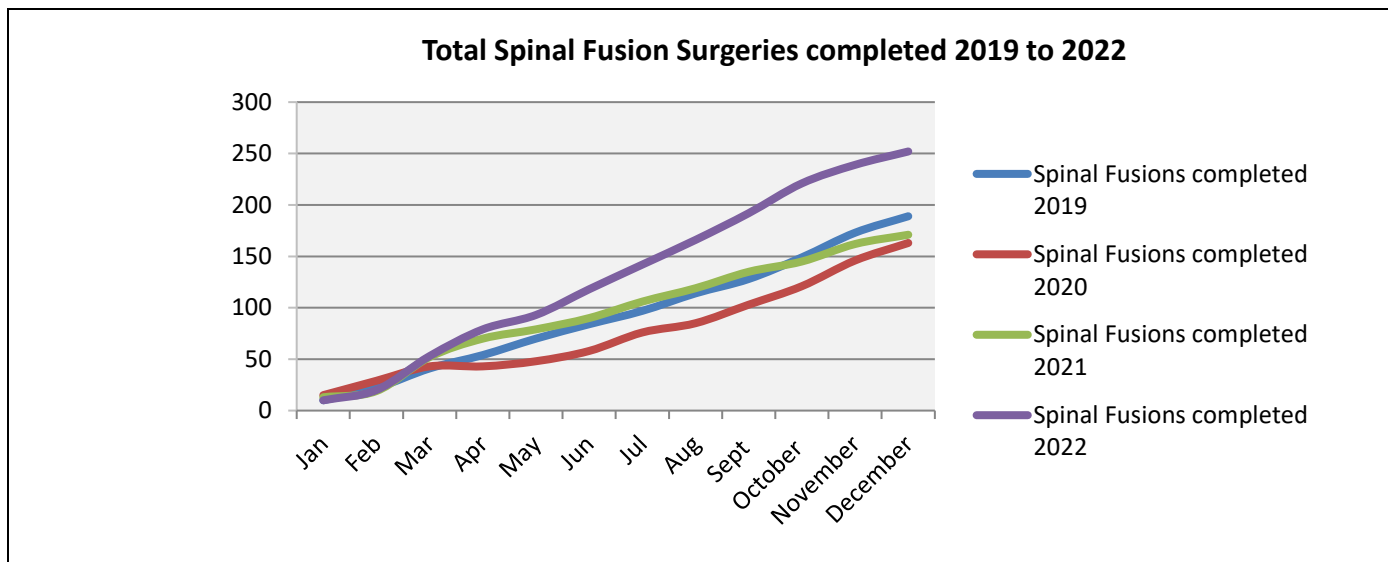
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<sup>1</sup> EUROCAT 1991. Working Group. Prevalence of neural tube defects in 20 regions of Europe and the impact of prenatal diagnosis, 1980–1986. *Journal of Epidemiology Community Health*, 45, 52–8.

<sup>2</sup> 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.

and care. Neurodisability in CHI at Temple Street leads the Spina Bifida MDT, with multiple specialists and professionals inputting to the child’s pathway of care from birth to transfer to adult services. The Spina Bifida MDT consists of a team of specialists in Neurodisability, Neurosurgery, Anaesthesiology, Orthopaedics, Urology, Health and Social Care Professionals and Clinical Nurse Specialists and a wider nursing team caring for inpatients. Complex spinal surgeries for patients with Spina Bifida are undertaken by a small surgical team, supported by the wider team.

Since 2016, spinal surgery for children with Spina Bifida primarily took place in CHI at Temple Street. With investment in orthopaedic services since 2019, Spinal Fusion surgeries in CHI have increased significantly, see Table 1.



**Table 1 – Total Spinal Fusion Surgeries completed 2019-2022**

Table 1 also demonstrates that due to cessation of elective surgery in CHI for significant periods during 2020 and 2021 due to COVID-19 and the HSE Cyber-Attack, the progress made in 2018 and 2019 was compromised resulting in increased waiting times and volumes (outpatient and inpatient) for access for spinal surgery, including for patients with Spina Bifida. Spinal surgery activity increased materially in 2022 due to new investment.

In 2022, the Minister of Health allocated €19 million for children who are in need of orthopaedic surgery to assist with these high demands, to include an increase in inpatient beds, MRI and theatre capacity and staffing in CHI at Temple Street and CHI at Crumlin. Prolongation of the new children’s hospital build programme was a factor considered to secure investment in 2022 for additional capacity in existing old facilities. Part of the plan to increase theatre capacity is the development of an additional new theatre in CHI at Temple Street (5<sup>th</sup> theatre). The capital funding approval for this theatre took several months to secure with implementation challenges

experienced due to refurbishing an existing space in an old building. The 5<sup>th</sup> theatre in CHI at Temple Street is due to open in September 2023.

In early 2022, CHI at Temple Street prioritised access for patients needing spinal surgery to reduce waiting lists. This included an increase in complex spinal surgeries for patients with Spina Bifida, see Table 2.

	Years					
	2017	2018	2019	2020	2021	2022
<b>Spinal Surgeries - Total Numbers in CHI at Temple Street</b>	93	109	95	87	98	124
<b>Percentage Difference in Activity to Previous Year</b>	-	+ 17%	- 13%	- 8%	+ 13%	+ 26%
<b>Kyphectomy Surgeries for Patients with Spina Bifida</b>	0	0	0	1	2	4

**Table 2 - Spinal Surgery Activity in CHI at Temple Street (Jan 2017- Sept 2022).**

In CHI at Temple Street spinal surgery activity increased from February to September 2022 by 26%. In July and September 2022, two serious incidents in spinal surgery patients were reported up through CHI's Incident Management Process on post-operative surgical outcomes in CHI at Temple Street (one Spina Bifida surgery and one non-Spina Bifida spinal surgery). Concerns were also raised by some members of the Spina Bifida MDT to their CD and the CHI CMO in September / October / November 2022. As a direct result of this, the CHI Executive instigated both an internal clinical review of spinal surgery complications and an external clinical review of complex spinal surgeries for patients with Spina Bifida in CHI at Temple Street.

## Approach and Methodology for the Clinical and Published Papers Reviews

### a) Mitigating Actions Undertaken at CHI while Reviews were being Carried Out

CHI was aware in November 2022 that these two clinical reviews were expected to take a number of months to complete. As an interim measure until the findings of these reviews were presented to CHI, the following actions and decisions were immediately undertaken to ensure patient safety:

#### i. Paused a specific spinal surgery procedure in CHI

CHI elected to pause the most complex spinal surgery, Kyphectomy, for patients with Spina Bifida in CHI at Temple Street until the outcome of the reviews was available. Specifically, on 14 November 2022 CHI paused the surgical technique of using short-segment fixation in spinal surgery for Kyphectomies for patients with Spina Bifida. The last patient who had a short-segment Kyphectomy performed in CHI at Temple Street was in July 2022.

#### ii. Waiting list management to ensure continuity of care in the immediate period

This pause in surgery impacted a small number of patients with Spina Bifida actively awaiting surgery, and interim plans for their care in CHI have been overseen and managed by the clinical leadership team and Clinical Directorate.

#### iii. Enhanced governance in place pending the outcome of the reviews

In addition to the interim changes to the spinal surgical governance, the following actions were also instigated:

- October / early November 2022, the CHI CMO and CD engaged with the Spina Bifida MDT to understand the issues and concerns with the service.
- Spina Bifida MDT meetings membership and attendance have been strengthened since 8 November 2022 to ensure full participation in case planning.
- Additional clinical controls / oversight implemented to include a second Surgeon to support in difficult surgical cases.

#### iv. Informed patients and families of their inclusion in an external clinical review

#### v. Informed the advocacy groups of decision by CHI to commission an external clinical review

## **b) Summary of Approach to Clinical Reviews and Review of Published Papers**

There are three components of work undertaken that contribute to this Report.

### **1) Internal Clinical Review in CHI at Temple Street**

The scope of the internal clinical review of surgical outcomes for spinal surgery in CHI at Temple Street commenced in November 2022 (completed May 2023) was to look objectively at the frequency and severity of surgical complications, and gross indicators of outcomes in patients with Spina Bifida who had undergone complex spinal surgery at CHI at Temple Street between 2018 and 2022. This clinical review was undertaken by a CHI Consultant Anaesthesiologist and a CHI Consultant Orthopaedic Surgeon, the latter was new to CHI and was not involved in the care or treatment of any of the cases reviewed.

The internal reviewers sought to better appreciate likely complications and positive / negative outcomes to fully inform the Spina Bifida MDT team of their patient outcomes and to inform patients and their families / carers, to plan resources, make changes to practice as necessary and to manage expectations of the MDT team.

#### **i. Methodology for internal review**

The case notes and system records on post-operative complications of sixteen patients with Spina Bifida who had undergone complex spinal surgery in CHI at Temple Street between 2018 and 2022 were reviewed as part of this examination. A thorough case note review was conducted, along with;

- radiology review (NIMIS)
- data from Paediatric Intensive Care (ICCA system)
- data from theatre management system (ORMIS)
- microbiology lab results (via Clinical Portal)
- blood bank transfusion records (forwarded by Haematology department)

The review contains a level of data detail that could result in individual patients being identified. Therefore, in keeping with General Data Protection Regulations (GDPR) requirements and patient confidentiality, we are including the findings and results from the review but not the detailed data on each patient.

### **2) External Clinical Review**

The scope of the external International review 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 Spinal Surgery Programme for patients with Spina Bifida including:

- clinical review of the Spinal Surgery Programme to identify any immediate patient safety concerns based on care provided during the review period for patients with Spina Bifida undergoing spinal surgery (1



October 2019 to 31 October 31 2022);

- review of CHI at Temple Street’s clinical processes related to the Spinal Surgery Programme, including current capabilities and Spinal Surgery Programme gaps;
- Spinal Surgery Programme structure; and
- reporting on the quality and outcomes of the Spinal Surgery Programme.

The 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.

### i. Methodology for external review

The team consisting of Clinicians with specialties in Orthopaedic 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
  - Orthopedic Surgery
  - Physical Therapy
  - Plastic Surgery
  - Psychology
  - Social Work
  - Theatre Nursing
- **Observation:** Orthopaedic case presentations were observed and tours were conducted of CHI at Temple Street, CHI at Crumlin, and the new children’s hospital site.
- **Medical Record Review:** The medical records of sixteen patients who received care by the Spina Bifida MDT and underwent spinal surgery during the review period commencing 1 October 2019 and ending 31 October, 2022<sup>3</sup> 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 the CHI at Temple Street Internal Review Report.

<sup>3</sup> Although the review period was requested during this time period stated above, the sixteen patients underwent surgeries from in 2018-2022.

### 3) Summary of Published Papers on Kyphectomy Surgery.

To provide context for the internal clinical review findings on spinal surgery post-operative complications and acknowledging that risks including mortality and post-operative complications are associated with this type of complex spinal surgery, a summary of internationally published papers on post-operative surgical complications for a specific spinal surgery procedure, Kyphectomy, was used to provide a comparative basis for the outcome data in CHI's internal clinical review of spinal surgery outcomes.

Six of the sixteen cases in the internal clinical review patient cohort had the Kyphectomy surgical procedure. From the papers reviewed it is evident that complications occur in this type of surgery and these are summarised in Table 3 below. The published data records mortality rates occurring with this procedure.

The issue for CHI is that the post-operative complication findings from the clinical reviews demonstrate that the Kyphectomy procedure outcomes in CHI at Temple Street are higher when compared to the results in the high-level summary of published articles on this procedure for returns to theatre and revision of metal work in Table 3 below. The number of patients in these reviews, as well as in the cases reported in the literature are too small to make detailed comparisons on outcomes.

High-level Summary of published articles on Kyphectomy in chronological order							
Year	n	Death	Mortality rate	UPROR*	UPROR rate %	Metal revised	Metal revised %
2000 to 2014	153	4	2.6	69	45%	51	33%
2014 to 2022	104	1	0.9	46	44%	14	14%
Total	257	5	1.9	115	45%	65	25%

\*Un-Planned Return to Operating Room (UPROR)

**Table 3. High Level Summary of Published Papers on Kyphectomy Surgery and Complication Rate.**

The CHI Executive and Board, having considered the findings from the clinical reviews and considering the comparison data in published papers for the Kyphectomy procedure, have developed actions including the continued cessation of this short-segment repair procedure in CHI and identified the need for post-operative outcome measurements and benchmarking on spinal surgery outcomes.

## Understanding the Current Environment and Fundamental Challenges

The below sets out the current environment and fundamental challenges that CHI needs to consider from the reviews:

### a) 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 healthcare 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 optimise patient outcomes.

### b) External Environment

- **Patient Volume:** Ireland has one of the highest rates of Spina Bifida in the world and the incidence rate remains 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 (there are 4 operating theatres). A state of the art paediatric hospital will open in 2025 which should help to alleviate the long wait times and provide updated infrastructure and physical facilities.

## Findings and Best Practice recommendations from Reviews

### a) Findings from the Reviews

In developing this **CHI Report on Spinal Surgery for Patients with Spina Bifida in CHI at Temple Street (August 2023)** the findings from both the internal and external reviews are incorporated, with a review of internationally published papers on post-operative surgical complications for a specific complex spinal surgery procedure, Kyphectomy, used to provide a comparative basis for the outcome data in CHI's internal clinical review of spinal surgery outcomes between 2018 and 2022.

One of the reviews advises that 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:

- **Clinical:** Optimise clinical care using evidence-based surgical techniques and consider surgical sub specialisations, if volume permits. Provide intensive, ongoing support in clinical oversight, standardisation of care, and education.
- **Programme:** Foster a multi-disciplinary, programmatic quality centric mindset, in both governance and amongst individual Clinicians. Include representatives from the Spina Bifida MDT in the quality improvement programme.
- **Culture:** Emphasise a culture of high reliability that values safety, quality, and efficiency. Ensure that all members of the Spina Bifida MDT are encouraged to speak up without any fears.

The high-value actions under the three areas of Clinical, Programme and Culture that enable programme success for spinal surgery for Spina Bifida outlined in the reviews have been fully adopted by CHI and put into an Implementation Plan included with this report (Appendix 1).

### b) Summary of Findings on Complications

It is universally acknowledged that complex spinal surgery in patients with complex underlying conditions as noted in this group of patients with Spina Bifida, has levels and types of risks associated with it due to the significant underlying condition of the patients and the complex surgery involved. The reviews' findings specifically relating to post-operative complications are outlined in Table 4 (see below) and support some of the concerns raised by some of the Spina Bifida MDT members on post-operative complications.

No	Complication	Internal Analysis finding
1	Unplanned return to surgery	<ul style="list-style-type: none"> <li>The analysis of the 16 case files showed that 13 of the 16 patients (81.2%) required further unplanned surgery. One of these patients who had multiple procedures, unfortunately died and this death is the subject of a Serious Incident Investigation Review currently in progress (as of August 2023)</li> <li>Patients with minor complications that did not need further surgery had superficial wound problems that were managed with oral antibiotics or nurse-lead wound care in the Outpatient Department.</li> </ul>
2	Infections	<ul style="list-style-type: none"> <li>The internal analysis showed the overall infection rate for these 16 cases was 73.4% based on microbiology and clinical findings; and the overall rate of wound complication requiring further surgery was 75%.</li> </ul>
3	Metal work complications	<ul style="list-style-type: none"> <li>Overall, 9 of the 16 of cases (56%) had mechanical complications of metal work requiring removal of metalwork.</li> </ul>

**Table 4. Post-operative Complications Findings from Clinical Reviews of 16 Spinal Surgeries for Patients with Spina Bifida between 2018 - 2022 in CHI at Temple Street.**

### c) Key Themes Identified in the Reviews

- Supporting a sustainable, high quality Spinal Surgery Programme / MDT for patients with Spina Bifida is important.** Members of the Spina Bifida MDT and leadership are committed and motivated to provide safe, effective, patient-centred, timely, and efficient care in order to optimise 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 carried out 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 surgeries in children with Spina Bifida.** To address these types of concerns early, programme metrics

designed to evaluate patient 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 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.

#### **d) Summary of Best Practices**

Below is a summary of some best practice recommendations from the reviews that should be considered when supporting a high quality Spinal Surgery Programme:

##### **i. Governance**

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

##### **ii. 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 structured Monthly Surgical Morbidity and Mortality (M & M) Rounds.
- Increase utilisation of the formal adverse event reporting system.
- Establish a culture of high reliability that demonstrates consistent excellence in quality and safety across the Spina Bifida MDT.

### iii. **Spina Bifida MDT Process**

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

### iv. **Evidence Based Surgical Techniques / Processes**

- Expand clinical team to assist in cases (Neurosurgery for dissections and nerve decompressions (in place), Plastic Surgery for wound closures).
- Incorporate the latest knowledge from high quality research studies and collaborate with other paediatric spine centres where clinicians care for high numbers of patients with Spina Bifida. This should include:
  - Utilisation of standard length constructs for corrections of spinal curvature, including Kyphosis.
  - Availability of intra-operative imaging of all surgical implants in multiple planes, including implants going to the pelvis.

### v. **Review / Triage of Waiting List**

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

## e) **Detailed findings**

### i. **Clinical**

- Optimise 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 centres where Clinicians care for high numbers of patients with Spina Bifida. This should include:
  - Utilisation 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 (in place).
- Enlarge the dedicated group of Orthopedic Surgeons with the technical expertise to operate on

children with complex spinal conditions - including those with Spina Bifida.

- Develop a specialised spine team in the theatre comprised of Anesthetists, Nurses, Orthopaedic 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 Orthopaedic 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 standardised, evidence based clinical guidelines and checklists, as well as order sets to improve the clinical efficacy, care efficiency, and patient safety.
- Develop a formalised informed consent / shared decision making process to optimise communication of the risks and benefits of surgery including the potential complications and need for additional surgeries.
- Encourage the Spina Bifida MDT to increase the caloric nutrition of patients with Spina Bifida in order to minimise 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.

## ii. Programme

- Appoint a Clinical Specialty Lead for Orthopaedics who has the responsibility and power to make changes and to advocate for staff both professionally and academically (in place).
- Develop and implement an effective Orthopaedic 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 utilisation. Benchmark to professional organisation metrics.
- Improve orthopaedic 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 the Spina Bifida 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 Orthopaedic Surgeons



and Neurodisability Clinicians (e.g., audit responsiveness to communications and core professional duties).

- Encourage full participation of all team members in case conferences, Spina Bifida 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.
- Not all information was available to support the reviews and there should be widespread encouragement across all specialties to improve documentation.
- Data retrieved for the reviews can and should be used in the consent process, when counselling these patients and their families for complex spinal surgery.

### **iii. Culture and Patient Safety**

- Encourage a culture of high reliability that demonstrates consistent excellence in quality and safety across the Spina Bifida 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 Orthopaedic Department to ensure safety and compliance, measure quality and performance, optimise 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 Spina Bifida MDT as early as possible in pre-operative planning.
- Reinforce that there will be no tolerance for unprofessional behavior; that all members of the 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 communications.

## Next Steps

### **a) Plan for Ongoing Activity and Continuity of Care**

Ongoing activity planning is being developed in partnership with clinical and operational teams. Solutions need to be carefully assessed to ensure there are no unintended clinical, patient safety and service consequences. These solutions are expected to include utilising theatre slots and additional bed capacity in another CHI site and formally transferring clinical care to appropriate Consultants across CHI. CHI is also exploring transfer of a small number of complex patients to appropriately skilled centres in other countries. Engagement with clinical teams and operations leads commenced on 18 July 2023 on transferring patients to other Spinal Surgeons in CHI. A Services Continuity of Care Plan was developed and submitted to the HSE Acute Operations on 25 July 2023. This Continuity of Care Plan will be an addendum to Scoliosis and Spina Bifida Plan submitted to HSE in May 2023.

### **b) CHI Spinal Surgery Programme Implementation Plan (August 2023)**

An Implementation Plan (Appendix 1) for spinal surgery for patients with Spina Bifida in CHI at Temple Street has been developed in response to the findings in the internal review of spinal surgery complications, results from a comparative data review of researched publications on post-operative complications in spinal surgery and an external quality review and programme assessment undertaken in a protected peer review process. These inputs were used by CHI Executive and clinical leadership to drive the recommended changes in spinal surgery services in CHI as outlined in the Implementation Plan. The Board of CHI endorsed the Plan with oversight by CHI Executive Operations, chaired by the Deputy CEO / Operations Director.

### **c) Communications**

Timely, open and coordinated communications with patients and families and all internal and external stakeholders to CHI on this report and Implementation Plan is critical. A detailed plan of communications for patients, families, staff and all internal and internal stakeholders on the report and Implementation Plan will be implemented.

## **Appendix 1: CHI Spinal Surgery Programme Implementation Plan (August 2023)**

A CHI Spinal Surgery Programme Implementation Plan to improve spinal surgery services for patients with Spina Bifida has been developed. This plan is based on the findings and recommendations of the reviews with actions tracked to ensure the recommended changes are being implemented within agreed timelines. It is therefore an iterative document and will be updated regularly.

## Appendix 2: Comparative Data Review of Internationally Researched Publications on Post-Operative Complications in Spinal Surgery

Table 1: Detailed Summary of articles on Kyphectomy in chronological order

Author	Country of Origin	Impact Factor	Year	Multicenter	Study type	n	Kyphectomy	Length of Construct	Death	Mortality rate	UPROR*	UPROR rate %	Metal revised	Metal revised %	Infection	Mechanical failure	Dural leak
Thomsen et al	Germany	1.1	2000	no	retrospective	9	9	long	0	0.0	3	33.3	3	33.3	?		
Niall et al	Ireland	1.6	2004	no	retrospective	24	24	long	1	4.2	19	79.2	18	75.0	19	?	
Akbar et al	Germany	3.8	2006	no	retrospective	24	24	long	1	4.2	10	41.7	7	29.2	3	7	
Ko et al	USA	3.8	2007	no	retrospective	9	9	long	0	0.0	8	88.9	6	66.7	8		
Altiok et al	USA	1.8	2010	no	retrospective	33	33	long	1	3.0	10	30.3	7	21.2	1?	7	
Comstock et al	Canada	1.8	2010	no	retrospective	22	22	long	1	4.5	9	40.9	7	31.8	?		
Samagh et al	USA	3.8	2011	no	retrospective	11	11	long	0	0.0	1	9.1	0	0.0	?		
Schroeder et al	Israel	NA	2011	no	retrospective	13	13	long	0	0.0	5	38.5	?	??	2		
Gepp et al	Brazil	NA	2013	no	retrospective	8	8	long	0	0.0	4	50.0	3	37.5	?	3	
Dunn et al	South Africa	1.7	2015	no	retrospective	7	7	long	0	0.0	2	28.6	2	28.6	2		
Petersen et al	Brazil	1.8	2019	yes	retrospective	28	28	long	0	0.0	19	67.9	5	17.9	18	?	
Ozcan et al	Turkey	2.6	2020	no	retrospective	33	33	long	0	0.0	17	51.5	5	15.2	?		
Koktekir et al	Turkey	NA	2020	no	retrospective	14	14	long	1	7.1	8	57.1	2	14.3	7		4
Hussien et al	Egypt	1.6	2022	no	retrospective	22	22	long	0	0.0	0	0	0	0	0		

\*UPROR - Unplanned return to OR  
 \*\* = Atypical

Table 2: High-level Summary of articles on Kyphectomy in chronological order

Year	n	Death	Mortality rate	UPROR*	UPROR rate %	Metal revised	Metal revised %
2000 to 2014	153	4	2.6	69	45%	51	33%
2014 to 2022	104	1	0.9	46	44%	14	14%
Total	257	5	1.9	115	45%	65	25%

Please note the following:

- 1) The data excluded case reports and papers published more than twenty years ago.
- 2) Both the patients and definitions of complications are heterogeneous.

## Appendix 3: Explanation of Certain Clinical Procedures

### Information about spinal anatomy and spinal conditions

Spines start growing as neural tubes in the early weeks of pregnancy. In some children this tube does not join up all the way along it and this leads to a condition called Spina Bifida. This gap could be in the spinal cord or the vertebrae or both. This leads to a variable anatomy, with variable impacts to the child or young person. These impacts can include neurological and muscular weakness or sometimes no neurological signals crossing the gap at all which causes total loss of nerve signals (mobility and sensation).

Scoliosis is a condition where the spine curves sideways, either in one direction or both. Kyphosis is where the spine curves outwards, with a larger degree of curve than standard anatomy or in a different place. Children and young people with Spina Bifida may also have scoliosis and / or kyphosis.

### Information about Kyphectomy

A **Kyphectomy** is a complex spinal procedure that involves removing part of the spinal bone structure (the vertebrae) and replacing it with a metal construction which fuses the spine into a straighter line, and reduces unwanted curvature. This is done when the impacts of the outward spinal curve (Kyphosis) are severe enough that the benefits of surgery outweigh the risks. These impacts include pain, difficulty sitting or lying and high risk of skin breakdown. These decisions require extensive consideration and planning between the child, their family and the clinical team. No two children or young people present with the same anatomy and functional challenges, meaning that all decisions about spinal surgery, including the optimum procedure, are bespoke.

The common version of this surgical procedure is a **standard length fixation Kyphectomy** where the metal construction continues down the spine to the pelvis and is fixed to the pelvis to provide rigidity and strength.

A variation on the procedure is described a **short segment fixation Kyphectomy**, which is where the metal construction does not reach right down to be fixed to the pelvis and relies on the vertebrae being fixed to each other. The scientific literature notes that this procedure may increase the amount a child or young person can bend, or reduce impacts on their spinal growth.

Patients who have had an index (first) Kyphectomy procedure will sometimes need planned follow-up surgical procedures. Sometimes patients have unplanned follow-up surgeries because the metal construction is failing, there is an infection, or because the metal construction is causing external effects such as skin breakdown.