

**Opening Statement by Children's Health Ireland
Oireachtas Committee on Health
Thursday September 28, 2023**

Introduction

Good afternoon. I want to thank the Chairperson and the members of the Committee for the opportunity to address you today.

My name is Eilish Hardiman, and I am the Chief Executive of Children's Health Ireland. I am joined by:

- Dr Allan Goldman, Chief Medical Officer
- Ms Paula Kelly, Clinical Director and Paediatric Orthopaedic Consultant
- Dr Ike Okafor, Clinical Director and Consultant in Paediatric Emergency Medicine.

We appear before you today, representing our 4,845 people in Temple Street, Crumlin, Tallaght and at Connolly Hospital who work diligently at the front line of healthcare in this country, delivering care through 39 clinical specialties, serving 25% of the Irish population for their national paediatric specialty needs, as well as, the secondary paediatric care needs of children and young people in the Greater Dublin Area.

Our teams treat and care for over 153,000 emergency department attendances, around 26,000 day cases, 23,000 inpatient admissions and carry out over 15,500 theatre procedures per annum.

The team at Children's Health Ireland deliver excellent care to children and young people every day, despite in most cases, dealing with outdated and inadequate infrastructure. I am very proud of our staff, the work they do, and the positive healthcare outcomes that they deliver.

The focus over the past number of days has been on matters of serious concern in Children's Health Ireland at Temple Street. The vast majority of our services in Temple Street and across Children's Health Ireland are not in any way implicated or subject of the reports that we are discussing today. Children's Health Ireland and specifically the team at Temple Street are proud of the history of care provision from that hospital – and rightly so.

An Apology

I want to begin my remarks this morning by reiterating the apology Children's Health Ireland has previously made to the children, young people and families included in the internal and external reviews that we published last week.

These reports show what we had feared when we commissioned this work. Children did not receive the level of care that they are entitled to and which they deserve.

For an organisation that exists with a singular focus which is to deliver safe, quality care to those we serve, these findings are distressing. And I know that for the patients and families involved, it is even worse.

We are deeply sorry that the children, young people and families did not get the care they deserved and apologise unreservedly for the harm that they endured.

As you know, tragically, one child that was included within the reviews has died. This child's case is the subject of a coroner's review and is also the subject of a Serious Incident Investigation.

These processes will determine the sequence of events that led to this tragic outcome, and we are committed to providing the child's family with the Incident Review Report as soon as it is completed.

All of us at CHI are distraught at this outcome. And want to offer my sympathies and profound apology to the family involved.

I also want to apologise to my colleagues and the whole CHI team for the negative focus these events have brought to Temple Street and to CHI as a whole and to thank them for their continued dedication and commitment to the children, young people and their families that they care for.

What Happened?

Things happened at CHI in Temple Street that should not have happened. Decisions were made, certain procedures were carried out, children were subjected to higher-than-expected unplanned return trips to theatre and, alarmingly unapproved, non-medical grade devices were implanted in three children.

This is a shocking litany of events.

CHI decided to commission two reviews into complex spinal surgery for patients with Spina Bifida in Temple Street which were completed in July 2023. These were triggered following the occurrence of two serious incidents and by concerns raised by staff on the surgical outcomes for these patients, on undertaken by a leading international children's hospital.

These reports will feed into the independent review that is now underway under the governance of the HSE. We welcome this external review and will co-operate fully with it.

It is essential that all aspects of these events are fully investigated, that any individual or individuals responsible are identified but more importantly that any institutional or systemic issues that contributed to enabling these events to happen are found and addressed immediately. I can assure you that actions have already been taken to prevent a re-occurrence of these events.

The Sequence of Events

As the reports identify, as soon as we became aware that the outcomes of these surgeries were not as they should have been, we acted. Dr Goldman, Chief Medical Officer, can outline these steps we have taken in response to your questions.

There is continued work ongoing with each of the patients included in the reviews to ensure continuity of care. Each child and family has received a copy of the reports, and all, except for one due to personal reasons, has had a clinical review by another Paediatric Orthopaedic Surgeon and a dedicated care pathway has commenced.

As members will also know, the clinician at the centre of this review is currently the subject of Human Resource and Irish Medical Council processes and we are precluded, to some degree, from commenting further – though we will endeavour to provide as much information to the Committee this afternoon as we can while respecting due processes and natural justice.

In addition to the apology we have already issued, I want also to apologise to children, young people and families for poor communication on our part across last week.

While we spoke and met with all 19 families whose children were the subject of the reviews, I am aware that more could have been done. I am aware too that there are families who, while their children were not the direct subject of the reviews, also feel hurt and upset. I know that children and families with Spina Bifida and others on the Spinal Surgery waiting list have been distressed by the findings of the reviews and I want to apologise to them that this has added further worries and concerns and has caused upset.

For over 150 years, excellent clinical care has been provided to children and young people in Temple Street by dedicated, passionate and talented people who get up and come in night and day to meet the needs of their patients despite the inadequate infrastructure.

I have heard the hurt and distress that the focus on CHI and Temple Street has caused to staff. I want to say to them – and to all the children, young people and families that continue to come through our doors – that best-in-class care and treatment is provided to those who need us every day, and every night, of the year.

I want to reassure parents, guardians, children and young people that high quality and safe care is being delivered by our teams of excellent staff.

The Events that led to the Current Review Processes

In terms of how it came about that issues relating to complex spinal surgeries came to our attention, I should start by saying that Spina Bifida services for children are delivered in CHI at Temple Street through a well-established and large Multi-Disciplinary Team (MDT) charged with their care. Spinal surgery by an Orthopaedic Surgeon is one element of this specialist service.

There have historically been long waiting times for access to spinal surgery for children in Ireland, including patients with Spina Bifida. This was exacerbated by the recent COVID-19 pandemic and by the cyber-attack, of which you are aware.

Supported by the increased HSE funding of €19 million to address these increased waiting times, a number of actions were taken. In April 2022, CHI at Temple Street increased the volume of complex spinal surgeries undertaken, including for patients with Spina Bifida, in order to improve access to the service.

Following the resulting increase in complex surgery activity between April and August 2022, it became evident by September that patients having complex spinal surgery were having longer hospital stays.

Concerns on surgical outcomes were raised by members of the MDT looking after these patients.

These concerns relate to higher-than-expected complication rates seen in this cohort of patients, and in particular, the high rate of unplanned returns to theatre and post-operative infection rates in patients with Spina Bifida under-going complex spinal surgery.

Following two significant incidents involving spinal surgery in CHI at Temple Street over the summer of 2022, a review of patient outcomes was commenced.

The aim of this clinical review process was:

- to assess if the clinical outcomes for these patients in the review were in keeping with other similar centres around the world;

- to evaluate if there were any specific safety concerns requiring response by CHI;
- and to seek recommendations to continuously improve the treatment and management of this complex group of patients.

These surgical procedures are extremely complex and involve insertion of metal rods into the patient's spine in an effort to correct its curvature. These are high risk surgeries, with high post-operative complication rates.

Concurrently, with commissioning this review in November 2022, the clinician elected to pause the most complex spinal surgery – known as a kyphectomy procedure - for patients with Spina Bifida until the outcome of the external quality review was available. This decision was supported by CHI.

The Use of Unapproved Springs

Members will, of course, be concerned about the unauthorised use in spinal surgeries of unapproved non-medical grade devices – or in other words, 'springs'.

Quite frankly, this is an unprecedented occurrence and is truly shocking.

The facts around this matter will be the subject of a serious incident investigation. This investigation will examine end-to-end processes within the hospital – including procurement and custody of these items. It will also look at who knew that non-medical grade devices were being used, how they were procured and why, at no stage, did someone say stop.

While innovative approaches to care might be considered on one-off compassionate grounds, it is unheard of for any clinician determine to use a non-approved non-medical grade device in a patient. It is simply not done.

No approval was granted and none would be granted for a non-medical grade device to be implanted.

The wider Scoliosis and Orthopaedic Surgery Programme at Children's Health Ireland

Obviously, I am aware that there is justifiable scrutiny not just of the specific complex spinal surgeries of concern to the review process, but to the wider Spinal Surgery and Scoliosis Programme in Children's Health Ireland.

While the ongoing issues relating to access to surgery, and unacceptably long waiting times, are not the subject of the review they are the subject of our concern.

We are keenly aware of the huge problems caused to children, young people and their families due to long waiting times, and I am happy to discuss that issue with you as well.

I want to put on the record, at this point, that on foot of the increased funding that I referred to, at the end of 2022, Children's Health Ireland (CHI) and the National Orthopaedic Hospital Cappagh (NOHC) had completed 509 spinal procedures. This was a 47% increase in activity compared with 2021, which equated to 162 more children who have had their spinal surgery. There has also been a 57% increase in children added to our spinal surgery waiting list. We are doing all we can to reduce waiting times and will continue to do so.

These surgeries are happening every week in our hospitals and making a profoundly positive impact on the lives of the children who receive them.

The Scoliosis and Spina Bifida action plan 2023/2024 is a two-year plan and builds on the work completed in 2022. The plan has been developed taking into account the learnings from 2022, particularly the impact of increased complexity of care on the acute hospital sites. The aim of the plan is to treat children and young people on the waiting list for complex spinal surgeries. Enhancing capacity to support spinal surgery includes the following (taking these as read):

- An additional theatre at CHI at Temple Street – October 2023
- Transfer of the intrathecal chemotherapy procedures from the theatre environment in CHI at Crumlin to a new location within the hospital to provide additional theatre capacity – November 2023
- Additional MRI scanner at CHI at Crumlin to support diagnostics associated with spinal surgery – October 2023
- Additional MRI Saturday sessions in CHI at Temple Street for children requiring general anaesthesia to support diagnostics associated with spinal surgery - October 2023
- Additional bed capacity in both CHI at Crumlin and CHI at Temple Street, 8 beds in total (4 on each site) - October 2023/November 2023
- National outsourcing of adolescent idiopathic (non-complex) scoliosis patients to private providers - in progress
- National outsourcing of general orthopaedic patients to private providers in Ireland and Northern Ireland in progress, to provide additional capacity for spinal surgery
- International outsourcing - CHI continues to build relationships with Boston Children's Hospital

<u>2023 Spinal Fusion Targets</u>	<u>2023 Spinal Other Targets</u>
CHI at Crumlin 158 CHI at Temple Street 23 NOHC 40	CHI at Crumlin 145 CHI at Temple Street 96

- To date CHI and NOHC have achieved 64% of the Spinal Fusion 2023 target
- To date CHI and NOHC have achieved 59% of the Spinal Others 2023 target
- The surgical management of all complex spinal surgery for patients with Spina Bifida is moving to CHI at Crumlin - in progress.
- A multidisciplinary team and non-spinal management of Spina Bifida patients is remaining in CHI at Temple Street. The group of Orthopaedic Consultant Surgeons who are managing complex spinal surgeries going forward is agreed.
- A CHI complex spinal surgery programme working group is in place to oversee, develop and implement the complex spinal surgery service in CHI at Crumlin, in line with the recommendations from the reviews

What we have done and are doing to make our Service Better

As has been stated in the reviews, CHI staff are committed and motivated to provide safe, effective, patient-centred and efficient care to patients with Spina Bifida to improve clinical outcomes. We care deeply about the quality of that care.

We have already spoken to the families of those patients whose cases are the subject of this review and shared findings.

I want to put on the record, too, that last week we have also spoken to four advocacy groups and briefed them on the review's findings, although I accept their unhappiness at that communication process.

Without in any way seeking to qualify the apologies that we have given, it should be said that complex spinal surgery in Spina Bifida children, unfortunately, has high complication rates. However, in these cases the level of infection was above what would have been expected and is unacceptable.

Children's Health Ireland has already acted on the recommendations made in the two reviews published last week and are committed to fully cooperate in the external review that has been announced by the HSE.

In particular, complex spinal surgery procedures for patients with Spina Bifida will now take place in CHI at Crumlin.

Open Disclosure commenced in August for patients and families in these reviews. Serious incident investigations are well advanced for the two spinal surgery incidents, with Open Disclosure and sharing of investigation reports with families.

The rollout of the CHI Professionalism Programme and the changes in Quality and Safety measurement and monitoring will be taken forward to address issues relating to culture and supporting our clinical teams to speak up about concerns.

We value patient safety, and we want our team members to speak up when they want to or when they feel they need to. And as I have said, the surgeon involved in these cases is no longer carrying out these surgeries and is in a Human Resources and Irish Medical Council process.

We are reviewing all aspects of our Governance and Risk and Safety processes and procedures.

As One CHI, and prior to our move to the new children's hospital, massive change and integration is underway.

Since April of this year, we are working as a 'cross city site' rather than as individual hospitals. This has resulted in more consistency and streamlining of processes, policies and procedures. Quality, risk and safety will all be overseen and managed by a single framework rather than on a site-by-site basis.

We will, in time, develop one single set of processes and guidelines across all our sites. And while we cannot do this overnight, our priority is to ensure that any gaps identified in those processes are addressed as soon as possible.

To be clear, we are implementing the review recommendations now – 20% are already completed with the remainder are all underway, scheduled to be completed by the end of this year.

Conclusion

To conclude, our job now, in implementing the recommendations of the reviews published last week and in working with the HSE on the wider review, is to ensure with certainty that the highest quality, safe care is provided to all children and young people at all times, as soon as is possible. We have listened to the issues raised by the Advocacy Groups and also intend to improve our communications.

While we have a road to travel, we will then focus on rebuilding trust and confidence amongst the children, young people and families who need services in CHI at Temple Street.

We are here to listen and work with children, young people, families and their representative bodies, all of whom have suffered as a result of what happened.

We will also provide whatever supports are necessary for patients, families and staff that have been hurt and upset by these revelations.

Thank you for giving me the time to address you and we will now hear your thoughts and answer your questions.

Eilish Hardiman
Chief Executive
Children's Health Ireland
27 September 2023

ENDS