Health Information and Quality Authority

An tÚdarás Um Fhaisnéis agus Cáilíocht Sláinte

Executive Summary: Independent review of governance at Children's Health Ireland in the use of implantable medical devices, including the use of non-CE marked springs in spinal surgery at CHI at Temple Street

A statutory review conducted under section 8 of the Health Act 2007 (as amended)

8 April 2025

About the Health Information and Quality Authority

The Health Information and Quality Authority (HIQA) is an independent statutory body established to promote safety and quality in the provision of health and social care services for the benefit of the health and welfare of the public.

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Executive Summary

This report sets out the findings of an independent review conducted by the Health Information and Quality Authority (HIQA) — in line with HIQA's remit under section 8(1)(c) of the Health Act 2007 (as amended) — into significant public concerns about certain paediatric spinal surgery procedures undertaken at Children's Health Ireland (CHI)[*] at Temple Street Hospital, Dublin, where non-CE marked[†] metal springs were implanted.

In November 2023, HIQA commenced examining the circumstances that had given rise to these concerns following a request from the Minister for Health on 4 October 2023. Terms of Reference for the review were developed and published on www.hiqa.ie. In accordance with its remit, HIQA assessed compliance against eight of the *National Standards for Safer Better Healthcare* relevant to the terms of reference for this review.

The review team engaged with a range of people who had relevant input to the review, including a number of families of the children impacted by the use of the non-CE marked springs, advocacy groups, and management and front-line staff in CHI. Input from a number of specialist experts was also included as part of this review.

At the centre of this review are the experiences of the children and families using the orthopaedic spinal surgery service in CHI at Temple Street. HIQA acknowledges the cooperation of those families who engaged with the review team and who provided valuable insights into their experiences of the service, having been directly affected by the use of the non-CE marked metal springs. HIQA would also like to acknowledge the cooperation of the management team and staff in CHI.

Background and scope of this review

Paediatric spinal surgery services are provided at two CHI sites: CHI at Temple Street and CHI at Crumlin.

[*] CHI comprises four hospital sites in Dublin: CHI at Temple Street, CHI at Crumlin, CHI at Tallaght (co-located with the adult Tallaght University Hospital) and CHI at Connolly (co-located with the adult Connolly Hospital Blanchardstown). Paediatric services at CHI at Tallaght and CHI at Connolly are jointly managed by CHI for governance purposes and are regarded as a single site within CHI.

[†] CE mark (Conformité Européene): Many products (including medical devices) require CE marking before they can be sold in the EU. CE marking indicates that a product has been assessed and deemed to meet EU safety, health and environmental protection requirements. It is required for products manufactured anywhere in the world that are then marketed in the EU. The requirements will depend on the product type and its intended purpose.

In September 2023, it emerged publicly that non-CE-marked equipment (in the form of metal springs) had been surgically implanted into a number of children who underwent spinal surgery at CHI at Temple Street. This led to concern among the families of the children affected and the wider public. This issue emerged alongside wider public concerns around the quality and safety of orthopaedic services at the hospital.

As a result of these concerns, the Minister for Health requested that HIQA carry out an independent review to monitor compliance with national standards, in accordance with HIQA's remit under section 8(1)(c) of the Health Act 2007 (as amended), into the end-to-end processes around the use of non-CE marked springs at CHI at Temple Street. The request also incorporated a review of the governance and oversight of processes in place within CHI on the use of surgical implants and or implantable medical devices.

This review covers the period from November 2018, when the use of the springs was first considered as a possible treatment option for a small cohort of children attending CHI at Temple Street, to July 2023, when it was confirmed internally by CHI that the springs implanted into a number of children during spinal surgery, between 2020 and 2022, were not CE marked.

Findings on governance and management arrangements at Children's Health Ireland

In 2013, the then Minister for Health established the Children's Hospital Group Board (CHGB), initially on a non-statutory or administrative basis with a remit to integrate the three children's hospitals in Dublin, develop a single clinical and corporate governance for paediatric services and act as client for the new children's hospital capital project in Dublin.(1) The three children's hospitals included Our Lady's Children's Hospital, Crumlin, and Temple Street Children's University Hospital, together with the paediatric services of Tallaght University Hospital. For context, administratively, the three pre-existing children's hospitals which currently comprise CHI had separate management and governance structures prior to 2019. In these structures, each of the three children's hospitals were governed by their respective boards up until 1 January 2019.

The Board of Children's Health Ireland (CHI) became effective from 4 December 2018, and on 1 January 2019 CHI was commenced as a statutory body under the Children's Health Act 2018. The children's hospitals and the paediatric services of Tallaght University Hospital merged into a single entity as CHI, under the

governance of a single CHI Board.[‡] In the planning for the move to the new National Children's Hospital,[§] CHI developed revised corporate and clinical governance arrangements to support delivery of patient care across its sites.

HIQA found that CHI was experiencing significant organisational and transformational change between November 2018 and July 2023. In parallel, the pre-existing children's hospitals were also preparing to move to the new purpose-built National Children's Hospital.[±] This change is ongoing.

In September 2020, as part of these governance changes, the CHI executive management team started to introduce new management arrangements. The hospital site-specific CEO positions in CHI at Temple Street and CHI at Crumlin were stood down and the clinical directors for the hospital sites assumed overall site management responsibility for these sites. A single clinical director was appointed as an executive lead at both CHI at Tallaght and CHI at Connolly.

In 2021, in further changes, these clinical directors were appointed to lead three new clinical directorates across all hospital sites in CHI (each of the three clinical directorates covers 12 to 14 clinical specialties). This cross-city clinical directorate structure was fully implemented in April 2023. Each clinical directorate was supported by a director of nursing and a directorate operations lead, known collectively as the clinical directorate triumvirate management team.

In this structure, the clinical directors retained their responsibilities for managing individual hospital sites, while also working to develop the new clinical directorates cross city in preparation for moving into the new hospital, and also maintaining varying clinical commitments.

In practice it meant:

- Each clinical director chaired two teams — a local hospital site-based management team and a CHI-wide clinical directorate (triumvirate) team covering a range of clinical specialist areas.
- The structure of these six teams included nine team members in total, three of whom were the clinical directors. The teams reported across multiple channels.
- Each team member sat on both a local hospital management team and a cross-city clinical directorate triumvirate team.

[‡] The facility at CHI at Connolly was opened in July 2019.
[§] Being constructed in Dublin and under development at the time of writing.

HIQA found that these governance arrangements were overly complex and placed an onerous and unrealistic workload expectation on the clinical directors and senior managers operating within this structure. These arrangements did not lend themselves to clear lines of reporting and oversight of operations on a day-to-day basis at each of the hospital sites for the delivery of high-quality, safe care.

The change in governance arrangements had a greater impact at CHI at Temple Street. Given the smaller number of clinical specialty services provided at CHI at Temple Street, changes to the governance arrangements meant that some structures, including some key members of existing senior management, moved off site. Prior ways of working were disrupted and the governance arrangements at the hospital for front-line staff delivering services at CHI at Temple Street became less clear under the new structures.

This clinical governance structure across CHI meant that doctors reported to a clinical director for operational matters and a cross-city Chief Medical Officer (CMO) for professional matters through the clinical director. HIQA found that these arrangements were complex and did not lend themselves to clear and accountable governance and may have affected the ability for those responsible for the service to effectively oversee the delivery of care.

To support the clinical directors in the cross-city integration of clinical specialties, clinical specialty leads were being appointed within each specialty; however, these appointments and the implementation of these roles were at various stages of development across the specialties at the time of this review. HIQA found that the clinical specialty lead roles at CHI are considered to represent a leadership role within their specialty, rather than a formal line management role with clinical governance responsibilities integrated into the wider governance structures in CHI.

Paediatric orthopaedic services at CHI at Temple Street

During this review, HIQA found that the orthopaedic service in CHI at Temple Street had been affected by long-standing issues with communications and team dynamics. HIQA also found that CHI at Temple Street had been experiencing sustained challenges in providing timely access to paediatric spinal surgical services for many years, with long waiting lists for children.

For context, in 2019, the senior management team at CHI at Temple Street recognised that there were behavioural and cultural issues within the orthopaedic department and sought external input over the following two years as a management intervention to address the challenges within the service. CHI management had been reporting to the CHI Board on issues in the orthopaedic service at CHI at Temple Street, including the management intervention, from July

2021. Two serious incidents were reported within the service in 2022 which led to both internal and external reviews focusing on clinical outcomes for patients.

In HIQA's view, the cultural issues on the orthopaedic surgical team were a significant factor in the introduction of the springs, as they impacted on important and relevant questions not being raised at various steps, in the absence of a formal process also not being followed, which are described in more detail below.

Key findings related to governance for the introduction and use of medical devices at CHI

The safe introduction and use of medical devices and surgical implants requires specific governance arrangements across a number of departments and functions within a hospital. HIQA found that while there were some arrangements in place at local hospital site level, relevant structures and processes were not in place for all of these functions. In addition, there were no overarching CHI-wide standardised governance structures and supporting policies and procedures in place for the introduction and use of medical devices. In the absence of standardisation across CHI, HIQA reviewed the individual governance arrangements in place in CHI at Crumlin and CHI at Temple Street for the introduction and use of medical devices. These included policies, processes and practices for the relevant regulatory requirements, research and ethics, procurement, approval mechanisms, decontamination and theatre.

In Ireland, the use of surgical implants in patients is governed by the EU and Irish legislation. The EU Medical Device regulatory framework was first put in place in the 1990s. The current framework is the Medical Device Regulations (MDR), which became fully applicable in Ireland in May 2021. Prior to this, medical devices were covered by the General Medical Devices Directive (MDD).

HIQA found there was a lack of formal documented procedures to be followed within CHI for the introduction and use of a non-CE marked medical device in any of the specific circumstances where a non-CE marked medical device could be used under the regulatory frameworks in place.

HIQA found that a comprehensive suite of procedures for the introduction and management of all aspects of the Medical Device Regulations (MDR), or the previous regulatory framework which applied from 1994 to 2021, was not in place across CHI.

There were well-established research and ethics committees at both CHI at Temple Street and CHI at Crumlin sites and these committees were integrated to form a single CHI Research Ethics Committee with an agreed terms of reference from August 2021.

CHI at Temple Street and CHI at Crumlin were operating in the absence of an overarching CHI-wide framework for the governance and approval of medical devices. HIQA also found that there were no formal multidisciplinary processes for assessing and approving implantable medical devices at CHI at Temple Street. As a consequence, the approval process, where followed, was described to HIQA as falling to the relevant clinical director. HIQA determined that this was inadequate to ensure effective oversight. The arrangements for the management of medical devices at CHI at Temple Street were not functioning in line with the HSE medical device equipment management policy.

At CHI at Temple Street, there was no formal mechanism for CHI senior management oversight of the functioning of the Medical Device Equipment Management Committee or the management of health technology and medical devices. In addition, there was no committee in place to approve and oversee the introduction of class III medical devices,[**] including implantable medical devices, at CHI at Temple Street.

HIQA found each hospital site operated with a separate procurement process. CHI at Crumlin had a centralised procurement function for the purchasing of all goods, while CHI at Temple Street had a system whereby certain departments could order products directly from the supplier through the business management system.

For the time frame covered by this review, HIQA found that while there were local decontamination structures and processes in place at CHI at Crumlin and CHI at Temple Street, the structures and processes for decontamination were not standardised across both sites.

There was no standardised set of policies and procedures for theatres across the CHI at Temple Street and CHI at Crumlin sites up to November 2023. HIQA reviewed the processes in place on these sites for the ordering, record-keeping and governance related to implantable medical devices and found that there were opportunities for improvement in the recording and documentation of the specifics of medical devices in CHI at Temple Street. HIQA noted there has been a single manager in place for theatres across both sites since December 2023 and CHI was moving to standardise its practice in theatres across its hospitals and there was a recently established CHI wide theatre governance committee in place.

[**] Class III medical devices include implantable medical devices and in this case would have included consideration of the springs.

Since commencement of this review, HIQA found evidence of evolving good practice for the management of field safety notices[††] on their receipt, with plans to integrate this practice as part of the newly established CHI-wide medical devices management structures and committee.

At the time of the review there were no standardised processes in place across CHI in relation to the governance for the introduction and use of medical devices in practice.

Furthermore, the governance changes at CHI in terms of hospital site and clinical directorate management introduced during a series of changes that occurred from 2020 to 2023, resulted in some gaps in hospital site governance structures at CHI at Temple Street.

HIQA found that these governance arrangements became increasingly complex and unwieldy through a series of changes. Crucially, these changes made to structures, senior leadership responsibilities and reporting lines did not fully take in to account a consolidation of key safety governance committees and approval processes that remained at hospital site level. This resulted in a misalignment of governance and reporting lines as it related to the introduction and use of medical devices at CHI at Temple Street. This had implications for ongoing clinical oversight of the spinal surgery services at CHI at Temple Street during the timeframe covered by this review. In particular, this is evident in the absence of the identification by CHI at Temple Street, of the further use of the non-CE marked springs in the surgery that was carried out in 2022.

In addition, the lack of standardisation in newly developing structures resulted in unclear lines of reporting and accountability across the wider organisation of CHI to ensure the safe introduction and use of new surgical implants and implantable medical devices. As a consequence, the governance model did not allow for effective oversight and assurances by the CHI Board to ensure that there were adequate safeguards in place to support consistent and safe practices within and across services in CHI to ensure the delivery of safe quality services involving medical devices during this time period.

Following a site visit to CHI at Temple Street, HIQA wrote to CHI's Acting CEO on 29 November 2023 to outline its concerns about the governance, management and oversight of medical devices at the hospital.

[††] Field safety notice: communications sent out by medical device manufacturers or their representatives in relation to actions that they may be taking in relation to their product that is on the market. These are published by the manufacturer and or published by the Heath Products Regulatory Authority (HPRA). Notices are issued for a wide range of products such as laboratory chemical products, cardiac monitors, medication infusion devices and implantable medical devices.

CHI confirmed to HIQA in December 2023 that immediate actions were underway to address HIQA's concerns around governance arrangements. These included the introduction of a revised medical device management system. In December 2024 and March 2025, CHI confirmed to HIQA that the CHI Medical Device Management System was established with ongoing supporting work planned around operations and communication with CHI staff.

HIQA acknowledges the work undertaken by CHI to develop these newly established structures; however, it was too early for HIQA to evaluate their effectiveness at the time of concluding this review.

Key findings related to the end-to-end process for the introduction and the use of the non-CE marked springs as surgical implants at CHI at Temple Street

The review team established that between 2020 and 2022, non-CE marked springs were implanted into three children who had undergone spinal surgical operations at CHI at Temple Street. They were used as an addition to a well-established and completely separate conventional growing-rod system in use in the hospital for treating irregular curvatures of the spine, a condition called scoliosis.[≠]

The review team is of the opinion that the use of the springs formed part of a well-intentioned but ill-considered effort to provide an alternative approach to surgical treatment, involving a single operation, for a number of children with life-limiting conditions at CHI at Temple Street who had otherwise been facing multiple operations, each with its associated risks. HIQA found through this review that the use of the non CE-marked springs as surgical implants was wrong.

The surgeon who conducted the surgical procedures using the springs, known in this report as Surgeon A, attended an expert international orthopaedic conference on early onset scoliosis in 2018 where a team of researchers from The Netherlands presented the initial findings of a new implantable 'spring-distraction system' for the treatment of scoliosis. Medical-grade titanium springs, manufactured by the university, were used in this study. The research team from The Netherlands told HIQA that they were not contacted by Surgeon A at any time to discuss their research.

Regulatory and ethical considerations

HIQA found there was a lack of formal documented procedures to be followed within CHI for the introduction and use of a non-CE marked medical device in any of the

[≠] Scoliosis develops when the vertebrae (the 33 small bones of the spine) grow in a curved shape and sometimes twist like a cork screw instead of growing correctly.

specific circumstances where a non-CE marked medical device could be used under the regulatory frameworks in place.

A research ethics oversight process was in place in CHI at Temple Street at the time when the springs were being considered for use. The terms of reference included the requirement for an application to be made to the committee for consideration for ethical approval in circumstances where the intended treatment required a change from accepted standards of clinical care. This would have been the appropriate course of action for a proposed new technique, such as that involving the springs.

HIQA found no evidence of any engagement with the formal ethical approval mechanisms and processes, for example, the Ethics and Research Committee, took place to support such an approach in advance of the springs being used.

HIQA found that there was no evidence that the introduction and use of the springs as implants in spinal surgery at CHI at Temple Street had been identified, described or formally enrolled in a clinical investigation, clinical study or clinical trial.

Multidisciplinary approach

HIQA found there were no formal structures and processes in place to support the surgical multidisciplinary team at CHI at Temple Street.

This review found that there were a number of underlying challenges, which may have contributed to a lack of questioning and debate about a proposed new technique. Had a formal multidisciplinary structure been in place, it might have mitigated the surgical safety issues and risks of using a non-CE marked medical devices in orthopaedics at CHI at Temple Street.

These challenges included problems with team working, poor processes for communication and documenting of associated actions, lack of a formal multidisciplinary structure or a single multidisciplinary team, or a standardised process to enable effective interaction between the two multidisciplinary teams. There was also an apparent absence of a culture which supported questioning — as described through prior management interventions. HIQA is of the view that the lack of formalised structures for the surgical multidisciplinary team and absence of integration with the spinal multidisciplinary team contributed to failures in the clinical governance of surgical safety in orthopaedics at CHI at Temple Street.

Had a fully functioning and effective multidisciplinary meeting process been in place, there may have been opportunities for more considered discussion and shared understanding amongst the multidisciplinary team that the implanting of the springs was not a usual practice.

Corporate and clinical governance approvals

HIQA could not identify any evidence to demonstrate that there was any written approval from any senior manager in CHI to sign off on the use of the springs or the spring distraction system in those procedures where springs had been implanted.

HIQA reviewed documentation that demonstrated that at all times during the time frame of this review, there was a senior clinician (for example, a clinical director) in post at CHI at Temple Street and across CHI who could be contacted in the event of an unusual or new treatment being considered. These post-holders were not made aware of the intended use of the springs nor of the new nature of the surgery.

Sourcing and procurement of the springs

CHI at Temple Street had a Medical Device Equipment Management Committee (MDEMC) in place for the procurement of specific medical device equipment, which required the relevant safety checks to be carried out prior to use. This process was supported by the CHI at Temple Street Clinical Engineering Policy from 2018 to 2020. However, these controls did not cover implantable medical devices. HIQA found that no formal structures and processes were in place for the consideration and approval of class III implantable medical devices in place at CHI at Temple Street.

HIQA found the absence of a clear and standardised process to support the requirements for authorising, assessing and ordering specialist medical devices at CHI at Temple Street was a key failure in mitigating the risks of miscommunication between key disciplines about the intended use of the springs.

Furthermore, HIQA confirmed that there were no controls in place to carry out any type of safety and technical checks on the springs prior to authorisation for purchasing regardless of their intended or presumed use. At no time throughout the purchasing process did the HIQA review team see any request for evidence of CE certification or any related manufacturer's documentation for the springs. This represented a key failure and a missed opportunity to access information on the springs that would have indicated that they were unsuitable for use as surgical implants.

In purchasing the springs at CHI at Temple Street, the local process of raising a purchase order number through the hospital business management system and applying it to an order form was not followed. The springs were not ordered, tracked or recorded on the business management system in line with the local practice or national procurement policy as set out in the 'HSE National Financial Regulations – Purchase to Pay'[(3)] 2006, nor were they listed on the hospital product database. This

meant the springs arrived in the hospital outside of the stores office, which later hindered traceability of the delivery of the springs to the hospital.

HIQA found that Surgeon A engaged with the then Principal Clinical Engineering Technician at CHI at Temple Street to purchase the springs. HIQA found there was an absence of structures and processes to support clear and adequate communication between Surgeon A and the Principal Clinical Engineering Technician on the intended purpose of the springs.

Decontamination and traceability

During the time period covered by this review, good decontamination systems were in place in CHI at Temple Street that aligned with the HSE's recommended practices.* However, there was a significant deviation from this policy in respect of the springs within the central decontamination unit at the hospital. Despite evidence of some efforts to obtain the required information for processing and decontamination (sterilisation instructions), the springs were processed in the absence of this information, contrary to local and national policy. HIQA found there was an absence of structures and processes to support clear and adequate communication between Surgeon A and the Decontamination Manager around the details on the sterilisation process for the springs.

The decontamination tracing system did not allow for a dedicated unique identifier to be applied individually to each spring. This lack of a unique identifier being applied to each spring meant that each spring could not be tracked individually when scanned for use in theatre or when the remaining springs went through subsequent decontamination cycles.

Consent

The National Consent Policy 2013 sets out that a cornerstone of securing consent is ensuring the availability of all relevant information to the patient to enable them to be fully informed prior to giving consent. This policy was in use across HSE and HSE-funded healthcare services, including CHI at Temple Street, during the time the springs were used as implants.

Given that the use of the springs had been described to HIQA by Surgeon A as "bespoke and experimental", HIQA found no evidence of written records to demonstrate appropriate detailed discussions with parents in line with the National Consent Policy 2013. Furthermore, HIQA found no evidence of any description of any written information provided to the parents to read, regarding the use of the

* Health Service Executive Standards and Recommended Practices for Central Decontamination Units (2011).

springs and the new nature of the intended surgery in seeking to replicate the spring distraction system.

If the spring distraction system was being conducted as an innovative procedure, and possibly a research study, HIQA found the level of documentation and information provided to the families was wholly inadequate to describe the exact nature of the intended procedures.

As such, HIQA found that while CHI was operating within the national policy for consent, in these cases, consent for these surgeries was not fully informed. Therefore, for the surgical procedures where the springs were implanted, the consent process carried out within the spinal surgery service, was not in line with the National Consent Policy 2013.

Theatre

HIQA found that the processes in the operating theatre for identifying all instruments and equipment available for use during a procedure was ineffective as the processes did not identify that the springs were an additional component to be used alongside the conventional spinal surgery system used for spinal surgery in CHI at Temple Street.

Theatre staff present during the surgical procedures where springs were implanted did not receive any training or information in advance of the procedures to indicate an additional item was to be used together with the conventional spinal rod system. There was no documentary evidence seen by HIQA to demonstrate that the use of these new springs had been highlighted to the surgical theatre team at any point of the surgical procedures.

HIQA found that there were structures and processes in place for communication across the surgical theatre team along the continuum of care — before, during and following surgical procedures — but they were not effectively used in the case of these procedures. Collectively, these findings represented a key failure and a missed opportunity to question the suitability of the springs for use as surgical implants.

Specification of the springs and their use as part of a medical device system

HIQA found the springs ordered were made of a material called non-alloyed spring steel. This is different to the initial description of the springs provided by Surgeon A during interview to HIQA, which described the product ordered as being made of medical grade stainless steel, a material sometimes used for surgical implants. This is important because non-alloyed spring steel is not used for surgical implantation. It is known to corrode in the presence of moisture and there is very limited information available on its use or the risks of its use for implantation.

Ongoing care for children and families affected by this review

At the centre of this review are the children and families using the orthopaedic spinal surgery services in CHI at Temple Street, and particularly the three children who had these springs implanted.

During the conduct of this review, CHI provided a number of updates on the care and management arrangements for the ongoing care in place for the three children who had the springs implanted and the wider patient cohort attending the spinal surgery service at CHI at Temple Street.

On 16 April 2024, upon learning of the risk of the material composition of the springs implanted, HIQA escalated the potential risk to patients to the direct attention of CHI management. This letter sought confirmation from CHI that there was an appropriate clinical response and care plan in place for patients and that the issue had been fully disclosed to the impacted families. Subsequently, CHI confirmed to HIQA on 29 April 2024 that open disclosure on the composition of the springs had taken place and that the potential for further risks associated with the use of the material implanted was being considered in terms of the ongoing care needs of the affected children.

Throughout this review, in listening to the experiences of the families affected, HIQA found that there were opportunities for CHI to be more proactive in the ongoing care and support of affected children and their families, particularly when things go wrong. This applies in the context of both the issues that are the subject of this review and the ongoing wider challenges being experienced in the provision of spinal surgery services at CHI. This represents an area for ongoing improvement and focus for CHI following the publication of this report. It is vitally important that children's healthcare services are supported by a child-centered approach.

Overall Conclusion

While corporate and clinical governance arrangements were in place at CHI at all times during the time frame covered by this review and beyond, the organisational change and associated revisions of governance structures from January 2019 onwards were not clear or easy to understand for all staff at either hospital-site or clinical directorate level.

The lack of standardisation in newly developing structures resulted in unclear lines of reporting and accountability across the wider organisation of CHI to ensure the safe introduction and use of new surgical implants and implantable medical devices.

HIQA found that supporting policies and procedures for services, such as for the introduction and use of implantable medical devices — were either not in place,

were not fit for purpose or were not followed. This meant that there were no formal assurance mechanisms in place for the effective oversight by CHI of the introduction and use of the non-CE marked springs in spinal surgery at CHI at Temple Street. In CHI at Temple Street, there was an absence of a clear and standardised process to support the requirements for authorising, assessing and ordering specialist medical devices which was a key failure in terms of the governance and oversight for the introduction and use of the springs.

While there were a number of controls in place, these did not provide adequate safeguards at each stage of the end-to-end process for the introduction and use of the springs. This occurred across a number stages in the process, including approvals processes, multidisciplinary teams, procurement, decontamination and use in theatre.

HIQA also found that the absence of questioning and verification was accompanied by a failure to adhere to policy and process in some instances with numerous missed opportunities to identify and prevent the use of the springs in the surgery of three children spanning the period from 2020 to 2022.

In tandem, there were underlying challenges that may have undermined effective team working and the promotion of a culture of questioning within and across teams. Overall HIQA found that due to failures in the design and delivery and oversight of end-to-end processes and controls within the spinal service at CHI, children were not protected from the risk of harm.

Ultimately, at the centre of this review are the experiences of the children and families using the orthopaedic spinal surgery service in CHI at Temple Street, in particular, those having been directly affected by the use of the non-CE marked metal springs.

HIQA acknowledges the cooperation of those families who engaged with the review team and who provided valuable insights into their experiences of the service. HIQA would also like to acknowledge the cooperation of the management team and staff in CHI.

HIQA found a number of non-compliances with the *National Standards for Safer Better Healthcare* in the governance and oversight of processes within CHI on the use of surgical implants and or implantable medical devices, including the use of non-CE spring implants during spinal surgery in CHI at Temple Street.

HIQA acknowledges the work done by CHI to date to introduce a revised medical device management system for CHI and to implement measures for the ongoing care for children and families affected by this review.

As a result of this review, HIQA has identified national learnings in relation to the governance of implantable medical devices and surgical implants for healthcare services with regard to:

- Governance for the introduction and use of implantable medical devices and surgical implants
- Corporate governance requirements during periods of organisational change
- Clinical governance, clinical accountability and clinical autonomy
- Medical device and surgical implant traceability
- The critical importance of organisational culture, including effective multidisciplinary working and communication for patient safety
- Futureproofing medical device introduction, innovation and use in practice at a time of major technological and regulatory change.

Based on the findings of this review, HIQA has made nine recommendations specifically for implementation by CHI and nine recommendations for implementation nationally by the HSE in all healthcare services, provided or funded by the HSE and one recommendation for implementation by all healthcare services, both those provided by private hospitals and those provided or funded by the HSE.

All healthcare services should consider the findings and recommendations of this report and use them as learnings to formally review and where necessary improve their governance and oversight of the introduction and use of medical devices, including surgical implants.

Recommendations

Recommendations to be implemented by Children's Health Ireland (CHI)

Reference	Recommendations
R1.CHI	CHI must review current organisation-wide corporate and clinical governance arrangements to ensure clarity and effective assurance of safe, quality care. Revised governance arrangements should ensure clarity around reporting lines, roles, and individual and collective accountability for clinical and operational oversight of services – from the CHI Board and the Executive Management Team to the frontline on clinical, operational and safety matters. As part of these changes, mechanisms to enable assurance around patient safety, patient experience issues with better patient input, and audit of policy and procedure implementation at CHI Board level should be put in place. Key to this is the development and implementation of standardised policies, procedures and processes, where they do not currently exist. This is required to ensure adequate safeguards are in place to support consistent and safe practices within and across services in CHI, and in particular to support the amalgamation and transition of services into the new National Children's Hospital.
R2.CHI	CHI must review the span of responsibilities of clinical directors across CHI with regard to operational management, clinical practice and clinical directorate development and ensure post holders are fully supported to carry out their roles effectively and in line with best practice.
R3.CHI	CHI must review the role of clinical specialty leads to ensure that: ▪ the roles and responsibilities of all clinical specialty leads are formalised with clear lines of reporting ▪ that each position holder has clear authority and accountability for leadership within their assigned specialty ▪ the role enables a greater level of support available for Clinical Directors in the exercise of their executive duties.
R4.CHI	CHI must review the governance arrangements for multidisciplinary team working in the orthopaedic service across CHI to ensure that: ▪ there are formalised structures and processes in place for effective multidisciplinary team working, management and oversight

	▪ there are clear terms of reference for multidisciplinary teams to include representation by all relevant clinical services ▪ there is a clear and agreed approach to effective decision-making, including meeting records ▪ orthopaedic multidisciplinary teams are patient centred, accountable, open and transparent.
R5.CHI	CHI must develop a formal plan to address and resolve any outstanding issues relating to culture and alleged interpersonal relationship challenges within the orthopaedic services and any other services where such issues may be present so that patients are at the heart of service delivery. Full implementation, monitoring and evaluation of this plan must be supported by clear visible leadership from the Board, CEO and Executive Management Team within CHI to drive the effective delivery of this plan.
R6.CHI	Within three months of the publication of this report, CHI should fully implement and embed its Medical Device Management System, with the associated checks and controls, to include ongoing monitoring and evaluation. This system should be aligned with national policy, best practice guidelines, regulation and statutory requirements and include the full lifecycle of medical devices from initial sourcing, through evaluation, procurement, decontamination, and use in theatres to disposal. The operation and implementation of the system must involve a multidisciplinary approach, with both clinical and technical expertise through the implementation of a Quality Management System to ensure checks, controls and processes to support safe and effective clinical practice.
R7.CHI	CHI must review its overall approach to communication with children and families on an ongoing basis, particularly when things go wrong or when care needs are complex, to ensure a more effective, empathetic and child-centred approach. This revised approach should ensure that the needs of all children and families – in terms of access to specialist services, advice and supports – are responded to effectively to ensure safe, timely access to care. CHI should ensure a particular focus on this requirement where the clinical conditions and the care needs of the children are complex.

R8.CHI	CHI must audit and assess its compliance with the HSE National Consent Policy and progress improvements where necessary to ensure the correct application of the policy across all aspects of care.
R9.CHI	CHI must immediately develop a Quality Improvement Plan for implementation of these recommendations. Implementation of this plan should be overseen by the HSE as part of its performance management arrangements with CHI, with clear timelines and named identified individuals with responsibility for implementation of each recommendation.

Recommendations to be implemented nationally by the HSE in all healthcare services, provided or funded by the HSE

Reference	Recommendations
R1.HSE	The HSE should develop a detailed and costed implementation plan – informed by an immediate gap analysis at institution level – to support healthcare services, provided or funded by the HSE to achieve and maintain full compliance with the EU Medical Device Regulation (MDR).
R2.HSE	The HSE must establish a centralised, national approach to multidisciplinary assessment and expert interpretation of best available evidence in the evaluation of suitability and approval of medical devices that are anticipated to be used at scale, inclusive of surgical implants. The HSE should put in place centralised oversight arrangements to assure itself that adequate institutional assessment has taken place and remove duplication of efforts across numerous organisations. These arrangements should also ensure that when exceptional or experimental use of devices is intended, the role for formal ethical approval, compliance with legislation and any requirement for engagement with the Health Products Regulatory Authority are fully adhered to.
R3.HSE	The HSE must conduct a review to assess how specialist expertise and leadership can be further enhanced to support medical devices governance at local and national level. In this context, there should be a particular focus on how required specialist expertise and input should be integrated into approval arrangements to support oversight and management in the areas of procurement and introduction of new medical devices. This is particularly important in light of new and evolving technologies in the health sector.
R4.HSE	The HSE must ensure that where services are planning for significant organisational change, they should evaluate their governance structures, processes and readiness for change at the outset as part of the planning of the change programme. Such a readiness assessment needs to consider managerial capacity and change management expertise across the services to address both the change itself, and also maintenance of ongoing services. Planning for such change needs to extend beyond consideration of management reporting lines, to also include careful evaluation of how pre-existing governance committees and processes are

	adapted to new arrangements. This is required to support service change and transition while continuing to provide safe quality care.
R5.HSE	As part of the HSE's current reform of clinical governance arrangements in the establishment of the new Regional Health Areas, the HSE should review the effectiveness of the clinical directorate model, with a focus on the role of the clinical director to ensure that: ▪ the role is assigned the appropriate level of responsibility and accountability to enable the clinical director to drive high quality, safe and effective care ▪ the role is assigned the appropriate level of authority to effect required change, in particular when things go wrong ▪ the scope of the role is clearly defined with clear and realistic responsibilities, in particular where services span across multiple hospital sites ▪ there is clear guidance and supports in place for clinical directors to carry out their day-to-day functions including performance review, supervisory support and management as well as, business and administrative support functions enabling access to and use of information. Arrangements to facilitate close working with other senior executives and the wider hospital consultant body should form a key focus for ongoing enhancement of the role. Such a review should take on board the learnings from this report and have regard for international best practice.
R6.HSE	The HSE must recognise, develop and formalise the role of clinical specialty leads so that each position holder has both clarity in what is expected of them in fulfilling the position and formal authority for leadership within each specialty, supporting and reporting to the Clinical Director.
R7.HSE	The HSE should develop a comprehensive national approach to tracking implant use and patient outcomes associated with implantation surgery. This should enable the electronic tracking of surgical implants to ensure traceability in the use of implants, across the product lifecycle, and enable patient identification and follow up, if needed, post-implantation, particularly where safety issues arise. The HSE should ensure that this is

	implemented consistently across the six newly established Regional Health Areas of the HSE.
R8.HSE	The HSE must establish formal professional supports and leadership at national level to assist senior clinical and corporate managers to address longstanding and unresolved interpersonal and cultural issues within healthcare teams in services at local level. This should incorporate training and, where necessary, external supports for managers and other staff to ensure the ongoing provision of safe, quality care to patients.
R9.HSE	The HSE must ensure that all acute hospital services, provided or funded by the HSE, carry out a self-assessment against the local and national recommendations within this report and develops and implements a quality improvement plan against the *National Standards for Safer Better Healthcare* where shortcomings exist. The HSE should ensure a standardised approach to the development of these plans and oversee their implementation as part of its performance management arrangements against which HIQA will monitor.

Recommendation to be implemented nationally by the HSE in all healthcare services provided or funded by the HSE and by private hospitals

R1.N	All healthcare services provided or funded by the HSE and private hospitals, conducting surgery in Ireland, must assure themselves that they have effective practices and controls in place for surgical implant approval and use. Such a review should include evaluating the effectiveness of processes, procedures and checks for: ▪ safety in advance of use, ▪ decontamination, ▪ staff education, and ▪ safety checking in theatre.

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