Health Information and Quality Authority

An tÚdarás Um Fhaisnéis agus Cáilíocht Sláinte

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.

Reporting to the Minister for Health and engaging with relevant government Ministers and departments, HIQA has responsibility for the following:

- **Setting standards for health and social care services —** Developing person-centred standards and guidance, based on evidence and international best practice, for health and social care services in Ireland.
- **Regulating social care services —** The Chief Inspector of Social Services within HIQA is responsible for registering and inspecting residential services for older people and people with a disability, and children's special care units.
- **Regulating health services —** Regulating medical exposure to ionising radiation.
- **Monitoring services —** Monitoring the safety and quality of permanent international protection accommodation service centres, health services and children's social services against the national standards. Where necessary, HIQA investigates serious concerns about the health and welfare of people who use health services and children's social services.
- **Health technology assessment —** Evaluating the clinical and cost effectiveness of health programmes, policies, medicines, medical equipment, diagnostic and surgical techniques, health promotion and protection activities, and providing advice to enable the best use of resources and the best outcomes for people who use our health service.
- **Health information —** Advising on the efficient and secure collection and sharing of health information, setting standards, evaluating information resources and publishing information on the delivery and performance of Ireland's health and social care services.
- **National Care Experience Programme —** Carrying out national service-user experience surveys across a range of health and social care services, with the Department of Health and the HSE.

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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.

1 Introduction and background

Between 2020 and 2022, non-CE[‡‡] marked metal springs were implanted into three children undergoing spinal surgery at Children's Health Ireland (CHI) Temple Street Hospital in Dublin. Each child had an underlying life-limiting condition, and spinal surgery was intended to prolong their life expectancy and improve their overall quality of life. The non-CE marked springs were used in surgery as an addition to a conventional spinal-rods system that aimed to correct scoliosis of the spine.

In the summer of 2023, public concerns were raised about the conduct of these surgical procedures, specifically around the nature of the non-CE marked springs used. This issue emerged alongside wider public concerns around the quality and safety of orthopaedic services at the hospital. These concerns have led to a number of reviews or investigations being initiated into the care of children requiring spinal surgery, which have run in parallel to this review.

On 4 October 2023, the Minister for Health wrote to the Health Information and Quality Authority (HIQA) regarding serious patient safety concerns relating to the use of non-CE marked springs that had been implanted during spinal surgery at CHI at Temple Street (Appendix A).[§§] The Minister requested HIQA to carry out an independent review for the purposes of monitoring compliance with 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.

HIQA developed terms of reference for this review, which were published on HIQA's website on 17 November 2023. The terms of reference are also included as an appendix to this report (Appendix B).

At the centre of this review are the children and families using the orthopaedic spinal surgery services in CHI at Temple Street. In particular, the three families of those children who had the springs implanted. HIQA invited these families to meet with its review team to inform this review. HIQA also spoke with relevant members of front-line staff and management in CHI and to relevant stakeholders at Health Service Executive (HSE) national level. HIQA conducted announced on-site assessments at

[‡‡] 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.

[§§] For the purposes of this report, HIQA refers to the hospital sites of CHI as CHI at Temple Street, CHI at Crumlin, CHI at Connolly and CHI at Tallaght.

two CHI sites: CHI at Temple Street and CHI at Crumlin, and undertook a review of relevant documentation and information.

This review covers the period from November 2018, when the use of springs was first considered as a possible treatment option, to July 2023 when it was confirmed that the springs implanted into three children during surgical procedures at CHI at Temple Street between 2020 and 2022, had been non-CE marked.

Since 2017, CHI has been experiencing sustained challenges in providing timely access to paediatric spinal surgery services with long waiting lists for children. As a result of the sustained challenges in terms of timely access to surgery and the significant impact on the health and wellbeing of affected children, CHI has been the subject of ongoing focus and investment in an effort to tackle service demand and the long waiting times for children accessing these services.

Furthermore, CHI management had been working to address challenges within this service that were impacting on communication and relationships in the orthopaedic team at CHI at Temple Street throughout this period.

HIQA found that CHI was experiencing significant organisational and transformational change during the time period of this review — November 2018 to July 2023. Relevant factors at national level which impacted this change included:

- the COVID-19 pandemic which presented an additional challenge for the overall healthcare system
- the cyber-attack which occurred across public healthcare IT systems in May 2021 which also impacted CHI significantly
- the continuing uncertainty of the substantial completion date of the National Children's Hospital having a significant impact on planning and implementation for the organisation, including the recruitment of specialist contract staff and consultants required to commission the National Children's Hospital.

This report sets out the findings and recommendations from HIQA's review. It is structured to outline HIQA's findings in relation to the assessment of compliance with relevant national standards of the 2012 *National Standards for Safer Better Healthcare* [(4)] in the areas of:

- governance and oversight of surgical implants and implantable medical devices in CHI; and
- the end-to-end process for the use of the non-CE marked springs that were implanted during spinal surgery in CHI at Temple Street.

This report also includes a section focused on the implications of the findings of this review for national services.

In accordance with its remit to review compliance with national standards under section 8(1)(c) of the Health Act 2007 (as amended), HIQA identified and considered eight national standards relevant to the terms of reference for this review. Compliance ratings for these standards are outlined at the end of each chapter.

The eight national standards assessed are:

- Standard 1.5 — Service users' informed consent to care and treatment is obtained in accordance with legislation and best available evidence.
- Standard 2.8 — The effectiveness of healthcare is systematically monitored, evaluated and continuously improved
- Standard 3.1 — Service providers protect service users from the risk of harm associated with the design and delivery of healthcare services.
- Standard 5.1 — Service providers have clear accountability arrangements to achieve the delivery of high quality, safe and reliable healthcare.
- Standard 5.2 — Service providers have formalised governance arrangements for assuring the delivery of high quality, safe and reliable healthcare.
- Standard 5.9 — The quality and safety of services provided on behalf of healthcare service providers are monitored through formalised agreements.
- Standard 5.10 — The conduct and provision of healthcare services are compliant with relevant Irish and European legislation
- Standard 5.11 — Service providers act on standards and alerts, and take into account recommendations and guidance, as formally issued by relevant regulatory bodies as they apply to their service.

The methodology for this review is reflected in Appendix C of this report.

Acknowledgements

HIQA would like to acknowledge those people who met with the review team and who facilitated and contributed to this review. In particular, the families who have been affected. HIQA would also like to acknowledge the co-operation of the Board, management team and staff in CHI.

2 Governance and oversight of surgical implants and implantable medical devices and use at Children's Health Ireland (CHI)

2.1 Governance and oversight

The 2012 *National Standards for Safer Better Healthcare* [4] (the national standards) state that a well-governed service is clear about what it does, how it does it, and is accountable to its stakeholders. The national standards set out that formalised governance arrangements ensure that there are clear lines of accountability at individual, team and service levels so that healthcare professionals, managers and everyone working in the service are aware of their responsibilities and accountability.

Effective and sustainable governance arrangements require that the necessary controls, systems and processes are in place. The implementation of these systems and processes require that staff understand, and have access to the necessary policies, procedures, guidelines and controls to guide their work in the delivery of care. In the context of healthcare settings, such policies and procedures provide safeguards and controls from a governance perspective to ensure that there are standardised and consistent ways of working within and across services. In a safe service, a focus on quality and safety improvement becomes part of a service-wide culture and is embedded in the service's daily practices and processes rather than being viewed or undertaken as a separate activity.

Ineffective governance in healthcare can occur where governance arrangements are unclear, ambiguous, excessively elaborate or where practices are not standardised or applied consistently. This can impact on the quality of care offered to patients and families. Clear accountability is critical to ensure effective performance. Where there is a lack of clarity around who is accountable for the delivery of certain aspects of a service, the ability to properly hold individuals to account for delivery can be hampered. People should be clear on their roles, and provided with an accurate and realistic job remit. This should ensure that expectations placed upon key management personnel are realistic, and that mechanisms are in place to enable an appropriate level of delegated responsibility and authority.[4] Within the context of healthcare, well-governed entities should have standardised structures, policies and processes in place, which are clearly understood by staff across all levels of the service to support both operational effectiveness and the delivery of an effective, accountable, safe service.

To ensure the governance arrangements support the delivery of safe care, the effectiveness of healthcare should be systematically monitored, evaluated and continuously improved. Such activities are important so as to provide assurance on the quality and safety of services to management, patients, staff and the public. The

information is available to managers to identify areas of high-quality care and areas for improvement. Such evaluation is enabled, inter alia, by having standardised policies, procedures and practice within and across entities. It allows boards to exercise their assurance role more effectively and it enables management to provide necessary assurance to their board and the public that there are safe and effective systems and controls in place.

In addition, when an organisation is embarking on a journey of significant transformation, this should be supported with arrangements to plan and manage service change and transition effectively and safely. An effective, responsive service is agile and needs to be able to adapt to these changes in a managed way. This requires consideration of managerial capacity across the services to address both the change itself, and also maintenance of ongoing services.

This chapter describes the evolving governance arrangements in CHI prior to and during the period when the surgical procedures took place to implant springs, and in subsequent years to date. This chapter focuses on the overall governance arrangements for the oversight of clinical quality and safety in services at CHI, through the lens of surgical implants and or implantable medical devices.

In HIQA's evaluation of governance through this review, it considered organisational structures, processes and measures applied to oversee service quality and safety at three different levels of seniority. Firstly, HIQA has considered overall oversight arrangements at CHI Board level. HIQA has also evaluated arrangements at senior executive levels within CHI, inclusive of senior clinical leadership level. These arrangements were in evolution across the time frame covered by this review to date. Finally, HIQA also assessed front-line and middle management arrangements. This assessment included governance arrangements to ensure regulatory and ethical approval of the introduction of new clinical practices. Governance arrangements for decontamination and theatre practices for the introduction of new medical devices was also explored. General observations in this regard are included in this chapter. Their application or otherwise related to the introduction of the non-CE marked springs into practice is then further discussed in detail in Chapter 3 of this report.

Complex orthopaedic spinal surgery services are provided on two sites in CHI: CHI at Temple Street and CHI at Crumlin. As such, this review focused on governance and management arrangements at these two sites for the introduction and use of implantable medical devices. This included a review of the policies, procedures and practices in place across the hospital sites of CHI to support standardised processes in the use of implantable medical devices.

2.2 Children's Health Ireland

Children's Health Ireland (referred to in this report as 'CHI') provides national health services for children and young people across Ireland and local services for the eastern regions. CHI is a statutory body established under the Children's Health Act 2018,[5] with the stated objective set out in that Act to:

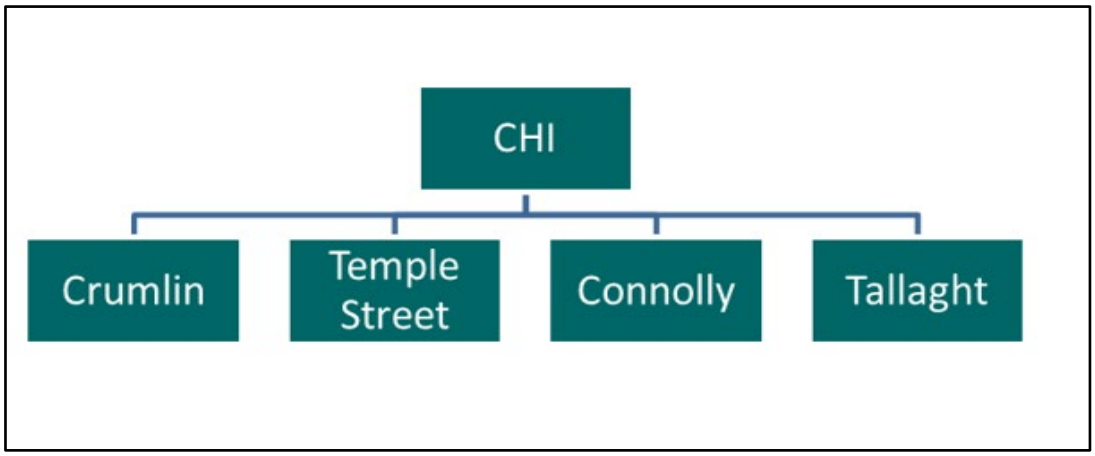
> improve, promote and protect the health, mental health and well-being of children in a manner that embodies the values of child-centred, compassionate and progressive care provided with respect, excellence and integrity and in doing so it shall have the right and responsibility to promote the culture and traditional principles of voluntarism in the conduct of its internal and external affairs.

Functions of CHI under that Act include the planning, conduct and development of specialist acute paediatric hospital services in Ireland and a requirement to provide for patient safety and quality in these services. CHI operates children's services at four hospitals within Dublin and the greater Dublin area:

- CHI at Temple Street (on the north side of Dublin city)
- CHI at Crumlin (on the south side of Dublin city)
- CHI at Tallaght, co-located with Tallaght University Hospital (in the southwest area of Dublin city)
- CHI at Connolly, co-located with Connolly Hospital (on the northwest side of Dublin city).

Services at CHI at Connolly began in 2019 with the opening of an urgent care centre and outpatient service at Connolly Hospital Blanchardstown.[6] The four CHI sites are outlined in Figure 1 below.

Figure 1. Hospital sites as part of CHI structure



Source: CHI documentation provided to HIQA as part of this review (November 2023)

CHI manages and delivers health services to children and young people on behalf of the HSE under Section 38 of the Health Act 2004.[7, 8] Under the provisions of the Health Act 2004, the HSE may enter into agreements with, and provide funding to voluntary agencies (including organisations covered under section 38) to deliver services on its behalf. This means that the HSE has entered into an agreement with and provides funding to CHI to deliver services on its behalf.[9] Such an agreement enables the HSE to provide funding to the service provider and for the service provider to deliver services as agreed with the HSE, through the National Service Plan.

CHI confirmed to HIQA that some services may be provided to CHI patients by a different hospital on foot of a service-level agreement (SLA).

HIQA reviewed the SLA that was in place between CHI and the National Orthopaedic Hospital, Cappagh. This service was established in 2021 to offer what the SLA described[***] as non-complex, short-stay orthopaedic surgery in an effort to address the waiting lists at CHI. HIQA confirmed that all clinical patient care that occurred through this agreement was under the governance of the National Orthopaedic Hospital, Cappagh, inclusive of oversight and governance of the use of implantable medical devices. Complex spinal surgical procedures did not occur at the National Orthopaedic Hospital, Cappagh as part of this arrangement. Furthermore, HIQA confirmed with CHI that surgical procedures involving implantation of non-CE marked springs did not occur at the National Orthopaedic Hospital, Cappagh.

In line with National Standard 5.9, there were formalised agreements in place between CHI and a number of external healthcare providers and with the HSE for the provision of clinical services on behalf of CHI.

2.2.1 CHI Board

The Board of any healthcare organisation holds a key responsibility for ensuring that the appropriate structures and process are in place, and reliably applied, to maintain service quality and safety.[10] In doing so, the Board is required to put effective mechanisms in place to know how well the organisation is performing in this regard, and to act if any issues of concern arise. The Board also plays a key role in setting and maintaining the organisations culture, which is a critical element in ensuring patient safety.[11]

[***] To note – the SLA did not define what constituted complex and non-complex spinal surgery.

In 2013, the then Minister for Health established a 12-member Children's Hospital Group Board (CHBG), initially on a non-statutory administrative basis with a specific 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 two children's hospitals, Our Lady's Children's Hospital, Crumlin and Temple Street Children's University Hospital, together with the paediatric services of Tallaght University Hospital merged into a single entity as CHI, under the governance of a single Board.

Under that Act, CHI is required to have a board of 12 members, appointed by the Minister for Health. The CHI Board is responsible for the governance and oversight of the operation of acute paediatric services for the greater Dublin area, including responsibility for all national tertiary[†††] and quaternary[‡‡‡] specialist paediatric services, acts as the client for the establishment of the new National Children's Hospital and is responsible for setting the organisation's strategic objectives and for oversight of the performance of the functions that are delegated to the CEO. The CHI Board is also responsible for:

- ensuring effective systems of internal control
- statutory and operational compliance
- risk management.

[†††] Tertiary care: specialised consultative healthcare, usually for inpatients and on referral from a primary or secondary health professional, in a facility that has personnel and facilities for advanced medical investigation and treatment, such as a tertiary level hospital.
[‡‡‡] Quaternary care has been defined as an extension of tertiary care in reference to advanced levels of medicine which are highly specialised and not widely accessed, and usually only offered in a very limited number of national or international centres.

Documentation indicated that regular Board meetings were taking place in line with the functions of the Board. There are five Board sub-committees supporting and reporting to the CHI Board. These include the Organisation and Remuneration Committee, Governance and Nominations Committee, Audit and Risk Committee, Capital Projects Committee, and the Quality and Patient Safety Committee.[§§§]

The function of the CHI Board Quality and Patient Safety Committee includes the provision of a level of assurance on appropriate governance structures, processes, standards, oversight and controls in place across CHI and has the following key duties:

- assure quality and patient safety on behalf of the Board. The responsibility for Quality and Patient Safety ultimately remains with the Board; and
- to strategically lead on quality improvement and to provide a level of assurance to the Board that there are appropriate and effective systems in place that cover all aspects of quality and patient safety including all child safety issues.

The Board delegates the day-to-day running and any of CHI's functions to the CHI CEO, who has a formal reporting line to the CHI Board.

2.2.2 CHI Executive Management

The Executive Management Team of a healthcare organisation holds responsibility for the operational running of services on a 24/7 basis. To do so safely and effectively, it is of critical importance that operations are structured and organised coherently, with clarity around reporting arrangements and levels of authority for decision making to fulfil required responsibilities.

At CHI, the Chief Executive Officer (CEO) of CHI reports to the Chairperson of the CHI Board. The CHI CEO, supported by the Executive Management Team, is

[§§§] CHI Board subcommittees include:

1. Organisation and Remuneration Committee — supports the board in defining CHI's Values, Vision and Mission.
2. Governance and Nominations Committee — supports the Board in establishing governance policies and processes.
3. Audit and Risk Committee — supports the Board with its responsibilities for risk, control and governance and that internal control systems, including audit activities, are monitored actively and independently.
4. Capital Projects Committee — the Board is the client of the new National Children's Hospital, and this committee supports the Board in considering strategic and operational issues relating to the design, build and equipping of the new National Children's Hospital.
5. Quality and Patient Safety Committee — to provide a level of assurance on appropriate clinical governance structures, processes, standards, oversight and controls in place across CHI.

responsible for the operationalisation of the overall strategic objectives of CHI and is the executive decision-making function for CHI. [****]

In accordance with funding arrangements under section 38 of the Health Act 2004, CHI is responsible and accountable to the HSE for the performance of the services it manages. This process is laid out in the HSE Performance and Accountability Framework. Under the section 38 agreement, the HSE agrees the allocation of funding to CHI in respect of the delivery of services in accordance with the HSE National Service Plan and deals with CHI as the service provider through the HSE Code of Governance.

The CHI CEO is in turn supported in the day-to-day operations of CHI by the CHI Executive Management Team. The CHI Executive Management Team comprises 12 members including the CEO. The senior accountable person is the CHI CEO. At the time of the review, this position was filled by the Acting CEO.[††††] HIQA reviewed documentation that shows formal reporting structures of the CHI CEO and Executive Management Team to the CHI Board, providing updates on a regular basis.

Since CHI was commenced in January 2019, a number of committees have been established at executive level and report to the CHI CEO. These included the CHI Quality, Safety and Risk Management Committee[‡‡‡‡] and the Serious Incident Review Group (SIRG) Committee.[§§§§]

Please see Appendix D for further detail related to CHI governance structures.

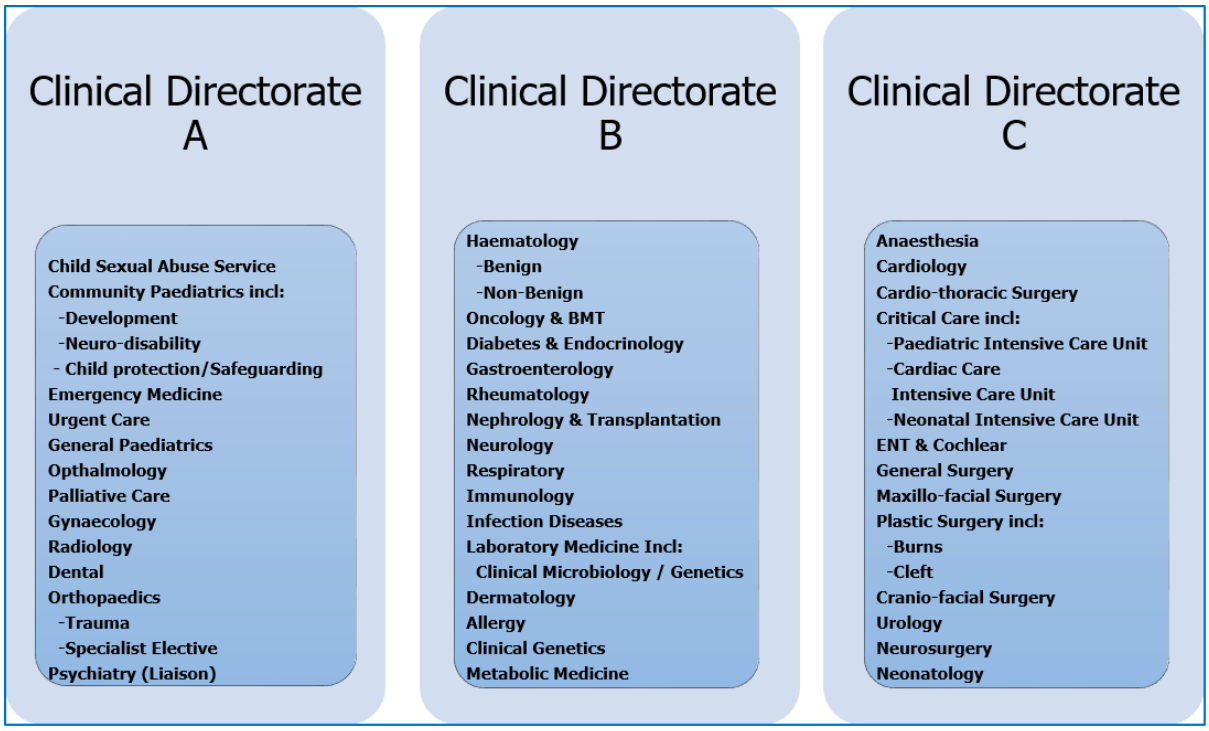
2.3 Clinical governance in CHI

The HSE's 2012 *Clinical Governance - Information Leaflet* describes clinical governance as a framework through which healthcare teams are accountable for the quality, safety and satisfaction of patients in the care they deliver.(12) It is built on the model of the Chief Executive Officer/General Manager, or equivalent, working in partnership with a service's clinical director, director of nursing/midwifery and professional leads. It outlines that effective governance recognises the inter-dependencies between corporate and clinical governance across services and integrates them to deliver high-quality, safe and reliable healthcare.

[****] The function of this team is to strategically manage corporate matters and the National Children's Hospital programme. The team has four main areas of focus which include services, operations and integration projects, commissioning of the new National Children's Hospital, operational performance management and strategic planning.
[††††] The CHI Chief Executive post was filled on a substantive basis on 20th January 2025.
[‡‡‡‡] The overall aim of committee is to ensure that quality improvement, patient safety and risk management are effective and central to the delivery of person centred, safe and effective care and operations across CHI.
[§§§§] The committee is part of the CHI Quality, Safety and Risk Management Executive Committee with responsibility for managing both clinical and non clinical serious incidents that occur in CHI.

CHI introduced three clinical directors into site management positions in late 2020 and CHI subsequently developed broader cross-city clinical directorate structures in 2021. This resulted in three clinical directorates A, B and C (see Figure 2 below) incorporating 39 clinical specialties in total, with 12 to 14 specialties assigned across each of these three clinical directorates. Each clinical directorate was led by a clinical director (already in a site management role) and supported by a director of nursing and a directorate operations lead, known collectively as the Triumvirate Team (described in detail in Appendix E). Each clinical director reported to the CHI CEO up to December 2022, when this reporting line changed to the newly created Deputy Chief Executive Officer / Operations Director in January 2023.

Figure 2. CHI Clinical Directorate Specialties



Source: Derived from CHI documentation provided to HIQA as part of this review (November 2023)

2.3.1 CHI Hospital Site and Clinical Directorate Management Team structures

2.3.1.1 Hospital Site Management Team and Clinical Directorate Triumvirate Management Team structure

From January 2019 to late 2020, CHI at Temple Street and CHI at Crumlin each had site-specific management teams headed by a site-specific CEO. This position holder was supported in their role by a clinical director, a director of nursing and a director of operations.

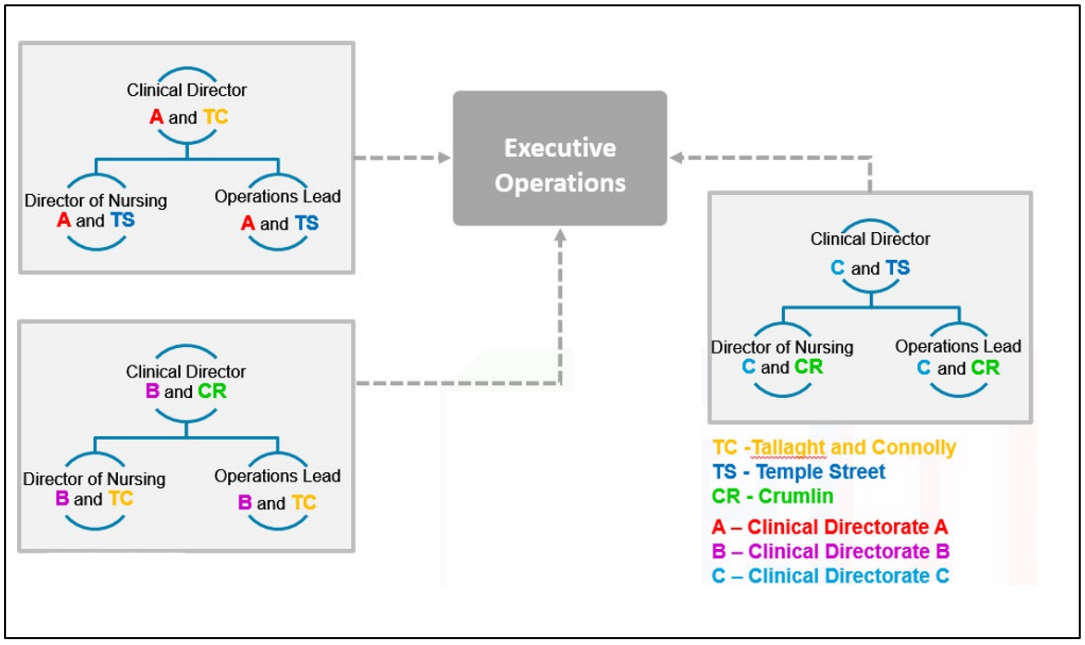
In September 2020, the site-specific CEO positions were stood down and the clinical directors for each site assumed overall site management responsibility for the CHI at

Temple Street and CHI at Crumlin sites, with a period of handover until December 2020 in the CHI at Temple Street site. At CHI at Tallaght and CHI at Connolly, a single clinical director was appointed as an executive lead for both of these sites.

In 2021, CHI appointed three clinical director roles to lead out on the establishment of the three cross-city clinical directorates. In practice, the clinical directors who were appointed to these roles were the same personnel that had been in the site-specific clinical director roles. These individuals retained their responsibilities for managing individual sites while also working to develop the new clinical directorates, which were cross city, and in preparation for moving into the new hospital.

In April 2023, CHI implemented the formal establishment of the three cross-city clinical directorates that had been in development since 2021. Six management teams in total were established to manage the hospital sites and the clinical directorates at that time. Each clinical director led a hospital site management team and a clinical directorate triumvirate team. Three of the six teams were hospital-site-based management teams: with one team at each of CHI at Temple Street, CHI at Crumlin and the combined (for governance purposes) hospital sites of CHI at Tallaght and CHI at Connolly. The three other teams (clinical directorate triumvirate teams) were assigned to the three Clinical Directorates A, B and C. Figure 3 below illustrates these structures as of January 2024.*****

Figure 3. Configuration of the CHI clinical directorate structure in January 2024



Source: CHI documentation provided to HIQA as part of this review (May 2024)

***** See Appendix E for a further break down of the structures by each clinical directorate A, B and C and the four hospital sites.

The six teams reported upwards to the CHI Executive Management Team. Each team has accountability and responsibility for mainly distinct, yet at times, overlapping functions.

2.3.1.2 Hospital Site Management Team and Clinical Directorate Triumvirate Team responsibilities

At hospital-site level, the three core members of the hospital management team were based at their assigned hospital site(s) for the most part and worked closely together.

In their role as hospital-site-based management teams, the management teams, led by the clinical director, were responsible for the day-to-day running of their assigned hospital site(s).

HIQA was informed that when the corporate functions moved to the cross-city governance structures in 2021, key members of the existing Senior Management Team at CHI at Temple Street either moved into other roles or were no longer based at CHI at Temple Street. HIQA found that this left some gaps in terms of local governance structures which resulted in the hospital management team members having to take on additional responsibilities of managing day-to-day corporate issues that arose on site, such as quality and safety, patient experience (complaints) and human resources issues. Similarly, when day-to-day issues arose within clinical services, these were managed firstly at site level by the hospital management team rather than the clinical directorate triumvirate team.

Each of the Clinical Directorates A, B and C is responsible for integrating the 12 to 14 clinical specialties within each clinical directorate, cross-site, in anticipation of each of the specialties coming together in the new National Children's Hospital under CHI. At clinical directorate triumvirate level, the three team members of each directorate hold responsibilities across the four hospital sites, as the clinical specialties within each directorate may be located on a single hospital site, or located across a number of sites within CHI. At interview, members of the clinical directorate triumvirate teams stated that this work was being progressed through regular meetings with key stakeholders across the four sites. This work was assisted by further supports and resources provided by external consultancy companies as part of the implementation of CHI structures in preparation for transfer into the new children's hospital.

HIQA found that the clinical and corporate governance structures, and in particular the clinical directorate triumvirate team model, established in 2021, were overly complex. In practice, there were six teams (three hospital site management teams and three clinical directorate teams). These six teams were made up of nine members, with different members making up each team, and each team having

responsibilities at both hospital-site and clinical-directorate level with dual reporting structures.

HIQA identified that such an arrangement placed an onerous and unrealistic workload expectation on the post-holders. Furthermore, each clinical director had the added responsibility of maintaining a clinical commitment of the order of 20%-30% of their overall responsibilities as per the relevant job description. HIQA was informed by clinical directors that the individual clinical commitment varied according to the needs of their clinical service, with some clinical directors spending more than 30% of their time fulfilling clinical commitments.

HIQA found that the changes made to senior management reporting arrangements across CHI from September 2020 onwards were aimed at enabling the day-to-day running of operations at each hospital site. They were also intended to support future management and governance requirements when services would be located at a single site in the new National Children's Hospital. HIQA identified that, in practice, these arrangements resulted in an especially onerous workload for senior managers, and 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. These changes also resulted in a dilution of the existing operational management capacity and capability in CHI at Temple Street, in advance of having a single integrated service at the new National Children's Hospital.

At interview, the Chair of the CHI Board told HIQA that, with the benefit of hindsight, these efforts to try to move to a cross-site clinical directorate structure were not as effective as they were intended to be, and may have been introduced too early.

2.3.1.3 Doctor and nursing reporting lines across CHI

In terms of medical governance, HIQA found that in addition to the clinical director roles there was also a Chief Medical Officer (CMO) in position at CHI from July 2021. This is an executive role designed to provide assurance on medical professional and clinical quality, safety and risk management and the post holder has a reporting relationship to the CHI CEO. The scope of the role was defined as a clinical professional leadership role with professional accountability to the CHI Board. As such, the CHI CMO had no operational responsibility for services and no staff reporting to them on these matters. Instead, operational responsibility rests with each clinical director who reports via the Deputy Chief Executive Officer / Operations Director to the CEO since January 2023.

To support the clinical directors in the cross-city integration of clinical specialties, clinical specialty leads were being appointed within each specialty and were at

differing points of development, with not all of the leads appointed at the time of this review. These leads were consultants within that specialty. HIQA found that the clinical specialty leads are considered to represent a leadership role within the wider specialty, rather than a formal line management role with clinical governance responsibilities and integrated into the wider governance structures in CHI.

This clinical governance structure across CHI meant that doctors report to a clinical director for operational matters and a cross-city 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 affect the ability to effectively oversee the delivery of care.

In terms of nursing governance, HIQA found that in addition to the three directorate director of nursing roles, there was also a Chief Director of Nursing in position at CHI. Similar to the CMO role, this is an executive role with no operational responsibility for services and no staff reporting to them on these matters. Instead, operational responsibility rested with each directorate director of nursing who reported to their clinical director. The primary purpose of the role was described by the Chief Director of Nursing as being to provide professional leadership for all aspects of nursing standards, practice, education and research in CHI, to strategically plan for all issues related to children's nursing in CHI, and to influence the wider children's nursing agenda.

HIQA found that nursing services reported upwards via their line manager to one clinical director at site level and a different clinical director at directorate level for operational matters. Nursing services also have a formal reporting relationship to the CHI Chief Director of Nursing in respect of professional matters only. The Chief Director of Nursing told HIQA they meet with the Directors of Nursing (DONs) on a regular basis and they represent nursing issues raised to the CHI CEO or Executive Management Team on matters including operational matters and specifically issues of concern. The Chief Director of Nursing also informed HIQA that they advocate a "no wrong door" approach and that all matters can be raised with them by the DONs.

HIQA found that these multiple reporting lines do not fully enable clear, accountable and easily understood governance arrangements to support delivery of care.

2.3.2 CHI Spinal Surgery Management Unit

In January 2024, CHI established a CHI Spinal Surgery Management Unit to address broader governance issues in spinal surgery. The clinical lead post for this unit is currently filled by a consultant orthopaedic surgeon working across CHI who reports directly to the CHI Acting CEO. The CHI Acting CEO stated that the clinical lead

position holder is supported by an operational team that includes an assistant director of nursing, business manager, quality and safety lead, stakeholder engagement lead, access (waiting lists) lead, two data managers and a communications manager. The objective of this team is to improve access to services for all children on the spinal surgery waiting list.

At the time of writing of this report, it was too early for HIQA to determine the full impact of this new team on the overall governance of the spinal surgery service and how this may influence and support the effective governance of implantable medical devices in this specialised service.

2.3.3 Use of quality and safety benchmarking data in CHI

The use of data to benchmark and oversee clinical services with comparable services is vitally important in the context of understanding clinical practice, including introducing new surgical procedures and new patient cohorts. It acts as an important dimension in terms of effective oversight and assurance of clinical service delivery. The benefit of the availability of good quality benchmarked data was highlighted to HIQA during this review through the example of cardiology/ cardiothoracic surgery services at CHI at Crumlin and paediatric intensive care services at both CHI at Temple Street and CHI at Crumlin. These services are part of national and international service quality and safety benchmarking systems, developed over years, which are designed to assure hospital management, healthcare staff, patients and the wider public on the quality and safety of services in an evidence-based manner which is in line with National Standard 2.8.

HIQA found no evidence that spinal surgery services at CHI reported into similar quality assurance benchmarking systems. In the absence of the proper establishment and maintenance of such systems in a formalised way, the ability to oversee service quality and safety effectively is hindered.

HIQA noted that there was an opportunity to improve and expand practice in the spinal orthopaedic service through the use of clinical data to quality assure and benchmark service quality with comparable services within Ireland and internationally, which would support CHI in compliance with National Standard 2.8. This national standard outlines that the effectiveness of care is systematically monitored, evaluated and continuously improved. For example, this may be achieved through the development or adoption of performance indicators and benchmarks in accordance with best available evidence to monitor and evaluate the quality and safety of the care provided and outcomes.

2.3.4 Paediatric orthopaedic services at CHI at Temple Street

Spinal surgery is carried out under the specialty of orthopaedic surgery (a branch of surgery relating to the treatment or study of bones that have not grown correctly or that have been damaged)[13] at CHI at Temple Street and CHI at Crumlin. The paediatric orthopaedic service offers a full range of services from emergency surgery to highly complex elective surgery. CHI at Temple Street offers secondary orthopaedic services in the local catchment area and tertiary and quaternary services for a number of sub-specialities.

Since 2016, spinal surgery for children in Ireland with spina bifida and certain other congenital conditions (structural or functional anomalies that develop prenatally and may be identified before or at birth, or later in life) has primarily been undertaken at CHI at Temple Street. This cohort of patients includes children with underlying congenital conditions which result in a limited life expectancy, and requires constant high levels of respiratory and other supports. With advances in medical research and treatments in recent years, some of these children are now living longer and have started to develop other complex issues, such as early onset scoliosis. As a result, their ongoing treatment and support has begun to present new clinical challenges for clinicians.

During the course of this review, staff across various professions in CHI told HIQA that there were issues with communications and team dynamics within the orthopaedic service at CHI at Temple Street. Staff alleged that there were difficulties and challenges in both managing and participating in the orthopaedic surgical team, due to the lack of team cohesiveness, unacceptable behaviours and difficult relationships within the team.

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. These issues were occurring in the context of ongoing and persistent waiting lists and access issues for children awaiting scoliosis surgery across CHI. Changes in ways of working required as part of the response to the COVID-19 pandemic temporarily addressed these issues during early 2020 and into early 2021. With the restoration of normal working arrangements in early 2021, these issues re-emerged and senior hospital management sought to address them by re-establishing a formal process. This intervention consisted of the CMO attending the orthopaedic service meetings, and operations and human resources (HR) supports being allocated to support the clinical director in dealing with this matter.

Minutes of the CHI Board meetings reviewed by HIQA indicated that this management intervention was first highlighted by the CHI CEO to the CHI Board in July 2021. HIQA reviewed documentation that indicated that the orthopaedic service was reflected regularly in the monthly CEO reports to the Board up to October 2022 as a general item along with a number of other services which were also experiencing challenges in delivering services.

In May 2022, the CMO presented a service report to the Board which outlined specific issues in the orthopaedic service at CHI at Temple Street that included team dynamics, behaviours, theatre capacity and waiting lists for specialty procedures, in particular for scoliosis and spina bifida.

In December 2022, there was a further update to the Board from the CMO noting that the orthopaedic service remained exceptionally challenged, and that work was underway on an external clinical outcomes review, expected to commence in March 2023. The Board noted the external clinical review. The next CMO service report was presented to the Board in May 2023 and reflected the ongoing issues in the orthopaedic services at CHI at Temple Street. This update outlined that the external review was underway.

The 2022 CHI Annual Report recognised that concerns had been raised by CHI staff regarding the spinal surgery outcomes in CHI at Temple Street and that CHI was commissioning an internal review and an external review to understand the facts and make recommendations to ensure patient safety.(14)

HIQA also found that CHI management had been reporting to the CHI Board on issues in the orthopaedic service, including the management intervention at CHI at Temple Street from July 2021.

The Chair of the CHI Board told HIQA that before November 2022 the CHI Board had no sense that the issues in the orthopaedic surgery services were as serious as they were later identified to be. The Chair noted to HIQA two key events that signalled to the CHI Board the seriousness of the issues: the reporting of serious incidents in the spinal surgery service, and subsequently the identification of the use of the non-CE marked springs as implants. These incidents came to light in 2022 and 2023 respectively.

HIQA reviewed a published report of the above mentioned external review titled 'Children's Health Ireland at Temple Street Spinal Surgery Programme for Patients with Spina Bifida External Quality Review and Programme Assessment'. This was prepared by a multidisciplinary team from Boston Children's Hospital and is dated 7 July 2023.(15) This report noted "more attention is needed to create a culture where all members of the care team are encouraged and comfortable sharing safety

questions and concerns". HIQA reviewed a report prepared in August 2023 of another review carried out by CHI entitled 'Children's Health Ireland Report on Spinal Surgery for Patients with Spina Bifida in Children's Health Ireland at Temple Street'.[16] The references to culture and communication among staff in the orthopaedic service in these reports are consistent with the issues that staff articulated to HIQA during interview.

HIQA notes that, at the time of publishing this report, the orthopaedic service at CHI at Temple Street remains an area of ongoing focus and priority for the CHI Board and Executive Management Team. It is imperative that these efforts achieve the required improvements within the service following the publication of this HIQA review report.

2.3.5 Key patient safety committees and approval processes

In healthcare services such as hospitals, conventional governance arrangements, HSE policies and procedures, and the national standards expect that a number of key multidisciplinary safety committees are established and operate effectively to oversee key areas of safety. These multidisciplinary committees are required to be formalised and integrated into the overall approach to governance within a hospital. They are crucial to oversee safety and act as a means of proper evaluation and, where necessary, approval related to the development and implementation of policies and procedures, and for the introduction of new practices. These arrangements represent critical internal governance controls and, as such, it would be the responsibility of the Board and Executive of a healthcare organisation to ensure that these structures were in place and functioning, as part of their overall governance responsibilities.

The following sections of this chapter explore the governance committees in place at CHI at Temple Street and CHI at Crumlin over the time frame of this review of relevance to the introduction and use of surgical implants and medical devices. Consideration of regulatory requirements in this area and their application within CHI are also considered.

2.4 Governance for the introduction and use of medical devices at CHI

The previous section outlines the corporate and clinical governance and management arrangements in place in CHI during the time frame covered by this review. The safe introduction and use of medical devices and surgical implants also requires specific governance across a number of departments and functions within the hospital. In addition to any local hospital policies, medical devices are covered by legislative requirements and by national policies from the HSE.

From the time when a new medical device or surgical implant may be identified as a potential option for clinical care to when it is implanted into a patient, input may be needed from across the organisation. This section considers where the controls and oversight of medical devices and surgical implants exist within the hospital structure.

Firstly, there are committees and professional groups that can input to and consider the proposed implantable device and assess its suitability and safety for use in a given clinical situation, so as to maximise potential benefits and minimise potential risks. HIQA has identified that these controls include engagement with hospital management, engagement with clinical management, multidisciplinary clinical team input, and consideration by the research ethics committee and the medical devices committee.

Once such processes are complete and there is an agreed decision to progress, the medical device or surgical implant needs to be sourced with supporting information and supply arrangements so that it can be available for the patient. This also requires input across a range of functions in the hospital. HIQA has identified that the following functions play a key role and can act as controls in the safety of medical devices: approvals mechanisms, ethical considerations, procurement (purchasing), clinical engineering, decontamination and theatre.

All of these controls require clear policies, processes and procedures to promote evidence based and standardised practice, so that staff are aware of what is required and can work together in a coordinated way.[(4)] Safe and effective management of medical devices also requires that there is oversight by hospital management and that the committees and departments involved report to hospital management, so they can provide assurance in relation to their functions and on the legislative requirements. Procedures to escalate issues or safety concerns are an essential part of this, including the management of safety notices which may issue after a medical device has been used. Audits of processes and patient outcomes can also ensure processes are consistently applied and safety of medical devices is monitored on an ongoing basis.

In the absence of standardisation across CHI, HIQA reviewed the individual governance arrangements in place in CHI at Crumlin and CHI at Temple Street in those areas related to the introduction and use of medical devices. These included policies, processes and practices for the relevant regulatory requirements, ethics, procurement, approvals mechanisms, decontamination and theatre. This assessment was conducted through meetings with staff, observation of processes and review of documentation provided.

2.4.1 The EU Medical Device regulatory framework and implementation in CHI

The EU Medical Device regulatory framework was first put in place in the 1990s. The Health Products Regulatory Authority (HPRA) (formally known as the Irish Medicines Board), is the competent authority for medical device regulation in Ireland. It carries out a number of functions that aim to ensure that medical devices are safe and perform as intended.

The regulatory framework in place prior to May 2021 consisted of three EU Directives – the General Medical Devices Directive (MDD),[(2)] the Active Implantable Devices Directive (AIMDD)[(17)] and the In Vitro Diagnostic Medical Devices Directive (IVDD).[(18)] The European Medical Device Regulation (MDR) became fully applicable in Ireland in May 2021, bringing together and updating the previous MDD and AIMDD into one regulation. The IVDD was also updated and replaced by the European In-vitro Diagnostics Regulation (IVDR).

The regulatory framework in place prior to May 2021, and at the time that the first two surgical procedures where the non-CE marked springs were implanted at CHI at Temple Street, included the three EU directives – the MDD, the AIMDD and the IVDD. The regulatory framework in place at the time of the surgical procedure for the third child was the MDR. At all times from 1994, the legislative framework in place in Ireland required that medical devices placed on the market carried a CE mark.[†††††] Both regulatory frameworks also describe circumstances whereby a medical device without a CE mark could be used.

Such circumstances are described as **special purposes** under the 1994 framework and include:

- **clinical investigations:** any systematic investigation or study in or on one or more human subjects, undertaken to assess the safety or performance of a medical device
- **custom-made:** means a device that it is manufactured specifically in accordance with a written prescription of a registered medical practitioner or a professional user which gives, under their responsibility, specific characteristics as to its design; and that it is intended to be used only for a particular named patient.

Pre-May 2021, an application was required to be submitted to the HPRA to carry out a clinical investigation, which would undergo technical and clinical review. The

[†††††] Further information on CE marking is available in Appendix F.

manufacturer was also required to have received a favourable opinion from the relevant ethics committee(s). The HPRA decision of objection or no-objection was referred to the HPRA Management Committee. Following the decision, the HPRA would issue a letter accordingly to the sponsor. Clinical investigations of CE-marked medical devices did not require prior notification to the HPRA.

Prior to May 2021, the HPRA did not approve or authorise custom-made devices. However, manufacturers within the State who placed custom-made devices on the market were required to register with the HPRA.

Pre-May 2021, the HPRA also had legal provision to authorise the placing on the market or putting into service in Ireland of an individual medical device in exceptional circumstances in the interest of public health or patient safety or health. This applied to use of a single device on an individual named patient basis in instances where the treating clinician believed that use of the non-CE marked device is in the best interest of that patient's health. This was a separate process and called 'acute compassionate use' (ACU).[‡‡‡‡‡] Both the relevant clinician and the manufacturer of the non-CE marked medical device were each required to submit an application to the HPRA to apply for acute compassionate use of a medical device. The application would undergo technical and clinical review and was subject to a decision to authorise or reject the application by the HPRA.

The MDR, in place since May 2021, sets out four specific circumstances where a non-CE marked medical device or accessory to a medical device may be used. These are:

- **derogation for compassionate use:** a competent authority[§§§§§] may place on the market or put into service a specific device for use that is not CE marked but which is in the interest of public health or patient safety or health.
- **clinical investigations:** is defined as any systematic investigation involving one or more human subjects, undertaken to assess the safety or performance of a device
- **custom-made devices:** that it is manufactured specifically in accordance with a written prescription of a registered medical practitioner or a professional user which gives, under their responsibility, specific characteristics as to its design; and that it is intended to be used only for a particular named patient.

[‡‡‡‡‡] This is also known as 'compassionate use'. This process was based on Section 12(10) of S.I. No. 252/1994, and Section 7(5) of S.I. No. 253/1994 for their respective devices.

[§§§§§] The Health Products Regulatory Authority (HPRA) is the competent authority for medical device regulation in Ireland

- **in-house manufacturing:** means a device is manufactured and used within a health institution, complies with the MDR and is not manufactured on an industrial scale

If any of these specific circumstances are to be used, there are particular regulatory requirements specified that need to be met to ensure that they are utilised safely. The HPRA has a direct pre-authorisation role in two of the circumstances above. An organisation is required to engage directly with the HPRA if a medical device is planned to be used on the grounds of compassionate use or as part of a clinical investigation as identified above. In the case of custom-made devices, manufacturers are required to register with the HPRA, and in the case of in-house manufacturing, information on these activities is to be made available to the HPRA.

At the time of conducting this review, 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 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 described above where a non-CE marked medical device could be used under the regulatory frameworks in place. Therefore, CHI was not adhering to National Standard 5.10 with regard to compliance with national and international legislation.[******]

In an update provided to HIQA on 16 July 2024, CHI stated that it was working towards achieving compliance with the relevant legislation which applies to medical devices, including the MDR, and CHI anticipated that it will achieve compliance by the end of 2024. In a further update to HIQA on 4 December 2024, CHI confirmed that the CHI Medical Device Management System was to be established by the end of December 2024 and the Medical System Operational Brief was to be presented to the CHI Executive Management Team in January 2025 for approval.

2.4.2 Research and ethics at CHI

Ethical considerations are important in all healthcare settings, including when new surgical procedures or medical devices are being considered for use in patient care.

HIQA found that there were research ethics committees and clear processes in place in each of CHI at Temple Street and CHI at Crumlin hospitals. The terms of reference of the committee at CHI at Temple Street stated that if a complex clinical

[******] At the time of writing, individual medical devices may be covered either by the older Directives or the new MDR. This is because there is a crossover period for the implementation of the MDR. This means that the three EU Directives which formed the legislative requirements may still apply from May 2021 onwards to certain medical devices but new medical devices may be covered by the MDR.

decision had ethical components, it should be considered in the first instance by the Ethics and Research Committee.

HIQA found an Ethics (medical research) Committee was in place at CHI at Crumlin from March 2017 to August 2021. The purpose of the committee was to safeguard the welfare and rights of patients participating in research studies. The committee was chaired by a medical consultant and had representation from the legal profession.

HIQA found a Ethics and Research Committee was in place at CHI at Temple Street from February 2016 to August 2021. One of the aims of the committee was to foster, promote and support a culture of research throughout the hospital, while ensuring children are protected from harm. The committee was chaired by a member of the legal profession. The terms of reference were clear regarding the requirement for an application to the committee for consideration for ethical approval in circumstances where the intended treatment required a change from accepted standards of clinical care.

HIQA confirmed the committees of each hospital were integrated to form a single CHI Research Ethics Committee, with terms of reference from August 2021.

In conclusion, HIQA found that there were well-established research and ethics committees at both hospitals during the time frame covered by this review, and at the time of writing this report both hospital committees had been integrated into a single CHI Research Ethics Committee.

2.4.3 Procurement and approval processes for Medical Devices at CHI

HIQA reviewed the governance processes for the procurement and approval of medical devices and surgical implants at CHI. Both 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. Each hospital site operated with a separate procurement process in accordance with local policies and or practices.

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 as described previously.

With specific reference to procurement of medical devices, HIQA found that theatre procurement at CHI at Crumlin was managed centrally through the buyer's office which is part of the procurement service. At CHI at Crumlin, there were no other processes through which purchases could be made from a supplier by other departments outside of this centralised buyer's office.

In addition, CHI at Crumlin had two committees in place for considering the purchase of all non-routine medical devices and equipment. These were the Clinical Products Procurement Committee (CPPC) and the Medical Equipment Procurement Committee (MEPC).

The CPPC was chaired by a medical consultant who was a consultant microbiologist. The committee reported to the hospital's clinical director and membership included clinical and administrative functions across the hospital site. The committee provided a process for staff to follow whenever a new or alternative clinical product has been requested and is required. Products that had recently been considered by the CPPC at the time of the review ranged in unit values from €100 to €2,220.

The MEPC was chaired by a medical consultant who was a consultant radiologist. The committee reported to the hospital's clinical director with membership from clinical and administrative functions across the hospital site. The committee provided a process for staff to follow whenever a new or alternative piece of clinical equipment has been requested and is required. Products that had recently been considered by the MEPC at the time of the review ranged in unit values from €5,000 to €70,000. Examples of products reviewed are ultrasound machines, laboratory diagnostic equipment and cardiac heart monitors. It was highlighted to HIQA that as equipment was sometimes purchased with charitable donations, there was a requirement for clear processes to ensure the effective use of such donations.

HIQA was informed at interview that there was no formal standard operating procedure document at CHI at Crumlin to inform the requesting of a new medical device or product from these two committees. However, during interview it was outlined that both committees followed the below process when requesting a new product or medical device at CHI at Crumlin:

- A detailed requisition questionnaire is completed by the requestor (proposal sponsor).
- The completed questionnaire is submitted to the relevant committee for consideration.
- The requestor presents the case for the clinical product or medical equipment to the relevant committee in person.
- A multidisciplinary discussion takes place at the meeting and a consensus decision is made.
- The request is either approved, not approved or additional information is requested for further consideration.
- The committee decision is confirmed in a letter to the requestor.

- For urgent requests, a fast-track option is available, but this option is only for use under exceptional circumstances, with additional safeguards applied, including close scrutiny of the application by the committee chairperson.

The clinical engineering department at CHI at Crumlin was under the governance of the hospital's clinical director. The clinical engineering department managed equipment only and had no function in the management of implantable medical devices. The Chief Clinical Engineering Technician at the hospital was a member of both the MEPC and the CPPC. HIQA was informed at interview that equipment managed by the clinical engineering department was checked for CE-mark certification and the manufacturers' instructions were followed in the use of all equipment.

CHI at Temple Street had a contract, procurement and supply chain office (stores office) that reports to the CHI Chief Financial Officer. HIQA was informed that the areas of responsibility covered contracts and procurement of general medical, surgical and household products. Staff told HIQA that not all purchasing was done centrally through the stores office and that a system of local department approvals is in place. Certain departments, which often purchase specialist products, such as the laboratories, clinical engineering and finance department, could access the business management system and order products directly from the supplier without direct input from the stores office. When this occurred, the ordered product and invoice was shipped straight to the ordering department with the invoice then forwarded to the finance department. This means that products could arrive into the hospital outside of the stores office, which made it harder to track goods received.

At the time of this review, the clinical engineering department at CHI at Temple Street was managed by the Chief Clinical Engineering Technician under the governance of the CHI Facilities Department. The department policy outlined that the overall responsibility of the clinical engineering department is the management of health technology and medical devices used throughout the hospital for the duration of their life cycle.

At CHI at Temple Street, for the time covered by this review, there was a single committee in place for considering the purchase of all non-routine medical devices and equipment, the Medical Devices and Equipment Management Committee (MDEMC). The chairperson was the Chief Clinical Engineering Technician. HIQA was informed during interview that this committee did not meet for a number of years and was reactivated around 2017 to formalise and manage the increasing numbers of new medical devices being introduced in the hospital. HIQA found that this committee did not report to any other senior management committee in the hospital or CHI at the time of this review. As a result, there was no mechanism for CHI

senior management oversight of this committee or the management of health technology and medical devices.

HIQA was informed that this committee did not consider or have responsibility for the approval of Class III medical devices[††††††] (which includes implantable medical devices) and there was no other committee in place for the approval of such implantable medical devices in place at CHI at Temple Street.

To inform this review, HIQA requested minutes from meetings held by this committee in the years 2020 to 2023 inclusive. HIQA received documentation which showed that only three in-person meetings of the Medical Devices and Equipment Management Committee were held in 2021 and 2022, and no meetings occurred in 2020.

Due to the challenges in convening meetings, HIQA was informed that the work of the Medical Devices and Equipment Management Committee moved online via email in 2023. This process involved the committee members completing sections of a Microsoft Excel spreadsheet. HIQA was provided with completed questionnaires and email communications that demonstrated the work of this committee continued to be carried out through this new online process via email. The process for the introduction of a new medical device at CHI at Temple Street was described to HIQA as follows:

- A detailed requisition questionnaire is completed by the requestor.
- The completed questionnaire is submitted to the chairperson for review and to ensure the questionnaire is completed correctly.
- The questionnaire is circulated to committee members by email with an accompanying Excel sheet.
- Each committee member reviews their relevant section and signs off on the approval or adds additional comments with the date and their initials on the Excel sheet.
- When all the sections are approved and the Excel sheet completed, the request is deemed to be approved by the committee.

[††††††] Medical devices are classified into four distinct risk classes. These classifications with examples include:

Class I	- bandages, beds, thermometers,
Class IIA	- catheters, syringes, orthodontic wires,
Class IIB	- incubators, analgesia delivery pumps, long-term contact lenses
Class III	- cardiovascular stents, absorbable sutures, joint replacements.

- An email is then sent to all committee members advising that the product has been formally approved for use in the hospital.

While this process offered members the opportunity to input their assessment into the product application, the absence of a meeting meant there was no effective forum to enable a meaningful multidisciplinary discussion or questioning on an application for the introduction of a new medical device at CHI at Temple Street.

At interview, the former hospital site CEO of CHI at Temple Street informed HIQA that on reflection the governance around the Medical Devices and Equipment Management Committee at CHI at Temple Street could have been more robust during the time frame covered by this review. HIQA reviewed an email sent in November 2021 by the Chairperson of this committee to the CHI at Temple Street senior management triumvirate team, which sought guidance relating to the formal reporting structure of this committee in the new governance arrangements. HIQA was informed that no formal action was taken by CHI at Temple Street senior management following receipt of this email to clarify the governance arrangements for this committee. This committee was not formally integrated within the wider hospital governance structures at CHI at Temple Street.

HIQA also found that the absence of standardised policies and procedures across CHI contributed to variations in practice across the hospitals for the management of medical devices. HIQA found that the absence of standardised structures and processes resulted in the reporting linkage between the Medical Devices and Equipment Management Committee at CHI at Temple Street and senior management being lost.

In the course of its review, HIQA confirmed that in November 2023 there was still no single CHI-wide governance approach to the management of medical devices. CHI did not have a single standardised approach to medical device management and governance, with the CHI at Temple Street and CHI at Crumlin sites operating independent governance processes. This meant that CHI senior management had different arrangements in place for the hospital-specific medical device committees.

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. Specifically, there was no mechanism for CHI senior management oversight of the functioning of this 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.

In conclusion, HIQA found that the arrangements in CHI for the management of medical devices at CHI at Temple Street were not functioning in line with best practice, or in keeping with National Standards 5.1 and 5.2 on formalised governance arrangements as it applies to the management of medical devices.

2.4.4 Decontamination at CHI

HIQA found that there were no standardised processes and policies in place across CHI with respect to decontamination. In the absence of same, HIQA reviewed local decontamination policies and procedures in place at CHI at Crumlin and CHI at Temple Street during the time frame covered by this review.

The central decontamination unit at CHI at Crumlin is under the governance of nursing services within the hospital, with the Decontamination Manager reporting to the Theatre Assistant Director of Nursing (ADON). HIQA found there was a decontamination committee in place at CHI at Crumlin, chaired by the Decontamination Manager, with membership drawn from medicine, nursing, engineering, operations and quality and patient safety services. The purpose of the committee is to ensure best practice and to meet the requirements of the relevant HSE[20] and HIQA standards.

The central decontamination unit at CHI at Temple Street is under the governance of nursing services within the hospital, with the Decontamination Manager reporting to the Theatre ADON. HIQA identified that the Decontamination Manager previously reported to the Director of Quality with the ancillary staff in the department reporting to the theatre ADON at CHI at Temple Street. There is no separate decontamination committee at CHI at Temple Street, but the decontamination manager was a member of the hospital Infection Prevention and Control (IPC) Committee and provided regular updates on decontamination issues to this committee.

2.4.5 Theatre Departments at CHI

HIQA met with senior nursing leadership from the operating theatres at both CHI at Temple Street and CHI at Crumlin. At the time of interview with HIQA, there had been a single manager in place for theatres across both sites since December 2023. Prior to that there was an Assistant Director of Nursing (ADON) in each hospital with responsibility for theatre.

At interview, the ADON for both theatres, based at CHI at Crumlin, stated that they had also recently taken over responsibility for theatres at CHI at Temple Street. This

replaced the previous management structure for theatres at CHI at Temple Street, which consisted of a site-specific assistant director of nursing, who as part of their responsibilities covered theatres at that site.

HIQA reviewed the processes in place on site in CHI at Temple Street and CHI at Crumlin for the ordering, record-keeping and governance related to implantable medical devices. HIQA found that there was no standardised set of the policies and procedures for theatres across the CHI at Temple Street and CHI at Crumlin sites in November 2023.

The Assistant Director of Nursing for theatre stated that any new device for use in the theatres at CHI at Crumlin must be approved by either the Clinical Products Procurement Committee (CPPC) or the Medical Equipment Procurement Committee (MEPC). They described the overall process for introducing any new medical device at CHI at Crumlin as consistent and tightly managed, including a requirement to ensure a device has a CE mark, decontamination instructions, and provision for staff training. They also described that, prior to any surgical procedure, the surgeon would speak with the Clinical Nurse Manager (CNM) of the theatre to ensure all the relevant equipment was available.

Staff in the theatres at CHI at Crumlin described the process in place for recording the details of implants that are implanted into a patient in the operating theatre. The implant details were recorded as part of the patient's intraoperative nursing healthcare record, as part of the patient's surgical healthcare record and in the hard copy 'Theatre Implant Log Book'.

The implant log book is a hardback, bound book. While on site in CHI at Crumlin, HIQA observed the implant log book for one of the operating theatres. This was confirmed as a long-established practice, and recorded specific implant and patient details. Staff described to HIQA that there was an implant log book in each operating theatre and the book was used as part of the perioperative process.

The use of the implant log book alongside the theatre log book ensured that there is a permanent written record available in the theatres of all patients that have undergone a procedure, as well a second record specifically for those patients who have had implants inserted.

There was a Theatre Management Committee in place at CHI at Crumlin. The Committee's purpose was to plan, schedule and optimise theatre usage, review theatre performance and risk management. At the time of this review, the committee was chaired by a consultant anaesthesiologist with multidisciplinary membership. The committee reported to the hospital's senior management team.

HIQA visited the theatre complex at CHI at Temple Street, and also met with senior leadership from the operating theatres at CHI at Temple Street. Documentation demonstrated that there was also a theatre log book was in use in CHI at Temple Street. Extracts from the theatre log book show that those patients who undergo a surgical procedure in a theatre have their details recorded. CHI confirmed to HIQA that until late 2023, there was no hard copy theatre implant traceability book in use in the theatre at CHI at Temple Street to record the details of those patients where implants were used. The newly appointed CHI Theatre ADON subsequently informed HIQA that CHI at Temple Street has an implant traceability book in theatre since late 2023, similar to that used in CHI at Crumlin.

At interview, nursing staff described to HIQA that one of the considerations when introducing a new device is the requirement for training of staff to ensure that all staff who might interface with a new device are fully informed. Typically, such training would generally be provided by a representative of the supplier company before the new device is introduced for use on a patient. At times, HIQA was advised that, particularly for complex medical devices, the supplier company representative may be present in theatre at the time of surgery to provide assistance in identifying instruments and equipment as required during a surgical procedure.

HIQA found a Theatre Users Committee was in place at CHI at Temple Street. The committee's purpose is described as to monitor, review, advise, implement and manage clinical practice in the operating theatre department. The committee was chaired by a theatre nurse manager, the vice chairperson was a consultant orthopaedic surgeon, and the committee had multidisciplinary membership. The committee reported to the hospital senior management team. The committee reviews theatre usage, monthly audit activity, workforce planning, risk management, correspondence and quality improvement. Meetings were held every four weeks.

At the time of writing, the CHI-wide Theatre Governance Group was newly established and both the CHI at Crumlin Theatre Management Committee and the CHI at Temple Street Theatre Users Committee were reporting in to this group.

During this review, HIQA found that there were opportunities for improvement in the recording and documentation of the specifics of medical devices in CHI at Temple Street and that this was not standardised across CHI in November 2023.

Since December 2023, CHI moved to standardise its practice in theatres across its hospitals. CHI updated its theatre processes and governance oversight with the introduction of the theatre implant log book to ensure implant recording and traceability is in line with best practice. CHI has confirmed to HIQA that the processes are now standardised across CHI at Temple Street and CHI at Crumlin.

2.4.6 Response to medical device related safety notices in CHI

Another essential element of effective oversight and governance is the management of safety alerts issued in respect of surgical implants and implantable medical devices. National Standard 5.11 requires service providers to act on standards and alerts from regulatory bodies, with regular reviews of standards, guidance and alerts, and to take prompt action on recommendations.

On occasion, issues may arise with medical devices that require the manufacturer to communicate to healthcare services pertaining to safety. Such alerts are brought to the attention of an organisation by the manufacturer and or regulatory authority and are termed 'field safety notices'.[‡‡‡‡‡‡]

HIQA found that there was no standardised set of the policies and procedures for the management of safety notices related to medical devices across the CHI at Temple Street and CHI at Crumlin sites.

At CHI at Crumlin, HIQA found there was a Medical Device Safety Alert Huddle in place that was meeting weekly. Its purpose was to record, review, assign responsibility and actions, follow up and close out the notices received.

HIQA reviewed documentation that demonstrated how CHI at Crumlin initially managed four field safety notices issued between March 2020 and December 2021 in relation to a spinal rod implant systems known as 'MAGEC rods'.[§§§§§§] As CHI at Temple Street did not use the MAGEC rods medical devices, the notice was not applicable to that site.

On receipt of the first three notices, CHI at Crumlin carried out an initial review of patients, and contacted families of patients and general practitioners (GPs) to update them on the clinical plan regarding these children. During this review, HIQA was informed that the 'huddle' meeting in CHI at Crumlin now included staff from CHI at Temple Street, with plans to integrate this meeting as part of the newly established CHI-wide medical devices management structures and committees.

HIQA found that the initial assessment and management of field safety notices following receipt at CHI at Crumlin was in keeping with National Standard 5.11. There was evidence of evolving good practice for the management of field safety notices on their receipt. HIQA found that further work is required by CHI to fully

[‡‡‡‡‡‡] 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.

[§§§§§§] MAGEC rods are an implantable medical device used in spinal surgery and in this instance used at CHI Crumlin.

embed the initial and ongoing management of standards and alerts, including field safety notices, as part of day-to-day operations. It is essential that such work should include arrangements to ensure effective ongoing communication between CHI with patients and their families as to any implications for their care.

HIQA's engaged with patient groups and families with children who require specialist orthopaedic services through this review. This highlighted the potential for significant improvements in the nature of ongoing communication and supports between CHI and patients and their families in both sites about their treatment and ongoing care, including when field notices are issued. This particularly referred to access to specialist services and advice and support about ongoing care needs. This is an area that will require ongoing follow up by CHI in respect of the care and management of these patients.

An effective and empathetic approach to communication with patients and families around issues affecting their care is essential particularly when the care needs are complex and or their conditions are critical. It is of paramount importance that when issues arise, the resulting needs of affected children and families in terms of access to specialist services, advice and support are responded to effectively and consistently to ensure safe timely access to care. HIQA has made recommendations in this regard as part of this review.

2.5 HIQA engagement with CHI on Medical Device Governance

HIQA found that overarching CHI-wide standardised processes and supporting policies and procedures were not in place for the introduction and use of medical devices. In addition, there was no standardised, overarching governance structure for medical devices across CHI.

At the outset of this review, and in the absence of the identification of a standardised approach across CHI, HIQA found that there were weaknesses with the governance arrangements in place at CHI at Temple Street for the introduction and use of new surgical implants and implantable medical devices.

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. The letter stated that, at the time of the on-site visit, the corporate governance and oversight of use of surgical implants and implantable medical devices in CHI at Temple Street was not in accordance with the requirements of National Standard 5.2. Specifically, HIQA highlighted that the Medical Devices and Equipment Management Committee had not been placed on a formal footing within the hospital, its membership was limited, it did not have senior managerial or clinical oversight and it did not have a role in the oversight of the

introduction to practice of the use of surgical implants or implantable medical devices.

HIQA also identified that the Medical Devices and Equipment Management Committee at CHI at Temple Street did not have an agreed terms of reference or a clear line of reporting into senior management. The position of the committee in the overarching governance structure for the hospital was unclear in terms of reporting lines and pathways to raise concerns.

On 13 December 2023, the CHI Acting CEO sent a detailed response to HIQA's letter. The response outlined the immediate actions that were underway to address HIQA's concerns around governance arrangements, as well as longer-term goals for 2024. These included the introduction of a revised medical device management system for CHI, incorporating a newly constituted CHI-wide medical device management committee. This system proposed to integrate the work of existing departments and working groups into a single organisational-wide system that intended to deliver both strategic and operational management of medical devices and equipment.

The letter described the revised CHI Medical Device Management Committee as providing a clear 'line of sight' view of responsibility and accountability from the CHI Board through to the CHI Executive Management Team. The new CHI-wide Medical Device Management Committee would be chaired and led by a member of the CHI Executive Management Team, with the first post-holder being the CHI's Acting CEO at the time. They would have overall executive accountability, responsibility, and authority for the delivery of high-quality, safe and reliable medical device management. A detailed plan of work up until May 2024 and initial draft supporting documentation accompanied this letter.

HIQA requested an update on the progress of this CHI-wide group medical device committee in July 2024. On 16 July 2024, HIQA received an update from CHI on the progress of this work. CHI stated to HIQA that:

- The CHI Medical Device Management Committee had been established, with approved terms of reference, and meetings were occurring monthly.
- CHI had revised the Medical Device Management System to consider strategic issues related to medical devices.

HIQA requested further updates from CHI in December 2024 and March 2025 on the progress of this work and CHI confirmed that:

- the CHI Medical Device Management System Policy was signed off in December 2024. This is the overarching policy which governs procedures associated with medical devices, medical equipment and implants.
- the Medical Device Management System Operational Brief (Medical Device Policy) was due to be presented to the CHI Executive Management Team in March 2025.
- a communications plan had been developed on the revised Medical Device Management System for CHI staff.

In December 2024 and March 2025 HIQA requested an update on the care and management of the children impacted by the use of the non-CE marked springs and on the wider cohort of children being treated by Surgeon A. CHI confirmed that all children are receiving follow-up care, that there is a Clinical Nurse Specialist available for support to families as required, and that the Spinal Services Management Unit Team includes the Spinal Patient Advocate Liaison Coordinator who is available to provide support to parents with specific concerns or complaints related to spinal surgery.

HIQA acknowledges the work undertaken to date and the plans by CHI to advance a Medical Device Management System. As these were newly established structures, it was too early for HIQA to evaluate their effectiveness at the time of concluding this review.

2.6 Conclusion on governance and management arrangements

In 2019, following its establishment as a legal entity, CHI developed the governance structures with an intention to promote integration of services in advance of movement to the new National Children's Hospital. HIQA found that this new governance model was introduced without the introduction of key internal structures, controls and processes in parallel. For example, there was no standardisation of committees, policies, procedures or introduction of standardised internal controls, including oversight and approval processes across all functions. The absence of these key internal structures and processes did not allow the CHI Board to have fully effective oversight and assurance 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 during this time period.

From the establishment in 2013 of the Children's Hospital Group Board and the subsequent commencement of Children's Health Ireland (CHI) as a legal entity in 2019, CHI has undergone significant change as an organisation. Specifically, HIQA notes that the development and implementation of the new CHI governance structures occurred alongside the work on merging the previous hospitals to form

the new CHI. In parallel, work was ongoing to progress the building of the new National Children's Hospital and to advance a significant ICT project to move to a fully digital hospital, including a full electronic health record system.

HIQA found, through its evaluation of leadership, governance and management through the lens of spinal surgery and implantable medical devices, that 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.

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.

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. In the period 2021 to 2023, efforts were extended by CHI to implement a cross site clinical directorate structure as part of revised governance arrangements. 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 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.

HIQA also found the triumvirate and management team structures and reporting mechanisms placed an unrealistic workload on the individual post-holders. Overall, CHI governance arrangements were not in line with what would be expected of a service in compliance with National Standards 5.1 and 5.2.

HIQA found that changes in governance across CHI meant that the hospitals moved from purely site-specific management to cross-city management structures. While this represented a change for both hospitals, this had a greater impact at CHI at Temple Street. This was because 37 of the 39 clinical specialties were available on site at CHI at Crumlin, which enabled a higher level of continuity and self-sufficiency in day-to-day services there. In some instances, governance structures at CHI at Temple Street moved off site, meaning that prior ways of working were disrupted. As a result, the hospital site governance arrangements for front-line staff delivering services at CHI at Temple Street became less clear under the new governance structures. This is not what would be expected in a service with clear accountability arrangements in keeping with National Standard 5.1. This national standard outlines the need for clear accountability arrangements, including formally reporting on the quality and safety of the service.

In line with National Standard 5.1, this finding indicates a requirement to further review overall governance arrangements within CHI to ensure effective and timely oversight and assurance arrangements at Board and Executive level to support early and appropriate intervention in terms of serious operational, clinical and risk issues.

Finally, HIQA found that CHI was not in compliance with relevant European regulations pertaining to the introduction and use of medical devices over the time frame of this review, therefore CHI was non-compliant with National Standard 5.10 regarding national and European legislation.

2.7 Key findings related to governance for the introduction and use of medical devices at CHI and compliance level judgments with national standards

Table 1 below represents the key findings of this review in terms of the governance and oversight arrangements in place at CHI through the lens of the use of surgical implants and or implantable medical devices, including the use of non-CE marked springs as implants in spinal surgery at CHI at Temple Street. Table 1 presents HIQA's judgment of compliance with five of the national standards, under the dimension of 'capacity and capability', which were monitored as part of this review.

Table 1. Assessment of compliance with the capacity and capability dimension of the *National Standards for Safer Better Healthcare*

Capacity and Capability Dimension
Theme 5: Leadership, governance and management
Standard 5.1 Service providers have clear accountability arrangements to achieve the delivery of high quality, safe and reliable healthcare. **Key findings:** This review covers the period from November 2018, when the use of springs was first considered as a possible treatment option, to July 2023 when it was confirmed that the springs implanted into three children during surgical procedures at CHI at Temple Street between 2020 and 2022, had been non-CE marked. <u>Governance and management arrangements at CHI</u> 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. 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. 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 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

hospital sites. 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 place for 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. 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. 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.

To support the clinical directors in the cross-city integration of clinical specialties, clinical specialty leads were being appointed within each specialty. 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 orthopaedics services at CHI at Temple Street

During this review, HIQA 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. HIQA also found that the orthopaedic service in CHI at Temple Street had been affected by long-standing issues with communications and team dynamics as far back as 2019. CHI management had been reporting to the CHI Board on issues in the orthopaedic service at CHI at Temple Street, including a 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.

Governance for the introduction and use of medical devices at CHI

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. 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 was

no overarching CHI-wide standardised governance structures and supporting policies and procedures in place for the introduction and use of medical devices.

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. This service was not functioning in line with the HSE medical device equipment management policy. 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.

HIQA found that the high-level governance focus meant that weaknesses, as identified on the ground at CHI at Temple Street relating to the oversight of medical device introduction and use, were either not known about or management efforts to address them were not effective.

Given these findings, HIQA found that in CHI there was a lack of clarity around accountability, responsibility and authority to ensure the delivery of safe quality services during this time period, and was found to be non-compliant with National Standard 5.1.

Judgment: Non-compliant

HIQA has made recommendations in this regard.

Capacity and Capability Dimension

Theme 5: Leadership, governance and management

Standard 5.2 Service providers have formalised governance arrangements for assuring the delivery of high quality, safe and reliable healthcare.

Key findings:
The safe introduction and use of medical devices and surgical implants requires specific governance across a number of departments and functions within the hospital. In addition to any local hospital policies, medical devices are covered by legislative requirements and by national policies from the HSE.

Medical Device Regulations
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. HIQA also 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. This is further discussed under National Standard 5.10 below.

Research and ethics
HIQA found that there were well-established research and ethics committees at both CHI at Temple Street and CHI at Crumlin sites. At the time of writing this report, both hospital committees had been integrated into the wider CHI Research Ethics Committee.

Procurement
HIQA found there were no standardised processes for procurement across both sites. Each hospital site operated with a separate procurement process in accordance with local policies and practices. CHI at Crumlin had a centralised procurement function for the purchasing of all goods. CHI at Temple Street had a system of local department approvals in place. This meant that not all purchasing was done centrally through the stores office, and that certain departments could access the business management system and order products directly from the supplier without direct input from the stores office.

Approvals within CHI for medical devices
HIQA found both 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.

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. 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. This meant that CHI senior management had different arrangements in place for the hospital-specific medical device committees.

Decontamination

HIQA found that there were local decontamination structures and processes in place at CHI at Crumlin and CHI at Temple Street during the time frame covered by this review. However, HIQA found that there were no standardised structures and processes for decontamination across CHI at Temple Street and CHI at Crumlin at the time of this review.

Theatre

HIQA found that there was no standardised set of the policies and procedures for theatres across the CHI at Temple Street and CHI at Crumlin sites in November 2023. HIQA reviewed the processes in place at CHI at Temple Street and CHI at Crumlin 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 is 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. Prior to December 2023, there were no standardised practices in place. At the time of this review, HIQA found there was a recently established CHI-wide theatre governance committee in place. The committee's purpose is described as to monitor, review, advise, implement and manage clinical practice in the operating theatre department.

HIQA found that the overall CHI governance arrangements of implantable medical devices were not in keeping with National Standard 5.2, which outlines that there should be clearly defined roles, accountability and responsibilities throughout the service for assuring quality and safety. HIQA also found that the absence of standardised policies and procedures across CHI contributed to variations in practice across the hospitals.

In conclusion, HIQA found that the arrangements in CHI for the management of medical devices at CHI at Temple Street were not functioning in line with best practice, or in keeping with National Standards 5.2 on formalised governance arrangements as it applies to the management of medical devices.

In December 2023, CHI confirmed the introduction a revised medical device management system, incorporating a newly constituted CHI-wide medical device management committee. This system proposed to integrate the work of existing departments and working groups into a single organisational-wide system. HIQA acknowledges the work undertaken to date. As these were newly established structures, it was too early for HIQA to evaluate their effectiveness at the time of concluding this review.

Judgment: Non-compliant

HIQA has made recommendations in this regard.

Capacity and Capability Dimension

Theme 5: Leadership, governance and management

Standard 5.9 The quality and safety of services provided on behalf of healthcare service providers are monitored through formalised agreements.

Key findings:
CHI manages and delivers health services to children and young people on behalf of the HSE under Section 38 of the Health Act 2004. Such an agreement enables the HSE to provide funding to the service provider and for the service provider to deliver services as agreed with the HSE, through the National Service Plan.

CHI confirmed to HIQA that some services may be provided to CHI patients by a different hospital on foot of a service-level agreement (SLA). These included Tallaght University Hospital, Connolly Hospital Blanchardstown, National Orthopaedic Hospital, Cappagh and a number of other healthcare providers. These SLAs supported governance around CHI services and engagement between CHI and the other healthcare providers.

HIQA confirmed that, in line with National Standard 5.9, there are formalised agreements in place between CHI and a number of external healthcare providers for the provision of clinical services on behalf of CHI.

Judgment: Compliant

Capacity and Capability Dimension

Theme 5: Leadership, governance and management

Standard 5.10 The conduct and provision of healthcare services are compliant with relevant Irish and European legislation.

Key findings:
The regulatory framework in place prior to May 2021 consisted of three EU Directives – the General Medical Devices Directive (MDD),[(2)] the Active Implantable Devices Directive (AIMDD)[(17)] and the In Vitro Diagnostic Medical Devices Directive (IVDD).[(18)] The European Medical Device Regulation (MDR) became fully applicable in Ireland in May 2021, bringing the previous MDD and AIMDD together into one regulation and updating it. The IVDD was also updated and replaced by the European In-vitro Diagnostics Regulation (IVDR).

The EU regulatory framework in place prior to May 2021, and at the time that the first two surgical procedures where the non-CE marked springs were implanted at CHI at Temple Street, included the EU directives; the MDD and the AIMDD. The regulatory framework in place at the time of the surgical procedure for the third child was the MDR.

At all times from 1994, the legislative framework in place in Ireland required that medical devices placed on the market carried a CE mark.******* Both the regulatory frameworks

******* Further information on CE marking is available in Appendix F.

describe specific circumstances whereby a medical device without a CE mark could be used. 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. Therefore, CHI was not in compliance with National Standard 5.10 which specifies that the conduct and provision of healthcare services are compliant with relevant Irish and European legislation.

Judgment: Non-compliant

HIQA has made recommendations in this regard.

Capacity and Capability Dimension

Theme 5: Leadership, governance and management

Standard 5.11 Service providers act on standards and alerts, and take into account recommendations and guidance, as formally issued by relevant regulatory bodies as they apply to their service.

Key findings:
HIQA found that there were no overarching structures and processes in place across CHI for the management of alerts and notifications, including field safety notices during the time frame covered by this review. HIQA found that the initial assessment and management of field safety notices at CHI at Crumlin during this time frame was in keeping with National Standard 5.11.

HIQA engaged with patient groups and families with those children who require specialist orthopaedic services. This highlighted the potential for significant improvements in the nature of communication between CHI and patients and their families in both sites about their treatment and ongoing care, including when field notices are issued. This particularly referred to access to specialist services and advice and support about ongoing care needs. This is an area that will require ongoing follow up by CHI in respect of the care and management of these patients.

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.

Further work is required by CHI to fully embed the initial and ongoing management of standards and alerts, including field safety notices, as part of day-to-day operations across CHI. It is essential that such work should include arrangements to ensure effective ongoing communication between CHI with patients and their families as to any implications for their care.

Judgment: Partially compliant

HIQA has made recommendations in this regard.

3 The end-to-end process for the use of non-CE marked springs that were implanted during spinal surgery at CHI at Temple Street

3.1 Introduction

This chapter examines compliance with national standards with specific reference to the end-to-end process for the use of the non-CE marked springs that were implanted during spinal surgery at CHI at Temple Street. This review considered the time frame from November 2018, when the use of springs was first considered as a possible treatment option, to July 2023, when it was confirmed that the springs implanted during surgical procedures involving three patients at CHI at Temple Street between 2020 and 2022, had been non-CE marked.

HIQA met with two of the three families of children who had undergone surgery where the non-CE-marked springs had been implanted to gain insights into the experiences of these families. The third family opted not to directly participate in this review. Information provided by participating families informed HIQA's lines of inquiry and findings. All three children attended CHI at Temple Street and were under the sole surgical care of one consultant orthopaedic surgeon, referred to in this report as 'Surgeon A'.

3.2 Corporate and clinical governance at CHI at Temple Street and the consideration of using the springs as surgical implants

In healthcare settings, the provision of safe and effective care is dependent upon ensuring effective and appropriate structures and processes for organisational governance, oversight and approval where necessary for the implementation of higher risk interventions. The application of such safeguards applies in the conduct of surgery in keeping with other areas of healthcare, and is of particular importance where it is intended that intervention extends beyond the norms of standard clinical practice. Such safeguards include the development and consistent application of policies and procedures to support the delivery of safe and effective care. With specific reference to this review, the governance arrangements should include policies and procedures to guide and oversee the end-to-end processes involved in surgical implants from ethical and clinical approval to procurement, decontamination and use in surgery.

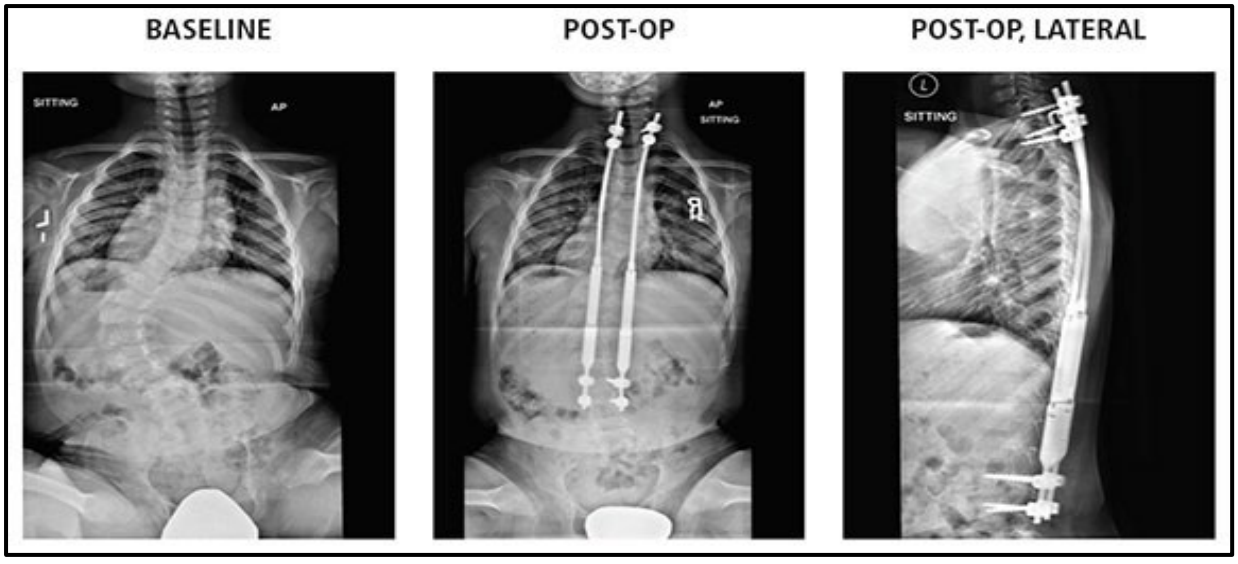
3.2.1 Clinical management of scoliosis

Early onset scoliosis is defined as any spinal abnormality that is present before 10 years of age, regardless of the cause. 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. As the spine grows in this way, it can limit the movement of the ribs and the ability of the lungs to grow in the thoracic cavity (chest cavity) and support development. This leads to reduced lung function, weaker respiratory muscles and increased effort to breath.

The aims of treating scoliosis are to prevent curves developing further, which will then require surgery, and to help develop lung function as the child develops and grows. Conservative management options include regular monitoring with radiology examinations, back bracing (using a device to limit the movement of the spine) and body casting (using a plaster cast to limit the movement of the spine). Surgical management is indicated for severe curvature. This involves spinal surgery and the insertion of growing rods (rods that can be extended as needed as the child grows) that are attached to the patient's spine and vertebral bones and assist in the growth and correction of the spine (see Figure 4 below).[21] As the patient grows, these rods require lengthening at regular intervals, necessitating a hospital visit. This is usually performed as a surgical procedure under a general anaesthetic. The rods are then removed when maximum lengthening has been achieved or the rods are replaced if further correction is required.

Figure 4. Illustration of X-rays demonstrating the use of growing rods to correct the spine at baseline and seven months post-operatively[21]



Source: This image is reproduced courtesy of Penn State Health for illustrative purposes only. Please note that this institution has no connection to the surgical devices under review in this report.

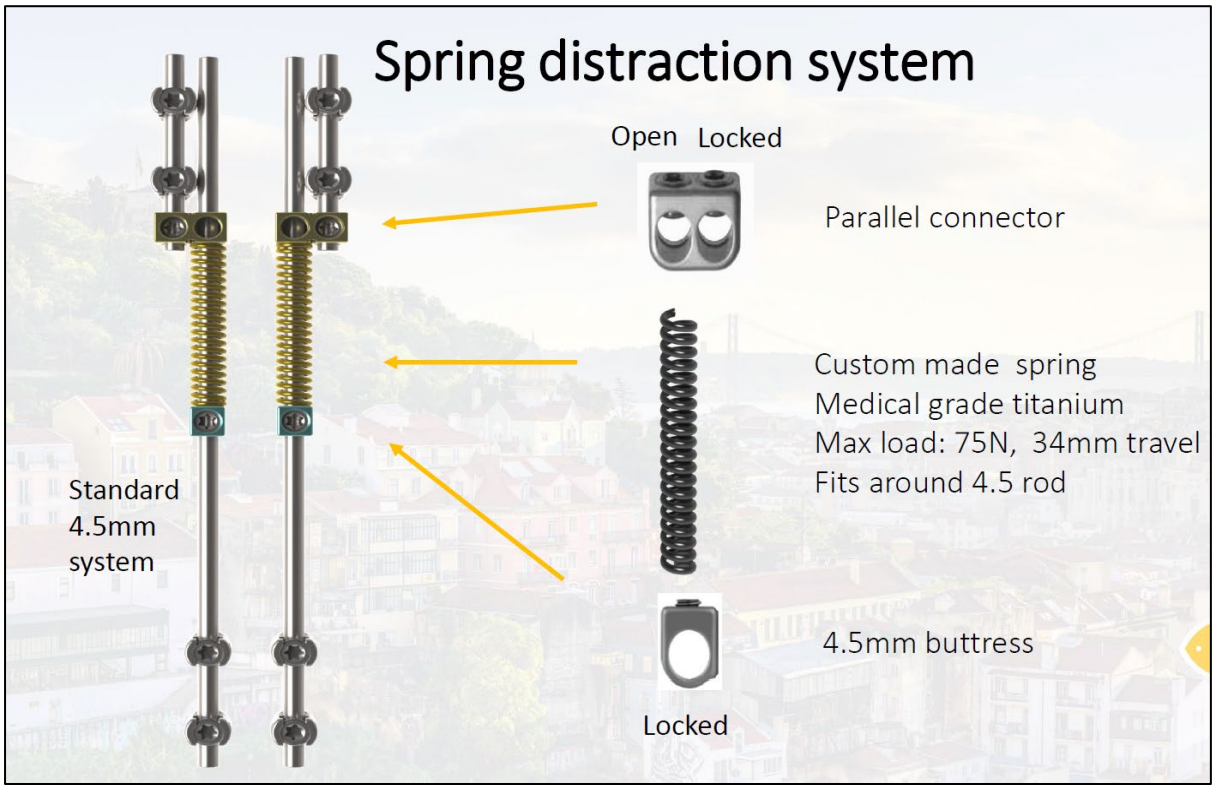
3.2.2 International conference presentation on the use of springs as part of the surgical management of early onset scoliosis

In 2016, a clinical study commenced at the University Medical Center (UMC), Utrecht, The Netherlands, which focused on a new surgical treatment option for the management of children with early onset scoliosis, known as the 'spring distraction

system'.[22] In 2018, the Utrecht team presented its initial findings of the ongoing clinical study at the 12th International Congress for Early Onset Scoliosis (ICEOS) in Lisbon, Portugal.[23] The presentation outlined the clinical results, and technical and mechanical performance of the spring distraction system. Surgeon A told HIQA at interview that they attended this conference and became aware of the ongoing work of the Utrecht team.

The spring distraction system involves placing titanium springs around the conventional growing rods which are surgically implanted into the vertebrae (individual bones) of the spine. The compressed helical coil spring applies a continuous distraction force, which aims to modify the growth of the patient's spine and correct the scoliosis. Figure 5 below illustrates the spring distraction system showing the component parts.

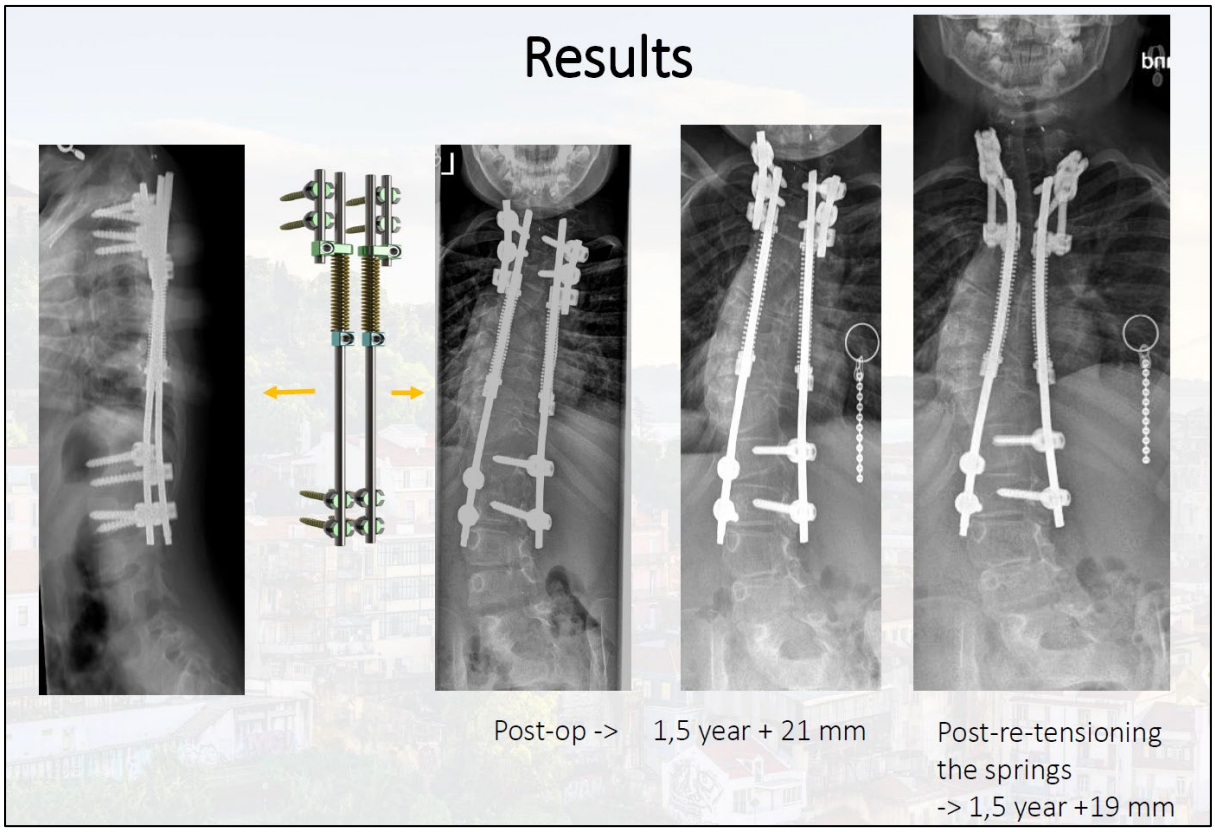
Figure 5. Illustration of the spring distraction system as presented at the ICEOS congress



Source: This image is reproduced courtesy of University Medical Center Utrecht. Please note that this institution was not the supplier of the medical devices or springs under review in this HIQA report.

The coiled spring then lengthens as the patient grows. This new approach means that these children do not require surgical or outpatient lengthening procedures at regular intervals. Figure 6 below shows the spring distraction system radiographically (as an X-ray picture), after insertion and at 18 months follow up.

Figure 6. Illustration of the spring distraction system as seen on X-ray post-operatively and after 18 months as presented at the ICEOS congress



Source: This image is reproduced courtesy of University Medical Center Utrecht. Please note that this institution was not the supplier of the medical devices or springs under review in this HIQA report.

Following the ICEOS congress in 2018, a subsequent peer-reviewed scientific paper by this research group was published in April 2021[22] (with e-publication in November 2020). It describes a prospective cohort study of 24 children that underwent implantation of the spring distraction system. This scientific paper presents the results of the study when patients were two years post-surgery. It reported the experimental nature of the device as well as the potential advantages compared to contemporary systems, including its ability to provide continuous correction forces, its ability to be easily contoured and the fact that it could be used with existing spinal instrumentation.

The authors concluded that the spring distraction system appeared to be a promising technique for surgical treatment of early onset scoliosis. The paper reported that the springs used in this clinical study were made from medical grade titanium.

The UMC Utrecht study was (partially) funded by a research grant. When contacted by HIQA in May 2024, the research team emphasised that developing and investigating a new implant takes significant effort and time and should be undertaken with utmost care. It also acknowledged the regulatory requirements,

outlining that the implants can only be broadly used in the EU after there has been regulatory approval through a notified body. An exception to this can be made in case of a strictly controlled research cohort, such as the study they were conducting.

The research team stated that prior to the start of the UMC Utrecht study, they created a research protocol which was approved by their Institutional Review Board.[†††††††] They further outlined that in one of their trials, where they implant the spring distraction system in a vulnerable patient cohort similar to that in CHI at Temple Street, an independent Data Safety Monitoring Board also continuously monitored the patient outcomes and the occurrence of adverse events, so that potential risks might be detected early and potential patient harm may be minimised.

The 2021 scientific paper reported that since the medical grade titanium spring manufacturer that created the springs for the study did not have a recognised quality management system for producing medical devices, the ISO-13485-certified Department of Medical Technology and Clinical Physics of UMC Utrecht acted as the manufacturer of the springs. This department took the lead in the design and manufacturing process and created an Investigational Medical Device Dossier, which outlined the protocol for quality control, risk analysis, and post-market surveillance and vigilance. ISO-13485 is an internationally agreed standard which sets out the requirements for a quality management system specific to medical devices.(24)

The UMC Utrecht team informed HIQA that it had not been contacted in relation to the spring distraction system during or following the 12th ICEOS congress in 2018 by any surgeon from Ireland.

3.2.3 Regulatory and ethical considerations on the use of the springs as implants

As outlined in Chapter 2, a EU Medical Device regulatory framework was first put in place in the 1990s. The regulatory framework in place prior to 2021 consisted of three EU Directives – the General Medical Devices Directive (MDD),(2) the Active Implantable Devices Directive (AIMDD)(17) and the In Vitro Diagnostic Medical Devices Directive (IVDD).(18)

The European Medical Device Regulation (MDR) became fully applicable in Ireland in May 2021 and brought together and updated the previous MDD and AIMDD into one regulation. The IVDD was updated and replaced by the European In-vitro Diagnostics Regulation (IVDR).

[†††††††] Such a board provides ethical approval for biomedical research involving human subjects in the relevant institution.

The regulatory framework in place prior to 2021, and at the time that the first two surgical procedures where the non-CE marked springs were implanted at CHI at Temple Street, included the two EU directives – the MDD and the AIMDD. The regulatory framework in place at the time of the surgical procedure for the third child was the MDR.

At all times from 1994, the legislative framework in place in Ireland required that medical devices placed on the market carried a CE mark.[‡‡‡‡‡‡‡] Both regulatory frameworks also describe circumstances whereby a medical device without a CE mark could be used.

Pre-May 2021, such circumstances are described as special purposes and include clinical investigations and custom-made devices. The HPRA also had a separate process in place to facilitate the placing on the market or putting into service an individual non-CE marked medical device for a specific patient. This was known as acute compassionate use and is described in more detail in section 2.4.1 above.[§§§§§§§]

The MDR, in place since May 2021, sets out four specific circumstances where a non-CE marked medical device or accessory to a medical device may be used. These are: derogation for compassionate use, clinical investigations, custom-made devices and in-house manufacturing. Given the EU and national regulatory requirements, any proposal for the use of non-CE marked medical devices should be progressed through the external regulatory process, the hospital's governance structures and the hospital's research and ethics committee for formal approval.

HIQA found no evidence or documented formal processes indicating that the introduction and use of the non-CE marked springs in the surgical procedures for these patients had been identified, considered or described for the following circumstances: compassionate use, a clinical investigation, in-house manufacture or as custom-made devices in conjunction with the manufacturer.

From the review of the arrangements for the introduction and use of medical devices in the above-mentioned specific circumstances at CHI at Temple Street, HIQA found that CHI was not in compliance with either the MDR or the earlier regulatory framework, and was, therefore, not in compliance with National Standard 5.10, which specifies that the conduct and provision of healthcare services are compliant with relevant Irish and European legislation. Furthermore, there was no evidence that any type of formal process was considered or followed in relation to the springs'

[‡‡‡‡‡‡‡] Further information on CE marking is available in Appendix F.

[§§§§§§§] This is also known as 'compassionate use'. This process was based on Section 12(10) of S.I. No. 252/1994, and Section 7(5) of S.I. No. 253/1994 for their respective devices.

application in clinical practice at CHI at Temple Street. This was not in keeping with the medical device regulatory framework or research best practice. Therefore, it was not in line with National Standard 3.1 in ensuring the service provider protects people using services from the risk of harm associated with the design and delivery of healthcare services. National Standard 3.1 outlines there should be structured arrangements to minimise the risks associated with possible increased risk of harm in the delivery of care, including where care involves research and clinical trials. It also outlines that safe and effective management of medical devices should be in place in accordance with legislative requirements and national policy.

As outlined, one of the specific circumstances where non-CE marked medical devices can be used is when they are part of a clinical investigation. A clinical investigation is defined as 'Any systematic investigation or study in one or more human subjects, undertaken to assess the safety and/or performance of a medical device'.[25] It is the name used for a clinical trial using medical devices and is a research activity with strict requirements.

In general, if a decision has been made to conduct a clinical investigation, clinical study or clinical trial within a hospital, ethical approval by an appropriately designated committee, as part of a formal governance and approval mechanism, should always be required. Such a situation would apply to proceeding with a new surgical technique such as that involving the springs at CHI at Temple Street.

HIQA found no evidence that this occurred. Surgeon A stated to HIQA that the use of what they described as "new and experimental procedures in children's surgery is not uncommon considering the increased complexity inherently associated with surgical procedures of this nature". They further stated that it was their view that this was neither "innovation nor research", and that "it was a bespoke solution for a small group of patients using an existing technique at the experimental stage of development." Surgeon A also stated to HIQA that while they did not engage with the Ethics and Research Committee, they would have engaged with this committee, had they been directed to do so by the CHI CEO in February 2020. This is discussed in section 3.2.5.

HIQA found a Ethics and Research Committee was in place at CHI at Temple Street from February 2016 until August 2021 when this committee was integrated in to a single CHI Research Ethics Committee. One of the aims of the committee was "to foster, promote and support a culture of research throughout the hospital, while ensuring children are protected from harm." This 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.

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.

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.

This was not in keeping with National Standard 3.1 which focuses on protecting people using services from harm associated with the design and delivery of healthcare services. National Standard 3.1 outlines that there should be structured arrangements to minimise the risks associated with possible increased risk of harm in the delivery of care. When considered through the lens of implantable devices, this national standard requires the minimisation of risk in the following situations:

- during surgical and invasive procedures,
- when care is related to the management and use of medical devices, and
- where there may be research and clinical trial considerations.

3.2.4 Clinical governance and input from multidisciplinary teams related to the springs intended for use as surgical implants

A multidisciplinary team******** is a group of healthcare workers who are members of different disciplines (professions) each providing specific services to the patient. They work together to discuss and deliver care required by an individual patient. Both the methods and documentation of communication are important in ensuring there is clear, accurate and shared understanding of the care being provided to patients and the opportunity for peer discussion, including challenge as needed, among healthcare professionals. Multidisciplinary team meetings are designed to facilitate collective debate and cross-discipline specialist input, so that consultants have this collective opinion to inform a patient's treatment plan.

From 2019, CHI and the children's hospitals were preparing to move services to the new National Children's Hospital and working to progress cross-site integration with this objective in mind. HIQA found during this review that the multidisciplinary team structures for the spinal surgery services operated separately on the CHI at Temple Street and CHI at Crumlin sites. The Orthopaedic Clinical Speciality Lead position was in place from February 2021.

******** A team combining or involving several academic disciplines or professional specialisations in an approach to a topic or problem.

HIQA was informed by CHI that there were two multidisciplinary team structures for the spinal surgery service in place in CHI at Temple Street. The 'surgical multidisciplinary team' (surgical MDT) consisted of orthopaedic surgical consultants and non-consultant hospital doctors, with some related specialty consultants invited as needed. The 'spinal multidisciplinary team' (spinal MDT) consisted of nursing and health and social care professionals. The two multidisciplinary teams met separately at different days of the week and it was not evident that there was structured overlap for each team to inform the work of the other. HIQA also established there were no formal agendas and minutes of the weekly surgical MDT meeting, but there were structured agendas and minutes of the spinal MDT weekly meeting.

HIQA found this was not a typical structure for multidisciplinary working in a clinical setting. Typically, multidisciplinary team working aims to ensure that different professional disciplines and professional groups come together to discuss the patient's care so that each profession can input from their own area of expertise. Best practice would require that other clinical specialties, including for example, radiology or anaesthetics, would be routinely in attendance as a matter of formal agreement.

In the orthopaedic service at CHI at Temple Street, the separation of the multidisciplinary team into two separate teams with no interface between them resulted in potential missed opportunities for questioning and peer review of the patient's care plan from other relevant disciplines with an understanding of the key requirements in the use of implantable devices.

When it came to discussions among clinical professionals at CHI related to the surgical procedures where the springs were ultimately used, HIQA was informed of and reviewed correspondence indicating that a specially convened multidisciplinary team meeting of consultants took place at CHI at Temple Street in or around August 2019, separate to the weekly meeting. HIQA was informed that this meeting discussed the surgical management of a small cohort of patients who had benefitted from new treatments which had successfully extended their lives, but who were now developing early onset scoliosis as a result of living longer.

In this cohort of children discussed above, surgical management is indicated for severe curvature, and non-invasive treatment options of braces or casting are not suitable. In addition, without surgery to correct their spines and which would allow the lungs to grow, it was determined by the surgical MDT that these children would suffer from progressive respiratory failure which would ultimately limit their further expected lifespan. The conventional surgical treatment would require multiple surgical procedures to lengthen the growing rods. The consultants interviewed told HIQA that given the complex respiratory needs and likely limited tolerances for

repeat general anaesthetics in these children, this presented a significant treatment challenge.

In this context, HIQA notes that there were likely well-intentioned efforts to seek to provide a new approach to surgical treatment for a number of children with life-limiting conditions at CHI at Temple Street.

HIQA was informed that two possible surgical solutions were presented at this meeting in or around August 2019. The first was the spring distraction system that had been presented at the 12th ICEOS congress in 2018. This was described by Surgeon A as a bespoke solution for a small group of patients. The technique intended to use a standard implantable rod system that was already commercially available and in routine use at CHI at Temple Street and which was to be adapted to include use of a spring which was to be sourced separately and added to the standard rod system. Unlike the Utrecht study, however, Surgeon A told HIQA that a decision was taken to seek medical grade stainless steel as in their view it is was deemed to be less likely to break than titanium. Surgeon A stated that they sought peer consultation with a consultant orthopaedic surgeon colleague, referred to in this report as 'Surgeon B', on this deviation. Through its review, HIQA did not identify any documented information on this decision-making process.

A second alternate surgical option known as the 'Drummond technique' was also presented. This is an older surgical technique using distraction rods and double folded wires to treat scoliosis.[(26)]

CHI confirmed to HIQA that there was no formal agenda or minutes available for this meeting. Therefore, HIQA is unable to confirm who attended the meeting, the detail that was presented on the two surgical techniques, the precise nature of the discussions that took place or whether any formal decision was taken.

HIQA was also informed that a second, specially convened multidisciplinary team meeting of consultants across a number of relevant specialties, was scheduled to take place via video conference on 27 September 2021. This meeting was convened by the clinical specialty lead for orthopaedics following requests from a number of consultants working in this area across the hospital sites in CHI, including Surgeon A. The meeting intended to discuss experience across sites in the management of the treatment of children in this patient group. The agenda included an item called 'description of surgical management of scoliosis' in this patient group.

The then clinical specialty lead for orthopaedics, who chaired the meeting, told HIQA that the meeting commenced but did not proceed as there was not the required representation of attendees from CHI at Temple Street. This meeting was not reconvened at a later date. It should be noted that this planned meeting was scheduled at a time point after two of the impacted children had already undergone

surgery to implant the springs at CHI at Temple Street, but in advance of the third child's surgery. The failure for this forum therefore to meet and discuss this matter represented a further missed opportunity to potentially prevent the use of non-CE marked springs in this third child.

During interviews, HIQA identified that there was an awareness among the orthopaedic consultant community at CHI at Temple Street, through discussions at routine weekly meetings of consultants, that a new technique using springs had been applied. HIQA was unable to determine the level of detail provided at these meetings on the use of the springs.

In the absence of formal meeting agendas and minutes, HIQA was unable to identify any evidence of questioning or debate among this consultant body — who would have expertise in this area — around any clinical aspects, material sourcing or efficacy of this proposed surgical technique.

HIQA found the processes to support questioning and multidisciplinary debate on the intended use of the springs were not adequate, which represented a missed opportunity for all those involved in patient care and medical device governance to contribute meaningfully to the decision to use the spring distraction system. 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.

In conclusion, HIQA is of the view that weaknesses in the structure and functioning of the surgical multidisciplinary team meetings, as well as the 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. These structural weaknesses persisted throughout the time frame of this review period, despite a number of changes to governance arrangements from 2020 onwards.

The arrangements as organised, and their application in practice, were not compliant with National Standard 5.2 which outlines there should be formalised governance arrangements for assuring the delivery of high-quality, safe and reliable healthcare.

3.2.5 Hospital governance and management input related to the springs intended for use as surgical implants

HIQA sought to identify the established procedures and processes for the consideration of a new implantable medical device in CHI at Temple Street at the time the springs were first introduced. At interview, the former hospital-site CEO of CHI at Temple Street outlined to HIQA that they would have expected Surgeon A to bring the idea of the new spring distraction system to them in the first instance so a

plan could be put in place. They said that typically the plan would also have included a presentation to the Ethics and Research Committee and then to the board with responsibility for the hospital.[††††††††] HIQA reviewed the terms of reference for the Ethics and Research Committee in place in CHI at Temple Street in 2019 and 2020 and found that this would have been the appropriate course of action for a proposed new technique such as that involving the springs.

In late 2020, the senior management governance structures were preparing to transition to the new management structure. During this time, when the spring distraction system was being considered as a potential surgical option, the hospital site CEO was still in position at CHI at Temple Street. There was a period of handover from September to December 2020 before the responsibility for management of the CHI at Temple Street site transferred from the then hospital-site CEO to the hospital Clinical Director in December 2020, when the new triumvirate management structure was formalised.

HIQA found that the then hospital-site CEO was not made aware of any newly proposed surgical technique by Surgeon A while they were in post up until the end of 2020. HIQA also established that Surgeon A did not submit the proposed surgical technique to the Ethics and Research Committee or to the Medical Device Equipment Management Committee for consideration.

HIQA received conflicting accounts around the occurrence of a meeting where these potential surgical procedures using the spring distraction system were discussed between Surgeon A and the CHI CEO.

Both Surgeon A and Surgeon B told HIQA that they had met with the CHI CEO on 20 February 2020 at CHI at Temple Street to discuss the surgical options for a specific cohort of patients, and that this included presenting the spring distraction system to the CHI CEO. Surgeon A stated to HIQA that the purpose of the meeting with the CHI CEO on 20 February 2020 was to seek guidance from the CHI CEO to ensure that they were doing everything correctly.

The CHI CEO told HIQA that they did not meet with Surgeon A and Surgeon B to discuss the use of the spring distraction system and that no such meeting to discuss the use of the springs occurred on the CHI at Temple Street site on 20 February 2020. HIQA was further informed by CHI that there was no record of an agenda or minutes available for this meeting.

[††††††††] Prior to December 2018, this was the board of Temple Street Children's University Hospital, and after January 2019 this was the CHI Board.

Of note, the CHI CEO stated to HIQA that a meeting did occur with Surgeon A at an alternate hospital on 20 February 2020. The CHI CEO stated to HIQA that the spring distraction system was not discussed at this meeting.

HIQA reviewed email correspondence between Surgeon A and the CHI CEO dated 20 February 2020 and a reply from the CHI CEO dated 21 February 2020. While there is a reference in these emails to a meeting on 20 February 2020, neither email specifically references spinal surgery and the spring distraction system.

HIQA was unable to conclusively confirm if the specific matter of the use of the spring distraction system was discussed between the CHI CEO, Surgeon A and Surgeon B on 20 February 2020.

HIQA also reviewed a copy of a letter dated 21 February 2020 addressed from Surgeon A to the CHI CEO which references a meeting between Surgeons A and B and the CEO that week. The letter is marked cc (carbon copy) to Surgeon B. The letter states:

> We appreciate you taking the time to meet myself and [Surgeon B] this week. As I have a dictaphone in my hand I wanted to follow up on the discussion for completeness and record.
>
> As we discussed we have come under significant pressure to implant the Magec rod from families. We are directing families who want to have this done to Crumlin. However, we don't want to fail in our duty of care since the Magec rod currently has a field safety notice attached.
>
> The other purpose of this letter that we discussed, and related to Magec [sic], is around the [specific patient cohort] and other fragile children now requiring scoliosis treatment and not suitable for multiple anaesthetics. We have met as an MDT [multidisciplinary team] under [lead consultant physician for this patient cohort] and the consensus is that treatment is required avoiding multiple procedures. However, the Magec [sic] is not suitable for reasons including the field safety notification.
>
> The solution presented to families will be a Drummond technique for [Surgeon B] and a spring assisted device for [Surgeon A]. Both techniques are not commercially available. We have told families and told them these are off label and experimental techniques using devices not designed for this purpose. However, a [sic] CEO, we needed to make you aware of this for any guidance we may need.

The letter does not provide further detail on the spring distraction system, nor any information on the springs, such as their sourcing or specifications. The letter does not specify the intended use of the springs as implants.

The CHI CEO stated to HIQA that they were not aware of the 21 February 2020 letter at that time, and that they have subsequently undertaken a review of correspondence to their office and are confident that the letter was never received. The CHI CEO reported to HIQA they first became aware of this letter in August 2023. Surgeon A stated to HIQA they did not have confirmation that the letter had been sent or received.

HIQA did not find evidence that the letter of 21 February 2020 was either sent from Surgeon A or received by the CHI CEO.

During the course of this review, HIQA observed that the 21 February 2020 letter was present in hard copy in the healthcare record of one of the patients who had subsequently undergone surgery where springs had been implanted. Surgeon A stated that it was their individual practice to request that their administrative staff at the hospital generate three copies of such a letter, with one being appended to the clinical chart, one being sent to the recipient through the hospital's internal post system and the final copy being retained by themselves. Surgeon A stated to HIQA that they had observed this letter on two sets of clinical charts during the course of this review.

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. This was not in keeping with National Standard 3.1 which covers the safe and effective management of medical devices, including having in place structured arrangements to minimise risk with their use.

3.2.6 Clinical governance and management related to the springs intended for use as surgical implants

HIQA found that a clinical director was in place at CHI at Temple Street throughout the period covered by this review. Therefore, CHI at Temple Street had a senior clinician for the hospital in place who could be contacted in the event of an unusual or new treatment being considered. HIQA also found that there was a clinical specialty lead for orthopaedics in place from February 2021, and a CHI Chief Medical Officer in place from July 2021.

All of these post-holders stated at interview that they had neither been made aware of the intended use of the springs nor of the new nature of the surgery.

Surgeon A confirmed to HIQA that they did not discuss this proposed technique, or the intention to procure and utilise the springs, with their Clinical Director for CHI at Temple Street. HIQA was not provided with any further evidence of any other engagement between Surgeon A and senior clinical management of CHI before the use of the springs in spinal surgical procedures. In addition, throughout the course of this review, HIQA has not identified any written evidence demonstrating that there was formal approval from any senior clinical leader within CHI for the conduct of the procedures where springs had been implanted.

HIQA found the governance arrangements as outlined did not clearly specify the processes for consideration of new or unusual treatments. This is not in line with National Standard 5.2 which outlines the need for clear roles, accountability and responsibility in ensuring governance and safety of services. National Standard 5.2 also outlines that the governance arrangements in place should ensure the quality and safety of outcomes for patients. This was also not in keeping with National Standard 3.1 which covers the safe and effective management of medical devices, including having in place structured arrangements, including approvals processes, to minimise risk with their use.

HIQA also noted that the Ethics and Research Committee was in place at CHI at Temple Street at the time the springs were being considered as a potential clinical option. This committee was then integrated into the CHI Research Ethics Committee in August 2021. HIQA found no evidence that the use of the springs was discussed with these committees.

3.3 Introduction of the springs at CHI at Temple Street from their sourcing to their use in theatre

In addition to the processes for consideration and approval of using the springs as implants, HIQA reviewed the pathway from the sourcing of the springs to their final use as implants in theatre. This covers input to the process of acquiring the springs from across departments and services in CHI at Temple Street, including procurement, clinical engineering, decontamination and theatre.

3.3.1 Sourcing and procurement of the springs

During the time frame covered by this review, there was a national procurement policy in place as set out in the 'HSE National Financial Regulations – Purchase to Pay'[(3)] 2006. This policy outlines the procurement steps that are to be taken when seeking to purchase a new product. In addition, local policies and procedures also apply. Therefore, there may be a number of steps involved and controls required before the product is available in the hospital for use in a patient.

3.3.1.1 Sourcing of the springs

The HSE has a well-established national policy in place for the management of medical devices – the HSE Medical Device Equipment Management Policy. This policy is in place to direct the introduction and use of medical devices and equipment, including surgical implants at local level.

The processes in place at CHI at Temple Street meant that there was a requirement for specific medical device equipment to be procured within CHI at Temple Street to have formal approval through the Medical Device Equipment Management Committee (MDEMC) and for relevant safety checks to be carried out prior to use. This process was supported by the CHI at Temple Street Clinical Engineering Policy in place from 2018 to 2020. There was no equivalent system in place for implantable medical devices. As such, the stated controls that were outlined in the policy to protect patients in these areas were not adequate as they did not cover the use of implantable medical devices.

HIQA found that Surgeon A had identified a company as a potential supplier of the springs. They stated to HIQA that they understood that this was the same company that had supplied the springs used in the clinical study undertaken by the UMC Utrecht team, and contacted the company through its website. This company is referred to in this report as Company 1. Company 1 was not a recognised manufacturer of medical-grade products supplied into the healthcare industry,[‡‡‡‡‡‡‡‡] and no evidence was provided to HIQA that suggests that Company 1 was professing to fulfil such a role in the supply of these springs.

HIQA found that the first contact by Surgeon A with Company 1 that supplied the springs, occurred in December 2018.

HIQA reviewed email correspondence between Surgeon A and Company 1 from December 2018 to June 2020, with the subject line in a number of emails referring to 'medical springs'. These emails show communication focused on the technical and mechanical specification of possible springs to be purchased.[§§§§§§§§]

This communication occurred outside any of the established procurement structures and processes for the purchase of goods at CHI at Temple Street at the time.

Surgeon A informed HIQA that they believed they had worked to source bespoke medical grade stainless steel springs for the purpose of surgical implantation through Company 1. It is noted that the email subject line was 'medical springs'. Surgeon A stated to HIQA that in their view, this meant they intended to use medical grade stainless steel and there no ambiguity about the requirement for medical grade.

[‡‡‡‡‡‡‡‡] This company (Company 1) describes itself as a springs supplier.
[§§§§§§§§] Please see section 3.5 of this report for information regarding the specification of the springs.

HIQA found no evidence that identified to Company 1 that the intended purpose of the springs was for surgical implantation.

HIQA found that Surgeon A engaged with the then Principal Clinical Engineering Technician at CHI at Temple Street to purchase the springs. In line with the procurement procedures for CHI at Temple Street, specialist orders could be placed by the clinical engineering department. This Principal Clinical Engineer did not have overall responsibility for the clinical engineering department as this was the role of the Chief Clinical Engineering Technician, a position that was vacant at the time. Surgeon A stated to HIQA their belief that the clinical engineering department in CHI were fully aware of the springs order and their intended use as a medical device.

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.

HIQA could not find any written correspondence confirming that Surgeon A informed the Principal Clinical Engineering Technician of their intention to implant the springs into patients. HIQA also found that the Principal Clinical Engineering Technician did not explicitly request or confirm the intended purpose of the springs nor was this formally verified in writing. Instead, they explained to HIQA that they presumed that the springs were to be used as spare parts or replacement parts for an external traction system that utilises springs in its design.********* They told HIQA that they and Surgeon A had worked together on such a traction system a number of years previously.

The evidence provided to HIQA demonstrates there was a lack of clear and adequate communication from the Surgeon A to Company 1 around the details on the intended use of the springs during the process of sourcing and purchasing them. HIQA found that a precise specification for the springs was not formally agreed and documented before the order was signed off and placed by the clinical engineering department.

The HSE Medical Device Equipment Management Policy refers to CE marking as 'the only marking which indicates that products conform to the relevant EC directives'. Compliance with the hospital's clinical engineering policy at the time required ensuring that medical devices and equipment for intended use were CE marked. For the above reasons, CE marking of any device to be used in surgery or to be implanted into a patient is required for clear reasons of safety.

********* This is a bone bracing device fitted with the majority of the parts outside of the body, for example, to a person's arm or leg after an injury to stabilise the bone and soft tissues while they heal.

At interview, Surgeon A stated to HIQA that it was their belief that these springs had been CE-marked as suitable for use as surgical implants. In the written engagement between Surgeon A and Company 1 reviewed by HIQA, there is no evidence that Surgeon A asked if the springs were CE marked, nor did Company 1 indicate in this correspondence up to June 2020 that the springs were CE marked.

CHI informed HIQA that the supplier was not a medical company and the springs were "industrial springs" and not a certified Class III medical product which is why there was no request for a CE certificate.

HIQA found that there were no formal structures and processes in place for the consideration and approval of class III implantable medical devices at CHI at Temple Street.

HIQA sought documentary evidence from CHI at Temple Street to determine whether a written technical assessment for the springs was undertaken to inform the decision to use them as implants. No such documentation was received by HIQA from CHI.

HIQA confirmed that at no time were there any safety checks carried out on the springs by the Clinical Engineering Department prior to the authorisation of the payment, to ensure that they had a CE mark present nor did they formally verify the proposed use of the springs in writing in advance of approving their purchase.

HIQA found that there were no controls in place to carry out any type of safety checks on the springs prior to purchasing regardless of their intended or presumed use. HIQA has concluded that adequate controls and processes were not in place to ensure checking for suitability for intended use and for decontamination requirements prior to placing the order for the springs.

Furthermore, there was no process in place that required all implantable medical devices sourced for and used in the hospital to be subject to an evaluation prior to procurement. In the absence of this process, there was no formal documentation of the evaluation and checks conducted on an implantable medical device prior to its use.

Consequently, HIQA found that the governance and oversight arrangements for the sourcing of medical devices at CHI at Temple Street were not in keeping with National Standard 5.2 and National Standard 3.1. National Standard 5.2 outlines the need for clear roles, accountability and responsibility throughout the service for assuring quality and safety. National Standard 5.2 also outlines that the governance arrangements in place should ensure the primary focus of the service is on quality and safety of outcomes for patients. National Standard 3.1 outlines that there should be systematic identification of aspects of the delivery of care associated with

possible increased harm to patients and structured arrangements in place to minimise these risks, including risks related to the management and use of medical devices. It also outlines the need for the safe and effective management of medical devices in accordance with legislative requirements and national guidelines.

3.3.1.2 Procurement of the springs

CHI at Temple Street has a contract, procurement and supply chain office (stores office) in place. The areas of responsibility cover contracts and procurement of general medical, surgical and household products. Staff told HIQA that not all purchasing is done centrally through the stores office and that a system of local department approvals is in place. This process allows some departments, including clinical engineering to order products directly from a supplier. This meant that the local procurement process in place at CHI at Temple Street allowed for local departments to raise a purchase order (PO) number on the business management system directly with a supplier without direct involvement of the stores office. This means that products can arrive into the hospital outside of the stores office, which makes it harder to track goods received.

During the time frame covered by this review, as stated above, the MDEMC was in place to deal with medical device procurement requests but this committee did not deal with class III medical devices, that is to say, surgical implants.

During December 2019 and January 2020, there were a number of email exchanges between Surgeon A and Company 1 about the type of spring to be sourced. These items of correspondence made reference to the company product catalogue number, invoicing and payment options. Surgeon A included the then Principal Clinical Engineering Technician in an email to Company 1 at this time, specifying it was by way of introduction. The then Principal Clinical Engineering Technician emailed Company 1 requesting an invoice.

The product catalogue from Company 1 lists the standard springs and pressings that they provide and offers information on the composition and specifications of the springs listed. Further detail is provided on this in the section 3.5 below covering the specification of the springs.

Email correspondence reviewed by HIQA demonstrated that Surgeon A highlighted the product catalogue number from the product catalogue to the then Principal Clinical Engineering Technician. HIQA could not find any evidence that the then Principal Clinical Engineering Technician checked or questioned the intended use of the springs through this interaction. HIQA noted that when the product catalogue number is applied to the pro-forma invoice and is reviewed against the product

catalogue, this number refers to compression springs in the product catalogue that were described as 'unalloyed spring steel', not stainless steel.

The documentation reviewed by HIQA indicates one box of 10 springs was paid for by CHI at Temple Street on 8 January 2020 at a cost of £4.58 sterling per spring.

Payment was made by bank transfer. The bank transfer request form stated that the purchase was for 'purchase of springs for medical traction system' in line with the then Principal Clinical Engineering Technician's stated understanding at the time. The bank transfer request form also states that the springs were requested by Surgeon A and the form was signed and approved by the then Principal Clinical Engineering Technician. This order was placed before any stated approach by Surgeon A to senior management at CHI.

HIQA confirmed at interview and when on site that the stores office at CHI at Temple Street was not involved in the procurement of the springs. In the purchasing of the springs, the local process of raising a purchase order number through the 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.

HIQA reviewed email correspondence which described the delivery details for the order as 'Department of Orthopaedics, FTA – [Surgeon A], Children's University Hospital, Temple Street, Dublin, Co Dublin, Republic of Ireland'. HIQA also reviewed the proof of delivery docket and associated emails for the springs provided by CHI. This describes the receiver for the order as 'Department of Orthopaedics, Children's University Hospital, Temple Street, Dublin'. It indicates that the springs were delivered by courier on 7 February 2020 to CHI at Temple Street. The stores department signed the proof of delivery docket.

This order was addressed to 'Department of Orthopaedics', with the order having been placed by the clinical engineering department. HIQA has observed email evidence that suggested that the springs were not assessed by the clinical engineering department on their arrival into CHI at Temple Street. As a consequence, an additional opportunity to further review the material nature of the springs and confirm and assess their suitability for the intended use was missed.

Furthermore, had a purchase order number been generated through the business management system and applied at the time of ordering the springs, this would have allowed for some level of traceability on the order in the purchasing system. This presented a missed opportunity for the ordering of a non-routine product to

potentially be queried further. HIQA found this was not in keeping with National Standard 3.1, which outlines that risks from the delivery of care associated with possible increased harm to patients should be identified and structured arrangements put in place to minimise them. This includes risks related to the management and use of medical devices.

3.3.2 Decontamination of the springs

The 'Health Service Executive Standards and Recommended Practices for Central Decontamination Units' dated 2011[20] is the national policy for the best practice standards to be applied to the management of decontamination units in the healthcare setting. By their nature, surgical implants and implantable medical devices are single-use items, but the principles for decontamination before implantation would apply. These national HSE standards define decontamination as "the combination of processes (including cleaning, disinfection and sterilisation) used to ensure medical devices are sterile and suitable for use on patients".[20] It is a highly specialised process undertaken within hospitals. This department is the Central Decontamination Unit and the Decontamination Manager oversees the running of the unit in line with the national policy.

The national HSE standards set out a number of principles to be adhered to in the decontamination of medical devices. These include ensuring the medical device has a CE mark and complying with the manufacturer's instructions to ensure correct and safe use. The national HSE standards set out the information requirements to be provided by a manufacturer to ensure the correct and safe use of that medical device. Each medical device should be accompanied by the information needed to use it safely and to identify the manufacturer. This information includes the details on the label and the instructions for use. The information must be set out on the device itself and or on the packaging, information leaflets or on the sales packaging for each unit.

Without quality assurances, such as the CE marking and the accompanying manufacturer's instructions, a hospital cannot be assured that a medical device:

- will be decontaminated in the correct way
- will not be damaged during the process in terms of exposure to chemicals and sterilisation temperatures, or
- that the medical device will function to the technical specifications as intended and not cause harm to the end user having been processed in this way.

In 2020, the policy in place at CHI at Temple Street entitled 'Procedure for New Medical Devices, DP15' 2019 (procedure for new medical devices) stated that all medical devices must bear a CE mark and be decontaminated according to the

manufacturer's instructions. The policy also outlines recommended disinfection at 92^{o} C and sterilisation at 134^{o} C for the decontamination of standard instruments.

It was confirmed to HIQA that the conventional spinal rods system for these surgical procedures was supplied by a company that routinely supplied implantable orthopaedic devices to CHI at Temple Street (Company 2).

Documentation provided to HIQA indicated that the springs were brought to the Central Decontamination Unit for processing by a company representative from Company 2.

HIQA was unable to establish who instructed the Company 2 representative to transport of the springs to the Central Decontamination Unit.

HIQA confirmed that, on receipt of the springs, the Decontamination Manager emailed Surgeon A advising receipt and asked Surgeon A if it was possible to have the manufacturer's instructions regarding the appropriate washing and sterilisation temperatures. The email further stated that the Central Decontamination Unit would need written confirmation that 92^{o} C disinfection and 134^{o} C sterilisation was suitable for the springs.

Following a request from Surgeon A to Company 1 asking for sterilisation instructions, Company 1 responded by email to Surgeon A that it had no data on sterilisation of the springs and, therefore, could not provide instructions on processing and sterilisation. The email further stated that the springs had been purchased "from the standard product catalogue range and were not something designed to be covered by any specific medical requirements".

A further email from Company 1 to Surgeon A on the same date stated:

> We don't have specific processing / sterilising instructions they are uncoated spring steel so although they can be autoclaved they are prone to rust unless thoroughly dried immediately alternatively they should be ok in sterilising solution with the same caveat that they need to be dried immediately. Going forward the solution is the springs need to be plated for protection, this is usually zinc with passivation which would move it away from a catalogue to a bespoke spring but is perfectly possible.

Autoclaving is a process where an item is sterilised through a process that involved heat, steam and pressure. Passivisation[††††††††] is a chemical treatment of the steel to create a protective coating which reduces the risk of corrosion.

[††††††††] Is a widely-used metal finishing process to prevent corrosion. In stainless steel, the passivation process uses nitric acid or citric acid to remove free iron from the surface. The chemical treatment leads to a protective

When processing the springs, the Central Decontamination Unit did not check for the presence of a CE mark or review to double check for formal manufacturer's instructions. This was contrary to the requirement of the national HSE standards and the policy of CHI at Temple Street.

Given that the advice by Company 1 in May 2020 indicated that the springs as purchased could be damaged by an autoclave process and that they were unable to provide details around how they might be properly decontaminated, these emails should have raised concerns with Surgeon A in advance of implantation. Surgeon A stated to HIQA that they did not "engage fully with the content of these emails, at the time".

In further email correspondence dated June 2020 and prior to the first surgery to implant the springs, Surgeon A subsequently informed the Decontamination Manager by return email which stated:

> This is a case providing patient care where no commercially available medical implant is available.
>
> The family have been informed and this is documented in the patient record.
>
> With regard to sterilisation I am happy with the 92^{o} C disinfection and 134^{o} C sterilisation as a processing method for the springs.

HIQA found that the details in this email did not align with the information provided by Company 1 in May 2020 which indicated that there was no data on sterilisation of the springs. HIQA found that Surgeon A provided information to the Decontamination Manager around decontamination instructions without having regard to the relevant instructions or information provided from the manufacturer to Surgeon A on this matter.

Surgeon A stated to HIQA that it was their position that is was the responsibility of the Decontamination Manager to check the sterilisation instructions with the manufacturer. The Decontamination Manager stated to HIQA that it is the role of the requester of the medical device to provide the manufacturer's sterilisation instructions. The Decontamination Manager did not contact the manufacturer separately to request or verify the decontamination instructions provided in the email from Surgeon A.

No evidence was provided to HIQA to confirm that the information provided by Company 1 to Surgeon A was forwarded to the Decontamination Manager, in reply

oxide layer, or passivation film, that is less likely to chemically react with air and cause corrosion. Passivated stainless steel resists rust.

to the Decontamination Manager's request for manufacturer's instructions regarding the appropriate wash and sterilisation temperature.

HIQA reviewed documentation that indicated that the Decontamination Manager documented the lack of manufacturer's instructions for sterilisation of the springs as a deviation from usual practice. This form states that Surgeon A had 'no instructions and that surgery was of a time-sensitive nature'. Furthermore, HIQA found that the information provided by Surgeon A to the Decontamination Manager confirming potential decontamination instructions were not directly verified with Company 1 by the Decontamination Manager.

CHI at Temple Street was, therefore, not in compliance with National Standard 3.1, as it applies to medical devices. National Standard 3.1 outlines that there should be systematic identification of aspects of the delivery of care associated with possible increased harm to patients and structured arrangements in place to minimise these risks, including risks related to the management and use of medical devices. It also outlines the need for the safe and effective management of medical devices in accordance with national guidelines.

HIQA found there was an absence of structures and processes to support clear and adequate communication between the Surgeon A and the Decontamination Manager around the details on the sterilisation process for the springs.

3.3.3 Traceability of the springs

Decontamination records for the springs show that 10 springs were initially put through the decontamination process in the Central Decontamination Unit across two separate dates during July 2020.

CHI confirmed to HIQA that a total of 10 springs were purchased, five of which were implanted in three children and two were disposed of during the surgical procedures (as they were unsuitable for use). Of the remaining three springs, one spring was disposed of in early 2023, following visual inspection in the central decontamination unit. There is currently one spring in the possession of CHI senior management. The remaining spring cannot be accounted for due to the lack of a unique identifier traceability system in CHI. CHI has told HIQA that there are no longer any springs available for use in the clinical area at CHI at Temple Street hospital.

Each spring was individually packaged once decontaminated — with an expiry date of six months applied on their status as a sterile product. As a number of springs remained in storage in theatre for a number of years, they were required to go back to the central decontamination unit to undergo reprocessing, including repackaging, every six months to maintain their sterility.

The central decontamination unit applied a barcode to the springs on each decontamination cycle. This barcode was generated from the decontamination tracing system. While this demonstrated a decontamination cycle had occurred, it was not a unique identifier for each spring.

HIQA found that there was no evidence of a unique identifier number being applied to each individual 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. Reference numbers and barcodes were assigned for each decontamination cycle only, but not to each individual spring. Therefore, it was not possible for HIQA to determine or trace exactly which spring(s) had been used in which surgery.

3.3.4 Consent for the use of medical implants

The requirements for consent are outlined in National Standard 1.5, which states:

> Service users' informed consent to care and treatment is obtained in accordance with legislation and best available evidence.[4]

The 'HSE National Consent Policy 2013' sets out the standards and principles of informed consent and CHI confirmed that this policy was in place in CHI at Temple Street at the time of the surgical procedures.[27]

When consent is sought in respect of children under 16[‡‡‡‡‡‡‡‡‡] years of age, it is a parent or legal guardian who gives consent on behalf of the child.[28]

For consent to be valid, the person giving consent must:

- have received sufficient information in a comprehensible manner about the nature, purpose, benefits and risks of an intervention or service, or research project
- not be acting under duress
- have the capacity to make the particular decision.

The policy also sets out a number of principles that govern the ethical conduct of research which aims to protect the rights of participants, and highlights the role of the Research Ethics Committee and stresses the importance of documentation of consent in circumstances where 'the intervention is innovative or experimental'.

[‡‡‡‡‡‡‡‡‡] Section 23 of the Non-Fatal Offences against the Person Act 1997 provides that a person over the age of 16 years can give consent to surgical, medical or dental treatment and it is not necessary to obtain consent for it from his or her parent(s) or legal guardian(s). The section covers any procedure undertaken for the purposes of diagnosis and any procedure, such as administration of anaesthetic, which is ancillary to treatment.

Doctors who are considering undertaking research should ensure consent processes are appropriate to the research being undertaken.

If the use of the springs as implants had been formally approved as a clinical investigation, clinical study or clinical trial, the principles for consent in research as laid out in this National Consent Policy ought to have been fully applied. The requirements for consent may also be affected by the non-routine use of a product or procedure.

HIQA met with two of the three families of those children who had received the springs as implants. The parents stated that at the consultation stage, prior to the surgical procedures, they were not given any leaflets, diagrams or any other written information by the surgical team to take away with them explaining the step-by-step procedure of the planned spinal operation or indicating that the risk of the additional use of springs as implants.

HIQA was informed that, as part of the consultation process prior to these surgical procedures, the parents were offered a number of surgical options. These included the Drummond technique, another spinal rod system called the MAGEC rods (an option which could potentially be provided at CHI at Crumlin) and the spring distraction system.

HIQA was informed by Surgeon A that the parents of the children were made aware that this surgical procedure was "experimental and an off-label use", as described by Surgeon A. Furthermore, Surgeon A stated to HIQA that consent is not a one-off event, and that they explain the treatment process, alternatives, expectations and complications associated patients and their families over many consultations. They said that they did this fully with all three patients.

HIQA reviewed the consent forms in place at CHI at Temple Street at the time of these surgical procedures and found that the individual parents had signed these consent forms on behalf of their child. Surgeon A stated to HIQA that they had discussed these proposed surgical procedures on a number of occasions with families. HIQA found that from the perspective of documenting the consent for these proposed procedures, the information on these forms did not specify that the procedures were experimental or new.

As part of the consent process, the foreseeable risks and benefits of a healthcare treatment should be described as accurately as possible, and documented in the patient's healthcare record. Accurate and clear documentation of the consent process in the healthcare record is emphasised in the HSE National Consent Policy 2013.

Given 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 HSE 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 springs and the new nature of what was intended in seeking to replicate the spring distraction system. Therefore, HIQA has established that the National Consent Policy in place at the time was not correctly applied. Surgeon A stated to HIQA that in their view the use of the springs was not for innovation or research purposes. HIQA found that there was an intention to replicate a new technique – which was being used as part of a scientific study for which outcomes had yet to be published in a peer reviewed scientific journal – but in a modified way.

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. CHI was also not in compliance with National Standard 1.5 which requires that informed consent to care and treatment is obtained in accordance with best available evidence and documented in the patient's healthcare record.

3.3.5 Theatre Department and the implantation of the springs

HIQA met with nursing staff, including nursing management, who were working in the orthopaedic theatres at CHI at Temple Street during the time that the surgical procedures were undertaken and who were present for the individual operations where the springs were implanted. All of the nurses who spoke with HIQA said they only became aware from media reports in September 2023 of the springs being implanted as a non-routine component of a conventional growing rod system into three patients.

The safe use of new medical devices, including implants, in the operating theatre involves careful planning and multiple stakeholders. These include the surgeons, nursing staff, other healthcare staff, the supplier of the device and the patient. Staff described to HIQA that prior to any surgery commencing, all of the equipment required would be opened, counted and documented by two nurses. There would

also be additional unopened packs and equipment available in the event of these being required.

Theatre nursing staff described that the surgical procedures where the springs were implanted were highly complex surgical procedures and that there are a large volume of instruments assembled and available for use during such surgical procedures. Staff who were present for the individual procedures stated that they were not aware that the springs were a separate purchase from a different company, and were not part of the spinal implant set being used at the time of each of these procedures. HIQA found it was not clearly identifiable to staff that these springs were an additional component to be used alongside the conventional spinal surgery set. This represents a key failure in the processes and procedures in theatre, and in these specific surgeries.

The 'HSE National Policy and Procedure for Safe Surgery' 2013[29] ('HSE safe surgery policy') was in place at the time that these surgical procedures were undertaken. The HSE Safe Surgery Policy endorses the use of the World Health Organization's (WHO's) Surgical Safety Checklist.§§§§§§§§§[30] This is a tool designed to bring together best practice about safety checks within the operating theatre at the time of a surgical procedure. A series of questions are asked and recorded on the checklist at three different stages of the surgery when all of the operating team are together. These are prior to commencement of anaesthesia, prior to the start of the surgery and when the surgery is completed, but before transfer of the patient from theatre.

CHI developed a 'CHI Safe Site Surgery Checklist', adopted from the HSE safe surgery policy.[29] HIQA reviewed the digital checklist that was in use in CHI at Temple Street at the time of these surgical procedures. There are two relevant questions:

- During phase one, the checklist asks:' Are there any equipment issues?'
- During phase two, the checklist asks: 'Confirmed plan for procedure and asked the operating surgeon, Anaesthesiologist, Scrub Nurse, Medical Consultant and HSPC [Health and Social Care Professions] [sic] if there are any critical areas or challenges?'

This *Safe Site Surgery* check was an opportunity for Surgeon A to highlight to staff the intended use of the springs and for the outcome of these discussions to be documented by theatre staff. It was also an opportunity for theatre staff to ask questions or raise concerns. At interview with HIQA, theatre staff present at each of

§§§§§§§§§ The WHO Surgical Safety Checklist was developed after extensive consultation aiming to decrease errors and adverse events, and increase teamwork and communication in surgery. The 19-item checklist has gone on to show significant reduction in both morbidity and mortality and is now used by a majority of surgical providers around the world

the procedures said that they did not recall having been made aware by Surgeon A during the *Safe Site Surgery* check of the use of the springs as an addition to the conventional growing rods system used in these procedures. Surgeon A stated to HIQA that they are always present for the *Safe Site Surgery* checklist and that they had mentioned the springs at this time.

HIQA found no evidence that the use of the springs was questioned during the surgical procedures by any of the clinical staff present in the theatre at the time of these procedures. Nursing staff who were present during the surgical procedures told HIQA that the use of the springs was not communicated to them prior to the surgical procedures. In addition, they stated that they did not receive any training or information in advance of the surgical procedures to indicate an additional item was to be used together with the conventional spinal rod system. It is therefore unclear why clinical and nursing staff did not raise this issue at the safety check stage.

Surgeon A described to HIQA that they routinely go through each piece of equipment and device required at this stage of the surgical procedure so they can be assured that they highlighted each piece of equipment required to the nursing team. HIQA found divergent views on this matter between the nursing staff present in theatre and Surgeon A. HIQA found key control failures, in the form of a failure to have training for staff in place, and to use the safety check to highlight that the springs were an additional item and not part of the usual spinal surgery kit.

HIQA found no written record in the hard copy healthcare record or digital record of these patients of any discussions during the safety check of a proposed modification in the procedure with respect to the use of the springs as an additional component to the conventional growing rod system.

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, and were not in keeping with National Standard 3.1. National Standard 3.1 outlines that patients should be protected from the risk of harm associated with the design and delivery of healthcare services, including the management and use of medical devices and during surgical and invasive procedures.

CHI confirmed to HIQA at the time of this review that any remaining stock — beyond those springs that had been implanted or disposed of during the surgical procedures — had been removed by CHI from the clinical areas by the time this review commenced. CHI stated that there were no springs available for use and that one remaining spring, which remained in its decontamination unit sterilisation packaging, had been securely stored by CHI outside of the clinical area of the hospital.

3.4 Overall summary of compliance with internal processes relating to the non-CE marked springs in CHI at Temple Street

At the time the spring distraction system was being considered as a possible surgical solution, CHI confirmed to HIQA that there was a Ethics and Research Committee in place at CHI at Temple Street. As outlined in sections 3.2.2 and 3.2.5 above, HIQA found no evidence of any engagement with the formal ethical approval mechanisms and processes in advance of the springs being used.

Surgeon A informed HIQA at interview that they were "not aware of any committee in place for the approval or purchase of new equipment at CHI at Temple Street". Surgeon A also said that since commencing employment at CHI at Temple Street in 2016 they had not been directed at any time to the relevant document or committee for the introduction of a new surgical implant or implantable medical device.

HIQA noted that the Medical Device Equipment Management Committee was also in place in CHI at Temple Street. However, as detailed previously in in section 2.4.1.7 of this report, it had limitations in terms of its governance, scope, frequency and form of meeting. HIQA found that the need to put applications to this committee was known about by other staff within CHI at Temple Street as evidenced by review of meeting minutes and interviews with staff.

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

HIQA found the absence within CHI at Temple Street of a clear and standardised process to support the requirements for authorising, assessing and ordering specialist medical devices was a key failure in terms of governance and oversight for the introduction and use of the springs. Furthermore, the absence of authorisation and oversight processes meant that the risks of miscommunication between disciplines about the intended use were not mitigated.

HIQA also found that while processes to verify decontamination instructions were in place, they were not complied with. HIQA noted that a deviation from this process was documented. HIQA found no evidence that there was a process for communication and or escalation of such deviations outside of the central decontamination unit. Had this deviation been notified, it may have raised further questions for consideration prior to the use of the springs in each surgical procedure.

In terms of the use of the springs in theatre, HIQA found no evidence that the individual theatre team present when the springs were implanted had been briefed on the use of the springs nor did the staff question its proposed use. Overall, HIQA found there was an absence of questioning and verification at each stage of the process by relevant disciplines to ensure appropriate procurement, decontamination and use of the springs. This absence of questioning and verification was also accompanied by a failure to adhere to policy and process in some instances, with numerous missed opportunities to prevent the use of the springs from being used being identified.

In conclusion, HIQA found that across the end-to-end process, formal structures and processes were either not in place, or the processes that were in place were not properly followed by the staff involved.

On the basis of information and evidence gathered during the course of this review, HIQA found that there were also underlying challenges that may have undermined effective team working and the promotion of a culture of questioning within and across teams. These challenges included problems with team working, poor processes for communication and documenting of associated actions, lack of a single multidisciplinary team or a standardised process to enable effective interaction between the two multidisciplinary teams involved in spinal services in CHI at Temple Street. There was also an apparent absence of a culture which supported questioning — as described through prior management interventions.

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

Implants for orthopaedic use can be made from different materials. Implanted materials, especially those intended to be retained for long periods, are designed to be biologically inert or near biologically inert. Biologically inert materials are ones which do not initiate a response or interact when introduced to biological (body) tissue. Biocompatibility considers the biological system of the human body and the interactions with living tissue that are may occur when the medical device comes in contact with the human body. For a product to be biologically inert or near biologically inert, it will have no or minimal effects when it comes in to contact with the human body.

The material choice, and the combination of different materials, is important as it helps determine certain mechanical properties and the biological compatibility so that no adverse impact on the porosity (this is the amount of pores or tiny holes in a material), chemical inertness, and strength to bear loads or toughness takes place.

There are a range of materials which can used in orthopaedic implants. Titanium is a common material in a variety of orthopaedic implants. It is biologically inert, proven safe for implantation and not prone to corrosion.

Traditionally, stainless steel represented the most commonly used material for implantation and has been used for several years. It should be noted that stainless steel — so long as it is of a grade and nature that is properly assessed and deemed suitable for implantation — may be acceptable for use in orthopaedic implantation surgery. There are a wide variety of stainless steel metal types available. The alloy (blend of metals) in the stainless steel determines its properties. Stainless steel (especially of the grades that are used for medical purposes) has a very controlled composition and is considered biologically inert. While a significant difference exists between stainless steel alloys, the majority of medical grade stainless steel is an alloy called 316L. In the oxygen-rich environment of the body, this material does not corrode.(31)

As outlined in section 3.2.1 above, Surgeon A told HIQA that they wanted to replicate a 'spring distraction system' used by the UMC Utrecht team group, in the children who had the springs implanted – but with stainless steel springs rather than titanium springs.

During this review, HIQA received documentation from a variety of sources on the material composition of the springs which had been implanted. In total, HIQA identified four terms that were used to describe the composition of these springs. The terms used were:

- Stainless steel
- Standard carbon steel
- Unalloyed spring steel
- Uncoated spring steel.

The last three terms are used interchangeably in the documentation reviewed. The terms presented in this section reflect the terms used in the information as it is presented.

At interview, Surgeon A said that they were seeking "medical grade stainless steel springs". HIQA also reviewed email correspondence from Surgeon A to Company 1 which initiated the process of enquiry around potential sourcing of the springs. The initial contact email from Surgeon A had a subject heading "Enquiry (via website)" with the content including "Looking for Medical Springs". In further follow-on correspondence between the company and Surgeon A, Surgeon A was provided by the company with an email template to fill in which included a part completed list of technical specification parameters. On this list, the "material" section had been pre populated by Company 1 with the terms "spring steel – stainless – medical grade

stainless". In reply to Company 1, Surgeon A filled in the technical parameters requested. However, the "material" section was not amended by the Surgeon. This is of relevance as, for the reasons explained below, the potential steel alloy being requested in seeking the springs could have been any of three different types of steel listed on this line of the email to be completed in specifying the request. It is unclear to HIQA if this was understood by Surgeon A at the time of this correspondence.

HIQA received copies of correspondence that indicate CHI contacted Company 1 in July 2023 for information on the springs purchased in 2020. In the reply email to CHI, the company described the springs as 'Carbon Steel - EN 10270-1 SH grade'.

HIQA reviewed the product catalogue used to order the springs. The product number was clearly identified in both email correspondence and on the pro-forma invoice. Using this product number, the product catalogue describes the springs as 'compression springs for general use'. The product catalogue also describes the composition of the spring ordered as 'unalloyed spring steel' and applies a code EN 10270-1-SH. In addition, the product catalogue describes the springs as part of the stock range, and that spring steel EN 10270-1-SH is 'a standard quality for spring wire without corrosion resistance requirements'.

The EN 10270-1-SH code is a multi-part standard code used in the common standards system across Europe to describe the composition of different types of steels.[32] The code indicates important factors such as its mechanical resistance and material characteristics. This particular code indicates that the springs were not stainless steel.

The springs ordered were not made of medical grade stainless steel, but were made of non-alloyed spring steel. Medical grade stainless steel and non-alloyed spring steel are different materials. Non-alloyed spring steel is not used for surgical implantation. It is known to corrode in the presence of water. There is very limited information available on its use for implantation or to conduct a risk assessment on the likely implications of its use as an implant. Since there were no checks conducted on the ordering or the receipt of the springs to verify their suitability for the intended use, it was not identified at either of these time points that they did not consist of medical grade stainless steel.

HIQA established that the springs were used as an addition to the conventional spinal rods system. The conventional spinal rods system for these procedures was supplied by a company (Company 2) that had a history of routinely supplying implantable orthopaedic devices to CHI at Temple Street. The supplier of the conventional implantable rods system (Company 2) and the company that had supplied the spring implants (Company 1) are not the same company.

Company 2 informed HIQA that, as outlined in its technique guide, there are no springs as components in their spinal surgery system; nor are springs recommended to be used in conjunction with their spinal surgery system. Company 2 does not manufacture or supply springs for spinal procedures.

HIQA requested from CHI the technical product manual and technical specification for the spinal rods system used in these surgical procedures. The document provided by CHI at Temple Street to HIQA outlined an overview of all the implantable parts and equipment, directions for use, technical options and additional information described as 'Important Information'.

This document states:

> Components of this system should not be used with components of any other manufacturer.
>
> The components of this system are manufactured from titanium alloy, pure titanium, stainless steel and cobalt chromium-molybdenum alloy. Mixing of stainless steel implant components with different materials is not recommended for metallurgical, mechanical and functional reasons.

Such advice is provided as it is recognised within orthopaedic surgery that if metals are mixed, there is a risk that a chemical reaction may ensue within the human body within which the metals have been implanted.[33] This can cause damage to the materials used as implants and may also be potentially harmful to the patient.

The use of unalloyed steel springs alongside the standard titanium rod system in this instance represented a further additional risk — a risk which was mitigated in the Utrecht study through the use of titanium springs and with the ISO-13485-certified Department of Medical Technology and Clinical Physics of the UMC Utrecht taking the lead in the design and manufacturing process and creating an Investigational Medical Device Dossier.

At interview with Surgeon A, it was queried why stainless steel was intended as a material for use in this instance. Surgeon A said it was chosen as it was felt that stainless steel would be less likely to break than titanium. Surgeon A stated to HIQA that they did not carry out any scientific or mechanical checks that would ensure using the springs (from Company 1) and the titanium rods (from Company 2) were a suitable and safe combination.

HIQA notes that the characteristics and potential risks outlined above with the use of a new product intended for implantation would have been considered as part of the assessment procedure conducted under a clinical investigation. The absence of and application of appropriate governance processes (such as approval and evaluation

processes) instead meant that these risks were not identified. In addition, if the use of the springs had been progressed under any of the specific circumstances for seeking to use a non-CE marked product as an implant product, the characteristics and potential risks would also have been considered as part of the relevant assessment procedure. This highlights the importance of governance structures and processes for a robust multidisciplinary assessment of new implantable medical devices, including the necessity for clinical engineering and decontamination input and controls. It also further supports HIQA's overall findings of non-compliance against National Standards 5.1 and 5.2 which relate to governance.

3.6 Ongoing care for the 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.

As part of the review, HIQA met with families and a number of support organisations advocating on behalf of patients and their families. The issue of communication by CHI was a recurring theme of these engagements. HIQA found that there were opportunities for CHI to be more proactive in the ongoing communication, care and support of affected children and their families particularly when things go wrong.

The findings of this review raise issues around the ongoing care and support to be provided for the children who had had the springs implanted in them through surgery.

CHI informed HIQA that it had first established the implanted springs were non-CE marked in July 2023. In addition, when this came to light, a clinical director told HIQA at interview that they and the orthopaedic team had reviewed the post-operative X-rays for all spinal surgery cases since the date of the purchase of the springs. This further confirmed the springs had been used in the three known patients only.

During the conduct of the review, HIQA wrote to CHI in January 2024 requesting assurances on the ongoing care and management of the three children who had the springs implanted. The request also queried the arrangement that CHI had put in place for the ongoing care of patients impacted. In February 2024, CHI outlined to HIQA that arrangements for ongoing care had been put in place for these patient groups. Such arrangements include arrangements for clinical review, referrals to new consultants within CHI as needed and access to the Clinical Nurse Specialist for Spinal Surgery. CHI also advised HIQA that the Clinical Nurse Specialist is available to assist with specific service needs as requested, such as psychological supports, medical social work, occupational therapy and physiotherapy as needed.

HIQA wrote to CHI again in November 2024 requesting an update on the ongoing care and management of the three children who had the springs implanted and the wider cohort of patients being treated by Surgeon A. CHI's response outlined that arrangements for ongoing care were in place for these patients. Such arrangements include clinical reviews, referral to new consultants in CHI and services abroad. This also included access to a Clinical Nurse Specialist and a Spinal Patient Advocate Liaison Coordinator to provide specific supports to parents with specific concerns or issues related to spinal surgery.

In addition, on 16 April 2024, upon learning of the risk of the material composition of the springs, HIQA escalated the potential risk to patients following implantation 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.

CHI further informed HIQA that with regard to all families included in the external review of the published report of the titled 'Children's Health Ireland at Temple Street Spinal Surgery Programme for Patients with Spina Bifida External Quality Review and Programme Assessment',[15] CHI proactively wrote to all families in advance of the review commencing. This included

- open disclosure for Boston review related families following the publication of the review report.
- extensive clinical support was provided for families such as clinics, visiting patient's homes, established a Helpline and maintained a log of all issues.
- ongoing communications with the families by letter and phone call.

In December 2024 and March 2025 HIQA requested an update on the care and management of the children impacted by the use of the non-CE marked springs and on the wider cohort of children being treated by Surgeon A. CHI confirmed:

- The three children continue to receive care at CHI and other healthcare institutions.
- The wider cohort of patients being treated or awaiting treatment have now been allocated to other spinal surgeons within CHI.

- There is a Clinical Nurse Specialist available for support to families as required in both CHI at Crumlin and CHI at Temple Street.
- The Spinal Services Management Unit team includes the post of Spinal Patient Advocate Liaison Coordinator who is available to provide support to parents with specific concerns or complaints related to spinal surgery.

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 this work is supported by a child-centred approach.

3.7 Key findings related to the end-to-end process for the use of non-CE marked springs that were implanted during spinal surgery at CHI at Temple Street and compliance level judgments with national standards

Table 2 below represents the key findings of this review in terms of the end-to-end process for the use of non-CE marked springs that were implanted during spinal surgery at CHI at Temple Street. Table 2 presents HIQA's judgment of compliance with three of the National Standards, all of which are under the dimension of 'quality and safety', and which were monitored as part of this review in line with the terms of reference.

Table 2. Assessment of Compliance with the quality and safety dimension of the National Standards for Safer Better Healthcare

Quality and Safety Dimension
Theme 1: Person-Centred Care and Support
Standard 1.5 Service users' informed consent to care and treatment is obtained in accordance with legislation and best available evidence. **Key findings:** HIQA considered the consent process as it applied to the use of the springs as implants. At the time of this review, the National Consent Policy 2013 was in use across HSE and HSE-funded healthcare, including CHI at Temple Street. Within this policy, 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. Given 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 HSE 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 springs and the new nature of what was intended in seeking to replicate the spring distraction system. If the spring distraction system had been 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, and therefore not in line with the National Consent Policy 2013. HIQA found that a process for obtaining consent for the surgical procedures was carried out in relation to the surgical procedures of relevance. HIQA has established, that the principles of the National Consent Policy were not applied in these cases. Therefore, for the surgical procedures where the springs were implanted, the consent process carried out within the

spinal surgery services, was not in line with the National Consent Policy 2013. Furthermore, CHI was not in compliance with this standard which requires that informed consent to care and treatment is obtained in accordance with best available evidence and documented in the patient's healthcare record.

Judgment: Non-compliant

HIQA has made recommendations in this regard.

Quality and Safety Dimension

Theme 2: Effective Care and Support

Standard 2.8 The effectiveness of healthcare is systematically monitored, evaluated and continuously improved.

Key findings:
HIQA found that some clinical services in CHI contribute clinical data to national and international quality and safety benchmarking systems, which are designed to assure hospital management, healthcare staff, patients and the wider public on the quality and safety of services in an evidence-based manner, which is in line with National Standard 2.8.

HIQA found no evidence that spinal surgery services at CHI reported into similar quality assurance benchmarking systems. In the absence of the proper establishment and maintenance of such systems in a formalised way, the ability to oversee service quality and safety effectively is hindered.

This national standard outlines that the effectiveness of care is systematically monitored, evaluated and continuously improved. Given the level of specialisation and the complexity of the spinal surgery services provided by CHI, there is an opportunity to improve and expand practice in the spinal orthopaedic service through the use of clinical data to quality assure and benchmark service quality with comparable services within Ireland and internationally, which would support CHI in compliance with National Standard 2.8.

Judgment: Partially compliant

HIQA has made recommendations in this regard.

Quality and Safety Dimension

Theme 3: Safe Care and Support

Standard 3.1 Service providers protect service users from the risk of harm associated with the design and delivery of healthcare services.

Key findings:

In healthcare settings, the provision of safe and effective care is dependent upon ensuring effective and appropriate structures for organisational governance, oversight and approval where necessary for the implementation of higher risk interventions. HIQA examined the controls necessary to support this and included consideration of relevant legislation, the research ethics committee, multidisciplinary clinical team input, corporate and clinical management. In addition, HIQA identified that the following functions and departments play a key role and can act as further controls in the safety of medical devices when the product is used within the hospital: procurement (purchasing), clinical engineering, decontamination and theatre.

Medical Device Regulations

At the time of conducting this review, 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. HIQA also 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 specific circumstances where a non-CE marked medical device could be used under the regulatory frameworks in place. This is discussed under National Standard 5.10 (in section 2.7) of this report.

Research and ethics

HIQA found no evidence of any engagement with the formal ethical approval mechanisms and processes, for example, the research ethics committee, took place to support such an approach in advance of the springs being used. HIQA found that the intention to use the non-CE marked springs as a new medical device was not considered as a formal clinical investigation, clinical study or clinical trial nor was it progressed through a regulatory or research ethics process. This was not in keeping with the medical device regulatory framework, or research best practice.

Multidisciplinary team

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

HIQA is of the view that the lack of formal multidisciplinary structure contributed to lack of questioning and debate about a proposed new technique which might have mitigated the surgical safety issues and risks of in orthopaedics at CHI at Temple Street.

On the basis of information and evidence gathered during the course of this review, there were underlying challenges which may have potentially reduced the likelihood of issues being identified through the various multidisciplinary meetings. These challenges included problems with team working, poor processes for communication and documenting of associated actions, lack of 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.

Corporate and clinical governance approvals

HIQA has not identified any written evidence demonstrating that there was official approval from the agreed management structures within CHI for the conduct of the procedures where springs had been implanted.

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 of the springs

HIQA found that there were no formal structures and processes in place for the consideration and approval of class III implantable medical devices at CHI at Temple Street.

At no time were there any safety and technical checks carried out on the springs by the Clinical Engineering Department prior to the authorisation of the payment. These checks, if carried out, would have ensured the suitability for intended use and the presence of a CE mark.

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

Purchase of the springs

In the purchasing of 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.

Decontamination

HIQA found that during the decontamination process neither the national policy nor local policy at CHI at Temple Street for decontamination of the springs was adhered to. The springs were decontaminated in the absence of the decontamination unit reviewing the formal manufacturer's instructions.

Traceability

HIQA found that there was no evidence of a unique identifier number being applied to each individual 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.

Theatre

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

HIQA also found that 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.

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 these procedures. Collectively, these findings represent a key failure in the processes and procedures in theatre, and in these specific surgeries.

National Standard 3.1 outlines there should be structured arrangements to minimise the risks associated with possible increased risk of harm in the delivery of care. This includes during surgical and invasive procedures, when care is related to the management and use of medical devices, and where there may be research and clinical trial considerations. It also outlines the need for the safe and effective management of medical devices in accordance with legislative requirements and national guidelines.

HIQA found that overarching CHI-wide standardised structures with supporting policies and procedures for the services examined as part of this review with regard to the introduction and use of implantable medical devices, were either not in place, were not fit for purpose or were not being 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. Overall HIQA found that due to these failures in the design and delivery and oversight of end-to-end processes and controls within the spinal service at CHI, patients were not protected from the risk of harm. Accordingly, CHI was not compliant with National Standard 3.1.

During the review, HIQA found that there was a need for CHI to undertake further assessment of the potential risks of implantation of non-alloyed spring steel in terms of ongoing care and overall management of the children impacted. This is to ensure that ongoing follow-up care is delivered in line with National Standard 3.1. HIQA wrote to CHI and received assurance that this was underway.

Judgment: Non-compliant

HIQA has made recommendations in this regard.

4 Implications of review findings for national services

4.1 Introduction

The Minister for Health requested HIQA to carry out an independent review for the purposes of monitoring compliance with 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.

As part of the Terms of Reference for the review, it was identified that where relevant, HIQA may make recommendations in this report for the purpose of further quality improvement which will reflect current best practice and the future vision for services in line with standards, policy and legislation. The Terms of Reference further state that in the interests of wider service improvement, national recommendations may be made where HIQA considers appropriate.

Through conducting this review, HIQA has identified national learnings in relation to the governance of implantable medical devices and surgical implants for healthcare services.

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.

This chapter sets out the learning and recommendations for implementation at a national level in the areas of:

- 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

4.2 Governance for the introduction and use of implantable medical devices and surgical implants

In conducting this review, HIQA examined European and national legislation, national HSE policies and procedures of relevance to the governance and use of medical devices, and local structures and processes in place at CHI.

4.2.1 European and national legislation on medical devices

Where new medical devices are proposed to be used, there are clear regulatory requirements in Ireland stemming from European legislation that need to be adhered to. HIQA has identified during the course of this review that implementation of the current regulatory framework outlined in the EU Medical Device Regulation (MDR) remains a work in progress in Irish healthcare institutions. The EU MDR came into effect in Ireland in May 2021. It is essential that, following the publication of this report, all healthcare providers work to ensure adherence to the regulatory framework required by the MDR.

CE marking is the only marking which indicates that products conform to the relevant EC directives. The MDR specifies that a CE mark is required for all medical devices to be placed and made available on the EU market. Further information on CE marking is available in Appendix F.

4.2.2 Research and innovation in line with legislation

The findings from this review reinforce the critical importance of research ethics committees in overseeing the appropriateness and safety of new techniques, including the use of implantable medical devices and surgical implants. It also highlights the need for other policies and controls to be in place to support clinicians and committees to fully comply with relevant EU and Irish legislation.

HIQA notes and acknowledges that there have been a number of important national developments to strengthen the approach to research and innovation including:

- The HSE Research and Development Office was established in 2021 to standardise the approach to research across the HSE.
- A *National Framework for Governance, Management and Support of Health Research* was published in 2021. This document lays out the principles for conducting health research in HSE and HSE-funded organisations.

These initiatives note that the Health Products Regulatory Authority (HPRA) is the recognised competent authority for approval of regulated clinical trials or medical

device investigations and that research must be conducted in accordance with relevant EU and Irish legislation.

It is imperative that clinicians have a full awareness and understanding as to the role and function of HPRA and their obligations under the medical device regulatory framework and national policies with regard to research and ethics. There is an additional consideration for clinical staff and management to ensure hospital policies and procedures are operational and adhered to fully, including the submission of new proposals to relevant hospital committees. Consideration of using a new medical device or surgical implant offers the opportunity for clinicians and management to consider all aspects of a proposed new treatment — such as safety, risks, ethics and consent. Such committees also offer a route for consideration and specialist input on issues later in the timeline of product use, for example, if field safety notices are issued or there is a product recall.

Research ethics committees offer a formal multidisciplinary process to support clinicians to provide care, especially in new, challenging or unusual clinical situations. However, it is essential that these committees have appropriate reporting arrangements into and oversight by senior hospital management. This may also include linkages with other committees as relevant to the medical device under consideration. For example, there should be a clear relationship with the medical device committee (discussed in section 4.2.3 below).

To ensure that the work of these committees is integrated into the functioning of the hospital, the committee should have clear lines of reporting and be supported by audit and reporting requirements, which may include key performance indicators (KPIs), to hospital management. Training supports and policies and procedures are an assurance for management and a support for clinical staff on the ground in accessing the specialist expertise of such committees.

Consequently, HIQA has made the following recommendation in relation to compliance with legislation related to medical device and surgical implants:

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).

4.2.3 HSE national approach to medical device governance and management

A consistent and formalised approach to governance across an organisation ensures best practice is promoted, procedures are implemented consistently and necessary controls can function to identify potential risks and trigger appropriate actions as required. It also ensures that staff have clarity and confidence as they engage with the processes on medical device and surgical implants. This is of particular relevance given the new devolved structures being implemented in the HSE through the Regional Health Areas.

The HSE has a well-established national policy – the HSE medical device equipment management policy – in place to direct the introduction and use of medical devices and equipment at local level.

At HSE national level, while there is a centralised approach to life-cycle management of high-value capital equipment, such as ventilators and magnetic resonance imaging (MRI) scanners, this approach does not include implantable medical devices and surgical implants. Under the national policy, responsibility for oversight of procuring implantable medical devices and surgical implants was devolved to individual hospitals, which were required to have local governance arrangements in place for the introduction and use of implantable medical devices and surgical implants. This means the evaluation of suitability and safety, as well as approval of such medical devices and surgical implants, is not undertaken at national or regional level, and is done by the individual hospital that purchases the device. It is also important that the medical devices and surgical implants are considered in terms of safety and quality, across the whole of the product lifecycle, from sourcing, procurement, evaluation, use in theatre and through to disposal, as appropriate.

The HSE national policy requires that devices such as implants need to be CE-marked in line with European legislation. However, once CE-marking has been attained, there is limited further evaluation of suitability for use in practice centrally within the HSE.

Instead, responsibility for the assessment for suitability and appropriateness of use of implants in practice falls to individual hospitals. In fulfilling this role, HIQA notes that individual services may be at different levels of maturity in implementing these national developments. This emphasises the need for a standardised approach to the application of national policies and procedures in the local context in order to ensure consistency and safe effective care.

Through its monitoring of acute hospitals, HIQA has found that having clear governance structures and policies and procedures in place for medicines, at local

and national level, can support best evidence-based practice and safe and high-quality care. Following this review, there is potential for all hospitals services to ensure that learning from the example of medicines is shared for the benefit of more consistent and effective medical devices introduction and usage in the Irish health service.

Governance arrangements for the use of medicines that may potentially support use of medical devices and surgical implants include, but are not limited to:

- formal inventory management, including as necessary conditions on ordering and use
- staff training
- assessment related to the potential interplay by the new device under assessment for use with other potential medical devices or surgical implants
- labelling and storage
- the potential for error in use or other human factor considerations, and
- a need for ongoing surveillance around safety in local practice.

In addition, certain medicines are subject to assessment through national-level structures, such as the HSE Drugs Group, the HSE Primary Care Reimbursement Service and the National Centre for Pharmacoeconomics, Ireland. There is no equivalent process for medical devices or implants in Ireland at the time of finalising this report.

Consequently, HIQA has made the following national recommendation in relation to governance of medical device and surgical implants:

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.

4.2.3.1 Medical device management committees

A key governance provision in the HSE medical device and equipment policy is the establishment of a medical device committee by each hospital.

It is critically important that the role and function of medical device committees at hospital level is clearly articulated through the terms of reference of such committees. Committees should have a clearly defined remit in terms of the types and classes of medical devices covered within their scope. Committees need to have clear criteria for the evaluation of devices, including safety, efficacy and cost — with a clear evidence base for their use in practice, including scenarios where a new device is to replace an old one. Committees need to meet at a frequency appropriate to the hospital's needs in order to keep pace with requests from clinicians and to provide timely reviews, considerations and decisions to support the safe introduction of new products.

There may also be a requirement to allow for a more rapid evaluation of a product by the committee in the event that something as yet unapproved needs to be evaluated under time pressure for use at short notice due to an emerging urgent clinical situation. In such circumstances, the same principles of evaluation apply, including the requirement for written request and approval.

Any governance forum, such as committees for use of medical devices, needs to be multidisciplinary with the required levels of skills and experience needed to properly evaluate products. Recognising the volume and complexity of modern medical devices, it should also include an ability to co-opt specialist expertise as needed, such as clinical or technical expertise. Crucially, it is important that there is strong medical representation on such committees, to ensure peer support and oversight of applications made by fellow medical staff. This may also include linkages with other committees as relevant to the medical device under consideration. For example, the drug and therapeutics committee or the research ethics committee.

To ensure that the work of the committee is integrated into the functioning of the hospital, the committee should have clear lines of reporting and be supported by audit and reporting requirements, which may include key performance indicators, to hospital management.

4.2.3.2 The role of leadership and specialist expertise, including the Clinical or Biomedical Engineering Department in hospitals

The HSE policy for medical devices and equipment management highlights the importance of clinical and biomedical engineering staff and departments in the proper evaluation and use of medical devices.

Through this review and its engagement with relevant key personnel, HIQA has identified that there is also a need to define the role and responsibilities of clinical and biomedical engineering functions within hospitals in the management of the introduction and use of new devices and technologies in clinical practice. Clear roles and responsibilities are necessary for effective governance under National Standard 5.1, and the technical nature of Class III medical devices such as implants, requires a clear gatekeeping function. Such personnel also have a key role in the ongoing evaluation of the quality and safety of such devices across their life cycle in a managed way.

This review has highlighted that the role of clinical and biomedical engineering is critical for patient safety, as it supports the independent and rigorous evaluation of a medical device or surgical implant.

Consequently, HIQA has made the following national recommendation in relation to multidisciplinary working to ensure appropriate specialist expertise for medical devices and surgical implants:

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.

4.3 Corporate governance requirements during periods of organisational change

HIQA found that the three pre-existing children's hospitals which together became CHI experienced significant organisational change. Firstly with the administrative establishment as the Children's Hospital Group in 2013, through to the establishment of Children's Health Ireland as a legal entity in 2019, and up to the time of writing this report. From 2019 onwards, the overarching CHI governance and management structures were evolving to integrate the individual hospital structures and children's

services from three hospitals—in preparing to move to the new National Children's Hospital—while also working to a build programme where the timelines had been extended multiple times.

Formalised governance arrangements that ensure that there are clear lines of accountability at individual, team and service levels are essential so that healthcare staff are aware of their responsibilities and accountability.

There must be clear and well thought through arrangements in place to plan and manage service change and associated risk in order to undertake the transition of services effectively and safely. These arrangements need to be flexible to adapt to changes internally and externally and reviewed regularly to ensure these are fit for purpose and meeting the needs of patients. Crucially, a balance between adapting for the future, while also maintaining safe services for patients the present, needs to be carefully navigated. Regular review and evaluation of the governance and management arrangements, aligned to ensuring adequate capacity to balance service provision and change, is essential to ensure the service has the ability to effectively adapt to ongoing change, internally and externally while delivering ongoing safe, quality care to patients.

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.

4.4 Clinical governance, clinical accountability and clinical autonomy

In 1999, the US Institute of Medicine published a landmark study in the area of patient safety entitled *To Err is Human: Building a Safer Health System*. This seminal report highlighted that, while recognising the importance of individual actions and professionalism in ensuring safe practice, errors in medicine were often as a result of the complex system of care delivery within which those actions were performed. This report represented a watershed in the field of patient safety in healthcare.

Today, this interaction between the individual practitioner, the teams that deliver healthcare to patients, the management of the hospital and the system of care

delivery is known as 'clinical governance'. The HSE's 2012 *Clinical Governance - Information Leaflet* describes clinical governance as a framework through which healthcare teams are accountable for the quality, safety and satisfaction of patients in the care they deliver.[12]

Medical and surgical consultants are highly trained individuals who are subject to qualification with their appropriate specialist medical college, and registration and ongoing regulation by their professional regulatory body, the Irish Medical Council.

It is accepted practice that such individuals should be in a position to perform their functions autonomously in the provision of care to patients. While medical or surgical consultants are clinically independent in relation to decisions on the diagnosis, treatment and care of individual patients and should be in a position to perform their functions autonomously, they cannot work in isolation.

Care is provided within the context of a wider system of supports involving other professions and support staff, equipment and resources which equally assist each consultant in the delivery of their functions. As such, multidisciplinary team working, structures for reviewing and reporting risk and learning from adverse events, ongoing organisational support and awareness are all necessary to ensure good clinical outcomes for patients.

In recognition of this fact, a number of intended safeguards have been built into practice in Irish healthcare in recent years to support safe medical and surgical practice. To assure the quality and safety of care, these include:

- the development of clinical governance structures and processes
- further advances in adverse event reporting and review mechanisms
- the use of multidisciplinary teams and associated team meetings as a means of both peer support and peer review
- consultant participation in clinical audit and proactive risk management.

These developments have also included the introduction of the role of clinical director in to leadership positions at hospital level throughout the HSE since 2008. The primary role of the clinical director is to deploy and manage consultants and other resources, plan how services are delivered, strategic planning as well as responding to service priorities within the speciality that they are leading. The 2023 consultant contract describes the clinical director as the 'key directorate resource' with respect to service delivery and the core decision-maker regarding utilisation of resources of the directorate and the organisation generally.

HIQA notes there are a number of consultant contracts currently in use which describe different provisions for reporting relationships.

The 2023 consultant contract describes the line management reporting relationship of the consultant (employee) to a Clinical Director/Executive Clinical Director. The contract further outlines that the employer reviews the employee's performance on a regular basis and this involves structured discussions between the consultant and their Clinical Director/Executive Clinical Director/line manager in relation to performance and conduct.

The 2008 consultant contract describes the employee reporting relationship to the Chief Executive/General Manager/Master of the hospital through the employee's Clinical Director. The contract also outlines performance monitoring arrangements through an annual review of the clinical directorate plan.

For consultants operating on contracts prior to 2008, there are limited provisions in the contract specifically calling out requirements for reporting relationships and performance management. Through its work across the healthcare sector, HIQA has observed that provisions outlined in the 2008 consultant contract and subsequent 2023 contract confer significant responsibility on the role of the clinical director, in particular, in terms of the organisational strategy and resource management.

HIQA strongly supports the critical importance of the appointment of senior medical staff to such leadership positions and see this role as a crucial component in the effective and safe running of clinical services in Irish hospitals. However, for this role to be effective and meet the objective of providing high-quality safe care, clinical directors should have formal authority as well as accountability to effect change. The role needs to be structured to better enable the clinical director to provide support to consultants. Efforts are also required to enable more comprehensive oversight of services by clinical directors, including in terms of performance review, supervisory support and management of consultant staff.

In order for clinical directors to be effective in their roles, it is important that they have the necessary authority to support and oversee the work of consultants that report to them, to better enable them to fulfil their role in overseeing patient safety, aided by access to necessary data to assure on individual and service performance.

Currently, clinical directors may have in excess of 100 consultants who report directly to them. This is an extremely onerous line management responsibility which does not readily enable appropriate levels of oversight and support. The role of clinical directors should be better structured and supported to ensure they have an appropriate 'span of control' – that is the number of people who directly report to a manager or supervisor.

To address this issue, clinical directors need to be better supported to carry out their role by clinical leads for the specialties, and other support functions, including

business and administrative support within their directorate. Through the totality of its monitoring work, HIQA has found that such supports are not always in place. Where clinical leads are in place, they bring specific specialist knowledge and work to provide leadership within the clinical team of a particular clinical specialty. In many services, such roles are well established and work very well; however, this is not always the case. Arising from the review, HIQA recommends that the role of the clinical lead should be formalised across health services so that each position holder has formal authority for leadership within each specialty, supporting and reporting to the clinical director.

As a decade has passed since widespread introduction and formal establishment of the role of clinical director across HSE services, HIQA believes that now is an opportune time to further examine and evaluate the roles and overall functions which apply to clinical directors and clinical leads. Such a review is needed to further support those who take up such positions to perform effectively. This should also ensure that roles have clear and realistic responsibilities – especially for services that span across geographic sites.

Clear guidance and supports for clinical directors and clinical leads in their day-to-day functions, including enhancing use of data and close working with other senior executives, should form a key focus for ongoing enhancement of the role.

HIQA has made the following recommendations in relation to enabling senior clinicians to support clinical governance arrangements:

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.

4.5 Medical device and surgical implant traceability

An essential component of quality and patient safety in the use of medical devices and surgical implants is the ability to trace the patients who received them and the key details of the medical device or implants used. To ensure full and easily accessible traceability records to individual patient level, best practice requires the consistent use of electronic systems which link unique identifiers for implants and core data sets with individual patient and procedure details. Such systems require organisational policies and procedures and are supported by staff training and audit.

Traditionally, implant details have been recorded in individual healthcare records and while this remains important, it has a number of limitations as the data is not easily accessible. For example, in the event of a field safety notice for an implant.

4.5.1 Traceability systems for medical devices and surgical implants

HIQA engaged with HSE staff involved in national clinical leadership roles across surgical specialties during this review. This identified opportunities to advance systems to ensure traceability in the use of implants to improve the health service's ability to identify patients and to ensure follow up for research and quality and safety purposes after implants have been inserted.

At the time of this review, a pilot system had been initiated at Our Lady's Hospital Navan to leverage pre-existing ICT systems for the decontamination of devices as a means of electronically tracking implantable medical devices. This programme was due to be extended to other hospitals in the northeast region on a pilot basis. HIQA welcomes this development towards improving the electronic traceability of implantable medical devices and notes the potential to extend to all hospitals following evaluation of the pilot.

In addition to the use of an electronic traceability system, the use of a Unique Device Identifier (UDI) will improve the specificity of data and traceability linking individual patients to individual devices. The introduction of a UDI, including the associated traceability systems, is a key feature of the EU MDR regulation. One of the primary goals of a UDI system is to ensure proper adverse event reporting among medical devices. UDI increases the accuracy of product traceability and enables medical device manufacturers, regulatory bodies, and other analysts to discover trends earlier and respond quicker in the event patient safety is at risk due to a certain device issue.

The initial HSE implementation priority for MDR has focused on this aspect of the MDR with regard to Class III medical devices,********** with work on the introduction of patient implant cards being a key component of this prioritised implementation.

4.5.2 Clinical audit in implants and medical devices

Clinical audit represents a key safety and assurance measure within healthcare to ensure that services are being provided as safely as intended, and to identify where possible opportunities for service improvement. HIQA notes the important work that has been undertaken by various stakeholders in clinical audit and implant registry development over recent years. This includes the following:

****

Class III medical devices are those devices that are classified as having a high risk to the patient and/or user.

- HSE Chief Clinical Officer's report on the National Review of Clinical Audit 2019
- the establishment of the HSE National Centre for Clinical Audit (NCCA) in 2019
- ongoing work of the National Office of Clinical Audit (NOCA), based in the Royal College of Surgeons in Ireland (RCSI)
- progression of significant national initiatives relating to medical devices within key clinical specialties such as orthopaedics and breast surgery to create condition-specific implant registries.

There are some other notable examples of clinical audit initiative in individual specialties. The Irish National Orthopaedic Registry published its first report in September 2021. This report includes an analysis of a subset of the total Irish population's experiences from a clinical perspective relating to hip and knee replacement surgery. This is a high-quality initiative to provide information for service assurance and improvement, and efforts to expand its coverage to include a greater number of services across the country inclusive of the private sector are to be welcomed.

The HSE and NOCA have sought to develop a breast implant registry. Again, this represents an important safety measure for an area of implant surgery that has experienced safety challenges internationally in the past.

As services develop and care becomes more complex, development and integration of registry and outcome data will become more and more important and necessary as a key control for patient safety and to inform and confirm quality and service improvements. Important progress has been made to seek to improve and digitise the physical recording of surgical implant usage through the use of pre-existing ICT systems, and in the case of implant registries to analyse clinical outcome performance in their use in a limited number of clinical areas. HIQA supports the need for this work to continue. At a minimum, it should include expansion to improve coverage of such traceability systems across all hospitals.

The use of patient outcome data is important for the effective oversight and assurance of clinical service delivery. High-quality benchmarked data is beneficial in improving patient care and enabling ongoing review of service quality and safety, and it allows comparison at national and international level. Improving data collection and tracing systems related to medical devices and surgical implants, across the product lifecycle, would allow this data to be available to support an evidence-based approach to improving patient care.

Consequently, HIQA has made the following recommendation in relation to the traceability of medical devices and surgical implants:

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.

4.6 The critical importance of organisational culture, including effective multidisciplinary working and communication for patient safety

Healthcare is very much a human endeavour with care provided to, and with people, by people. Good organisational culture is a key factor in the promotion of safe, high-performing health services. There is also a strong and ever increasing evidence base which points to problems with organisational and team culture, interpersonal relationship failure and poor communication as being a major contributor to service quality and safety failures.[34, 35]

4.6.1 Team working

In addition to the relationships between individual clinicians, the nature and functioning of teams is an important aspect of communication and decision-making. This is particularly the case in situations where the care and treatment being provided is highly specialist and complex, such as in paediatric spinal surgery.

Good team working and safe clinical care can be supported by effective multidisciplinary team membership to allow engagement and input from a variety of healthcare professions. To ensure consistent and timely decisions, highly specialised services should include formalised arrangements for multidisciplinary teams. Such teams operate as a core part of the service, have processes in place, report patient outcomes and are integrated into the hospital's governance structures. For example, in cancer services, such models are supported by the HSE National Cancer Control Programme.

This review outlined the end-to-end process along the continuum of care that resulted in the implantation of unsuitable springs into three children. It details a number of failures in communication and governance oversight across these structures and processes, and indeed failure to adhere to pre-existing policies and procedures at certain points, when they were in place. All of these failures occurred within the context of an orthopaedic service at CHI at Temple Street where problems

around persistent access challenges for spinal surgery, pressures to seek to address waiting lists and team dynamics and interpersonal relationship problems were an ongoing feature.

4.6.2 Conflict management

Given the strains and pressures associated with healthcare provision, like any workplace, personality differences, disagreement between individuals or groups may inevitably occur from time to time.

In situations where long standing and unresolved interpersonal relationships emerge, it is critically important that sustained intervention occurs which resolves issues. Management also has a key role in the oversight and resolution of such situations, and to address any underlying structural challenges that may act as contributory factors which manifest as conflict within teams. If such difficult relationships become intractable and remain unresolved, service delivery and patient care and experience may be impacted.

Through HIQA's ongoing monitoring of services, the identification of circumstances where poor team working and communication persist or escalate is always a major cause of concern and requires concerted action. HIQA has also observed that the resolution of such situations can, in practice, be extremely challenging for the management of the service to address. Consequently, and in reflecting the learning from this review, HIQA has made the following recommendation for implementation by the HSE, which is aimed at ensuring a more consistent, effective and timely approach to the management of these uncommon but serious situations:

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.

4.7 Futureproofing medical device introduction, innovation and use in practice at a time of major technological and regulatory change

Technology is advancing in healthcare at an ever-increasing pace. The range of potential medical devices and implants that are being brought to the market are increasingly complex and diverse. Furthermore, the role of digital technology as a component part of a wider device or implant is beginning to emerge to a greater extent in clinical care. Indeed, the use of software and artificial intelligence (AI) to assist clinicians in achieving therapeutic goals is no longer a thing of possibility – it is already happening in healthcare settings, including in Ireland.

This review has highlighted the critical importance of ensuring a fully considered and controlled approach to the introduction of potentially new, disruptive or innovative technology to clinical practice. There are very clear pathways for the conduct of clinical investigations or other forms of innovation in the use of medical devices as required by the EU MDR. There will always be a requirement for innovation in healthcare, especially for rare conditions or unusual clinical circumstances. A clear balance needs to be struck between encouraging appropriate innovation and ensuring adequate protections, inclusive of informed consent from patients and their families as appropriate.

A full evaluation of the potential impact of the new EU MDR in ensuring an appropriate balance is struck between innovation and governance for the benefit of patients is beyond the scope of this review. It is clear that these regulations will continue to place demands on healthcare institutions and that these will need to be supported beyond the confines of the discipline of clinical and biomedical engineering. In particular, there may be a requirement to enhance the quality management systems in place for decontamination and in-house manufacturing in hospitals which will take training and investment. This should be advanced in a concerted way across the HSE and HSE-funded hospitals following this review.

Furthermore, as the potential for the use of advanced technologies, for example AI, to assist clinicians or augment medical devices or surgical implants advances, there is a requirement within healthcare institutions to properly govern its introduction and use into clinical practice. This is required to realise potential benefits but also to control against possible risks. This includes both known or anticipated risks, and also unanticipated consequences. Significant expertise, both technical and clinical, is required to fully evaluate and manage risk in this area.

The potential governance weaknesses identified in this review relating to introducing and using new implants should represent a call to action to not only strengthen

governance of current healthcare technologies but to ensure emerging technologies are included, such as AI or other types of software.

A need for a governance approach which ensures the use of standardised processes, policies and protocols to guide the use of new technologies and independent oversight by suitably qualified individuals will be required. Relying on an individual healthcare institution to provide oversight in this area—in the absence of other means of technical support—represents a potential risk that requires an immediate response to ensure that there are appropriate and consistent safeguards within clinical environments to guide the introduction of new technologies. This area requires immediate focus and action having regard to the pace of technological change and innovation.

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.

The following recommendation is to be implemented nationally by the HSE in all healthcare services, provided or funded by the HSE, and by private hospitals:

RN.1. 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.

Appendix A Correspondence of 4 October 2023 from Minister for Health to HIQA Chief Executive

An Roinn Sláinte
Department of Health
Office of the Minister

4nd October 2023

Angela Fitzgerald
Chief Executive Officer
Health Information and Quality Authority
Georges Court
Georges Lane
Smithfield
Dublin 7

CHI Temple Street

Dear Angela,

As you are aware, there is a comprehensive review being undertaken in relation to patient safety concerns which have arisen in the paediatric orthopaedic surgical services in Children's Health Ireland at Temple Street.

One of these serious patient safety concerns relates to the use of non-CE spring implants in surgeries in Temple Street Childrens Hospital. The available information indicates this relates to use in three patients during 2020 and 2022.

I am writing to request that HIQA, for the purposes of monitoring compliance with standards in accordance with Section 8 (1)(c) of the Act, conduct an independent review of the following issues:

(1) The end-to-end processes around the use of the non-CE spring implants during spinal surgery in Temple Street Childrens Hospital

(2) The controls and oversight processes and governance within CHI on the use of surgical implants / implantable medical devices, including processes around regulatory requirements and notifications.

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The need for wider assurance, as per the second point above, was raised by patient advocates at a recent meeting. While the non-CE springs issue is of the utmost urgency, I would be grateful if you would reflect these wider concerns in your work.

I would appreciate it if you would liaise with my officials in scoping Terms of Reference for this work and ensure it proceeds in a timely manner.

Yours sincerely,

Stephen Donnelly T.D.

Minister for Health

Appendix B Terms of reference published on 17 November 2023

Terms of reference

The following terms of reference have been determined for the conduct of this review.

1. To make an assessment of the governance, leadership and management arrangements in place within CHI for the use of use of surgical implants / implantable medical devices, including processes around regulatory requirements and notifications, and consideration of the controls and oversight processes.

2. To monitor compliance with the *National Standards for Safer Better Healthcare*, in accordance with Section 8(1)(c) of the Health Act 2007 as amended. In doing so, HIQA may use existing information available to it, as relevant.

3. To conduct the assessment of compliance in 2 phases, in the following order:
    a. Phase 1: The end-to-end processes around the use of the non-CE spring implants during spinal surgery in CHI at Temple Street. It is intended to conclude this phase of the review as quickly as possible in the interest of providing answers to the Minister for Health no later than the end of 2023.
    b. Phase 2: The controls and oversight processes and governance within CHI on the use of surgical implants / implantable medical devices, including processes around regulatory requirements and notifications.

4. In assessing the ***quality and safety*** of services, HIQA will:

    - assess the extent to which the governance arrangements support a child-centred approach to care and the provision of safe and effective care, as they relate to the use of surgical implants / implantable medical devices in the provision of care, including assessment of arrangements for:

        - how the needs of children and families using the services are being met

        - monitoring and evaluation arrangements for quality improvement and sharing learning

        - protecting children using the services from the risk of harm

5. In assessing the ***capacity and capability*** of the services, HIQA will:

   assess the effectiveness and sustainability of the governance, and management and accountability arrangements in place within CHI as they relate to the use of surgical implants / implantable medical devices in the provision of care, including assessment of arrangements for:

   - controls and oversight processes
   - risk management and reporting, including identification, assessment and mitigation of risks to service users
   - regulatory requirements and notifications processes

6. On conclusion of phase 1 and no later than the end of 2023, HIQA will brief the Minister for Health on initial interim phase 1 relevant findings. In doing so, HIQA will ensure it will not undermine, interfere or inhibit phase 2 of this review.

7. On conclusion of phase 2, a report of the findings and conclusions across both phases of the review will be provided to the Minister for Health. This report will be published in order to promote quality, safe use of surgical implants / implantable medical devices for the benefit of the health and welfare of the public.

8. Where relevant, HIQA may make recommendations in this report for the purpose of further quality improvement which will reflect current best practice and the future vision for services in line with standards, policy and legislation. In the interests of wider service improvement, national recommendations may be made where HIQA considers appropriate.

Appendix C Methodology

Introduction

HIQA's functions are outlined in section 8(1)(c) of the Health Act 2007 (as amended) (the Act). One such function is for HIQA to monitor compliance with national standards in publicly-funded healthcare services.

In line with its functions under section 8(1)(c) of the Act and following a request from the Minister for Health on 4 October 2024, HIQA carried out an independent review for the purposes of monitoring compliance with standards, 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.

HIQA identified and considered eight national standards of the *National Standards for Safer Better Healthcare,*[4] 2012 relevant to the terms of reference for this review.

The terms of reference for this review were published on HIQA's website on 17 November 2023. The methodology for this HIQA review was defined based on the terms of reference and the national standards.

This review covered the period from November 2018, when the use of the springs was first considered as a possible treatment option, to July 2023 when it was confirmed that the springs implanted during surgical procedures at CHI at Temple Street between 2020 and 2022, had been non-CE marked.

Overall approach

As part of its methodology, HIQA identified the systems and processes in place in CHI at Temple Street along the end-to-end process of the introduction and use of non-CE marked springs implanted during spinal surgery at CHI at Temple Street. This included relevant legislation and ethical considerations, CHI at Temple Street multidisciplinary clinical team and clinical governance, sourcing, procurement, decontamination and theatre.

The HIQA review team met with relevant staff and representatives of CHI, including medical consultants, nursing staff and others, responsible for and involved in aspects of care provided to patients receiving spinal surgery between 2020 and 2022 at CHI at Temple Street. The review team reviewed and evaluated information through documentation and data review, on-site observation, interviews and meetings and healthcare record review.

At the centre of this review are the children and families using the orthopaedic spinal surgery services in CHI at Temple Street. HIQA also engaged with advocacy groups who represent families using the orthopaedic surgery services at CHI at Temple Street at the outset and during this review.

The review team consisted of HIQA staff members who were appointed by the Minister for Health as authorised persons under Section 70 of the Health Act 2007 (as amended).

HIQA Programme Board

HIQA established an internal governance and oversight board called the review programme board, in line with HIQA policy, to ensure this review would be conducted in line with the review terms of reference. The programme board included external expertise in patient advocacy and surgery, as listed in Appendix G. HIQA also established an Expert Advisory Group.

In order to consistently carry out its function as required by the Health Act 2007 (as amended), HIQA appoints 'authorised persons' under the Act to monitor compliance with the national standards. These members of the HIQA review team were appointed by the Minister for Health as authorised persons under Section 70 of the Health Act 2007 (as amended) for the purposes of monitoring compliance with standards in line with section 8(1)(c) of the Act.

Expert Advisory Group

To support the review, HIQA convened an Expert Advisory Group (EAG), which met for the first time on 21 November 2023 and met seven times in total during this review. It brought together expertise in orthopaedic surgery, theatre governance, decontamination, biomedical and clinical engineering, as listed in Appendix G. The advice and guidance provided by the EAG reflected national and international evidence and best practice. One member of the EAG was made an authorised person in line with Section 70 of the Health Act 2007 (as amended), for the purposes of conducting interviews in line with section 73 of the Health Act 2007 (as amended). One member of the EAG participated in an observer capacity. HIQA carried out a number of workshops with members of the EAG on an individual basis towards the end of the review for the purposes of finalising the review report.

HIQA Programme Board

HIQA established an internal governance and oversight board called the review programme board, in line with HIQA policy, to ensure this review would be conducted in line with the review terms of reference. The programme board included external expertise in patient advocacy and surgery, as listed in Appendix H. HIQA also established an Expert Advisory Group.

In order to consistently carry out its function as required by the Health Act 2007 (as amended), HIQA appoints 'authorised persons' under the Act to monitor compliance with the national standards. These members of the HIQA review team were appointed by the Minister for Health as authorised persons under Section 70 of the Health Act 2007 (as amended) for the purposes of monitoring compliance with standards in line with section 8(1)(c) of the Act.

Review approach

HIQA uses what it terms a common 'Authority Monitoring Approach' (AMA) when conducting monitoring activity to assess compliance with the *National Standards for Safer Better Healthcare,* 2012.

The aim of the Authority Monitoring Approach is to:

- ensure a consistent and timely assessment when monitoring compliance with national standards
- ensure a responsive and consistent approach to the assessment of risk within healthcare services
- contribute to the improvement of the service being inspected through the application of the inspection process.

While AMA provides HIQA authorised persons with a range of measures to assist them in carrying out their functions, it does not replace their professional judgment. It helps to ensure that the healthcare service is treated fairly and that the assessment of compliance against the national standards is timely, consistent and responsive to any identified risks, such as those associated with the use of surgical implants and or implantable medical devices during spinal surgery at CHI, which is the focus of this review report.

The scope of this review focused on eight specific national standards within four of the eight themes contained within the national standards relevant to the terms of reference of this review. (See Table 7 below). These spanned both the dimensions of capacity and capability and quality and safety.

HIQA has applied AMA in the design and development of the assessment approach for this review and used a tailored assessment-judgment framework to support the assessment of compliance with the eight national standards identified for assessment.

The assessment-judgment framework

The assessment-judgment framework was organised into two overarching elements of care under the *National Standards for Safer Better Healthcare*, which are termed as the dimensions of:

1. **Capacity and capability**
2. **Quality and safety**

The dimension of ***capacity and capability*** is concerned with how CHI sustainably delivers services involving surgical implants/implantable medical devices, and how it is aware of what is going on in all levels of the service.

The dimension of ***quality and safety*** is concerned with the experiences of and quality of care provided to children and parents when surgical implants or implantable medical devices are being used in all CHI sites.

Under each of these dimensions are a series of 'themes', or aspects of care, such as 'Leadership, Governance and Management' and 'Safe Care and Support'.

These dimensions and their respective themes are illustrated in Figure 7 on the following page, with the dimension of *quality and safety* forming the upper half of the circle and *capacity and capability* forming the lower half of the circle.

One dimension cannot exist without the other and services will never sustainably deliver a good service without having good governance and oversight, the right resources, active use of information and a competent and confident workforce.

Figure 7. The themes of the *National Standards for Safer Better Healthcare, 2012*

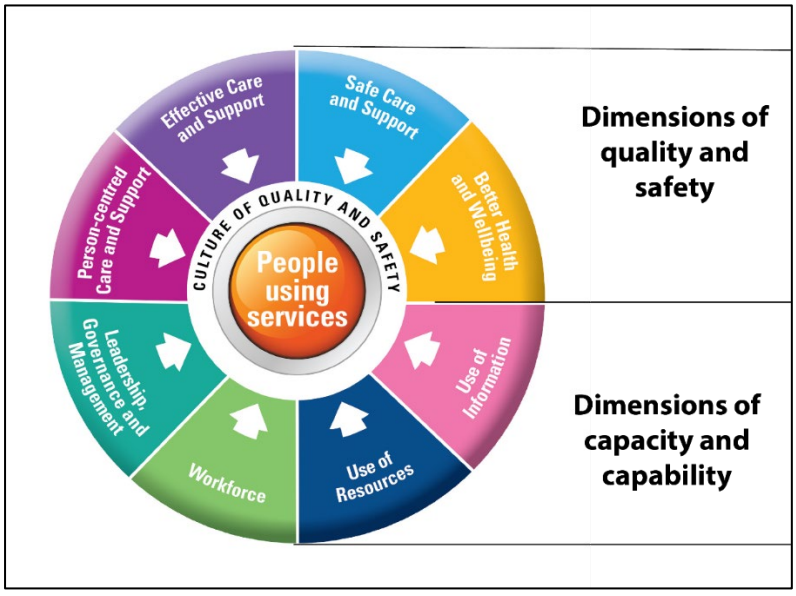


Table 3 below lists the eight national standards assessed.

Table 3. Eight national standards assessed as part of this review carried out under section 8 of the Health Act 2007 (as amended)

Capacity and Capability Dimension
Theme 5: Leadership, governance and management
Standard 5.1 Service providers have clear accountability arrangements to achieve the delivery of high quality, safe and reliable healthcare.
Standard 5.2 Service providers have formalised governance arrangements for assuring the delivery of high quality, safe and reliable healthcare.
Standard 5.9 The quality and safety of services provided on behalf of healthcare service providers are monitored through formalised agreements.
Standard 5.10 The conduct and provision of healthcare services are compliant with relevant Irish and European legislation.
Standard 5.11 Service providers act on standards and alerts, and take into account recommendations and guidance, as formally issued by relevant regulatory bodies as they apply to their service.
Quality and Safety Dimension
Theme 1: Person-centred care and support
Standard 1.5 Service users' informed consent to care and treatment is obtained in accordance with legislation and best available evidence.
Theme 2: Effective Care and Support
Standard 2.8 The effectiveness of healthcare is systematically monitored, evaluated and continuously improved.
Theme 3: Safe Care and Support
Standard 3.1 Service providers protect service users from the risk of harm associated with the design and delivery of healthcare services.

Each national standard was represented in the assessment-judgment framework to guide the review approach as follows:

- national standard statement taken from the *National Standards for Safer Better Healthcare*
- the scope of the specific national standard††††††††††

†††††††††† It is important to note that not all features of a standard may be relevant to the scope of the review.

- the lines of enquiry aligned to each standard
- examples of the type of information and evidence that authorised persons would review to assess compliance with the specific national standard.

Assessment of compliance with the national standards assessed was determined across the totality of evidence gathered during the review. The compliance descriptors are described in Table 4 below. Compliance with the national standards assessed is described in the findings of chapters 2 and 3 of this report.

Table 4. Descriptors of compliance

Compliant	**Substantially compliant**	**Partially compliant**	**Non-compliant**
A judgment of compliant means that, on the basis of this inspection, the service is in compliance with the relevant national standard.	A judgment of substantially compliant means that the service met most of the requirements of the national standard but some action is required to be fully compliant.	A judgment of partially compliant means that the service met some of the requirements of the relevant national standard while other requirements were not met. These deficiencies, while not currently presenting significant risks, may present moderate risks, which could lead to significant risks for people using the service over time if not addressed.	A judgment of non-compliant means that this inspection of the service has identified one or more findings, which indicate that the relevant national standard has not been met, and that this deficiency is such that it represents a significant risk to people using the service.

Documentation, data and information requests

In line with section 73 of the Health Act (as amended), HIQA issued formal documentation, data and information requests to accountable persons in CHI.

HIQA obtained information which covered areas such as the:

- corporate and clinical governance structure and management arrangements in place for the use of surgical implants and implantable medical devices at hospital level, hospital group level and national HSE.

- the end-to-end processes around the use of the non-CE marked spring implants during spinal surgery in CHI at Temple Street — this process encompasses the sourcing, buying and decontamination of the springs and their use in spinal surgery in CHI at Temple Street.
- risk management systems including management of notifications and alerts relating to surgical implants and implantable medical devices.

On-site review at CHI

The HIQA review team conducted announced on-site assessments at two CHI sites: CHI at Temple Street and CHI at Crumlin. The purpose of these on-site assessments was to obtain information about the end-to-end processes around the use of the non-CE marked spring implants during spinal surgery in CHI at Temple Street as well as the governance and oversight arrangements and the systems and structures in place to support the management and use of surgical implants and implantable medical devices across CHI.

HIQA authorised persons visited a number of service areas relevant to the scope of the review to gather information. Authorised persons spoke with staff working in these areas and observed the working environment. Information was gathered through direct observation and review of documentation and information systems.

Authorised persons also assessed reference material for the service; for example, relevant policies, procedures and guidelines. Service and clinical areas observed included the:

- Stores and Materials Management Departments
- Decontamination Departments
- Theatre Departments.

Healthcare record review

The review team reviewed the healthcare records of the children who had springs implanted during spinal surgery at CHI at Temple Street. This review of healthcare records informed HIQA's lines of enquiry in accordance with the terms of reference of the review.

Interviews and group meetings

Individual interviews and group meetings were conducted with relevant staff members from CHI at Temple Street, CHI at Crumlin, CHI executive management level, CHI Board and HSE national level. These interviews and group meetings were conducted in person and or remotely using videoconferencing technology.

The interviews were used to:

- clarify issues that may have been identified during the review of documentation, data and information, and or on-site inspection at CHI at Temple Street and CHI at Crumlin
- gather information generally
- consider any further information that was provided to inform the review findings.

HIQA provided interviewees and group meeting attendee's with a draft copy of the interview/meeting summary note and were invited to respond in writing, within a minimum of 10 working days, to HIQA with feedback, comments and or clarifications relating to the draft summary note.

Clarifications

To ensure fair procedure, HIQA issued requests for clarification to some interviewees where further information was received subsequent to their interview that was relevant to the information they had provided to HIQA. This allowed these interviewees the opportunity to provide clarification as they considered necessary.

Due process feedback

To ensure fair procedure, HIQA provided a copy of the relevant excerpt or excerpts of the confidential draft report of this review to relevant individuals to provide them with an opportunity to review the draft report and provide feedback to HIQA before it concluded its review. This included provision of the report to the service provider for a period of 21 days.

Quality Assurance

To maximise the consistency and reliability of the review approach, HIQA has a series of quality assurance processes in place. These included:

- designing the review methodology and supporting quality controls in line with the terms of reference and having these agreed by the Board of HIQA
- setting up the review team of staff as authorised persons, with the skills, knowledge, experience and competencies required
- establishing an internal programme board governing the review processes
- establishing an expert advisory group with the specialist expertise relevant to this review

Appendix D Governance at Children's Health Ireland

Executive Management Structures

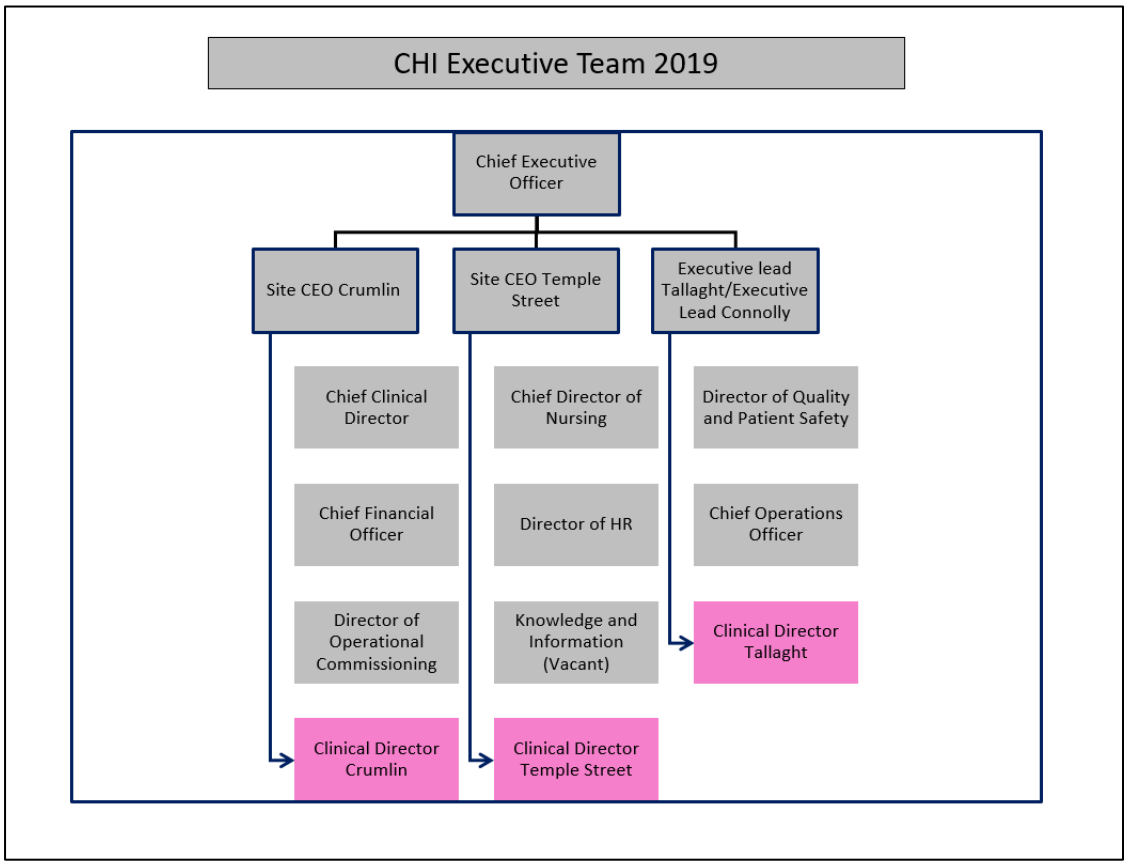
HIQA reviewed two organisational structure charts dated December 2019 that showed a CHI CEO and an Executive Management Team in place. Figure 8 below illustrates the CHI executive structure. The first chart showed the Executive Management Team membership comprised 11 members, including the CEO CHI.

The executive management membership for the CHI was:

- Chief Executive Officer (CEO)
- Hospital Site CEO at CHI at Crumlin
- Hospital Site CEO at CHI at Temple Street
- Executive Lead for CHI at Tallaght and CHI at Connolly
- Chief Clinical Director
- Chief Director of Nursing
- Chief Operations Officer
- Chief Financial Officer
- Chief Director of Human Resources
- Director of Quality and Safety
- Director of Operational Commissioning

A second chart demonstrated the addition of the roles of three clinical directors highlighted in pink (at the bottom of each of the three columns). Figure 8 below demonstrates the Executive Management Team Structure, inclusive of existing clinical directors, in 2019. In this chart, the clinical directors reported to their respective hospital Site CEO at CHI at Temple Street and CHI at Crumlin and to the executive lead for CHI at Tallaght and CHI at Connolly hospitals.

Figure 8. CHI Executive Management Team, December 2019



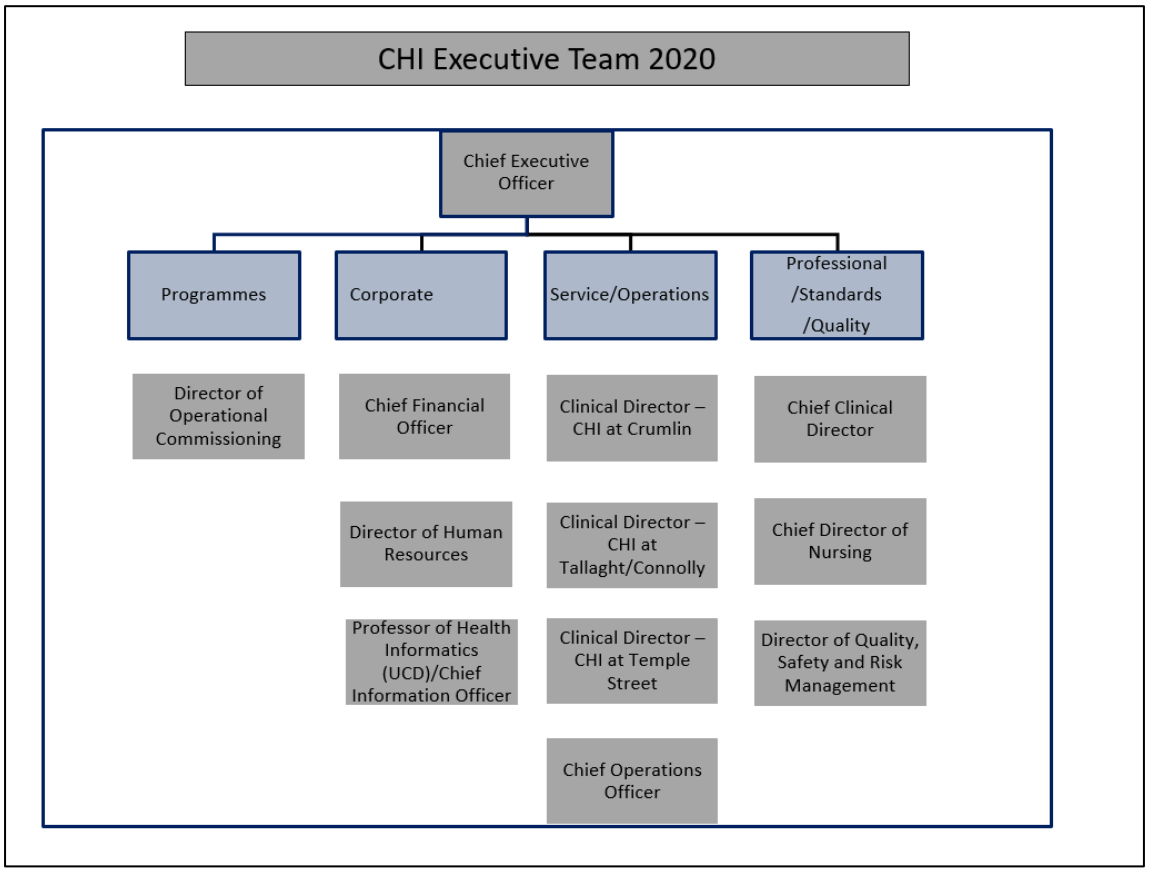
Source: Derived from CHI documentation provided to HIQA as part of this review (November, 2023)

HIQA reviewed further evidence that outlined the CHI executive structure in September 2020 (Figure 9 below). The 11 positions in the Executive Management Team had been assigned across four pillars, namely:

- Programmes (commissioning of the new National Children's Hospital)
- Corporate (Finance, HR, Health Informatics)
- Service and Operations (across the four hospital sites)
- Professional Standards and Quality (Chief Clinical Director, Chief Director of Nursing, and Director of Quality, Safety and Risk Management).

The hospital Site CEO's at CHI at Temple Street and CHI at Crumlin and the executive lead for the combined sites of CHI at Tallaght and CHI at Connolly (for governance purposes) were now held by three clinical directors in these site management positions. The previous site-based clinical directors were also no longer in position.

Figure 9. CHI Executive Management Team, September 2020



Source: Derived from CHI documentation provided to HIQA as part of this review (January, 2024)

From 2020 to 2023, the development of the CHI structures was interrupted due to start of the COVID-19 pandemic in Ireland (from March 2020) and the HSE cyber-attack (May 2021).

HIQA reviewed further organisational structure charts for the Executive Management Team dated June 2023 and September 2023 which demonstrated:

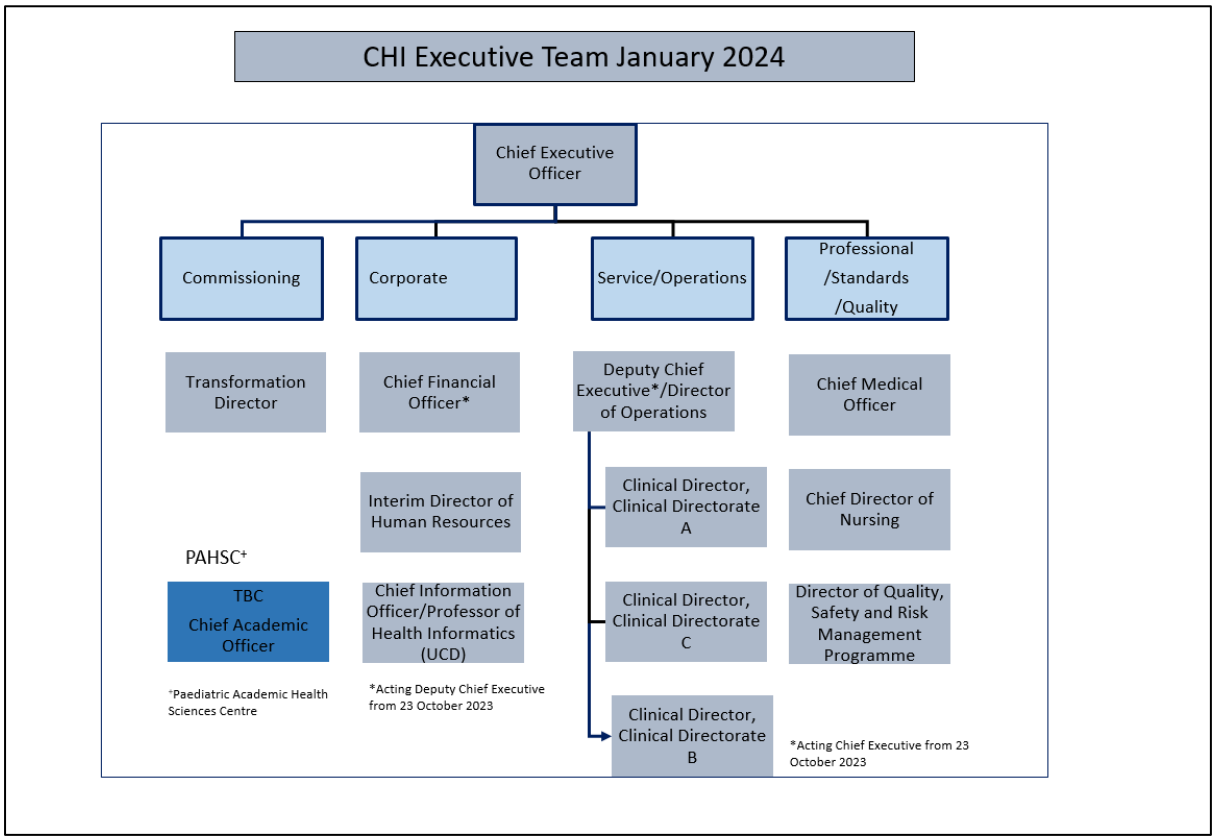
- the addition of a deputy chief executive officer incorporating the operations director
- This new deputy chief executive officer/operations director post replaced the previous chief operations officer position.

HIQA reviewed a further organisational structure chart dated January 2024 and at the time of HIQA's review, (Figure 10 below) that showed:

- the CHI Deputy CEO was now in the CHI Acting CEO position and whom HIQA wrote to in November 2023.
- The CHI Chief Financial Officer (CFO) was now in the CHI Acting Deputy CEO position.

- The newly formed clinical directorate structure which is described in more detail in Figure 10 below.

Figure 10. CHI Executive Management Team, January 2024



Source: Derived from CHI documentation provided to HIQA as part of this review (April, 2024)

Appendix E Clinical Directorate structure at Children's Health Ireland

The overall CHI hospital site and clinical directorate structure (January 2024) is illustrated in Figure 11 to Figure 13 below. Each of the three clinical directorates A, B and C are also explained in more detail.

Figure 11. Clinical Directorate A

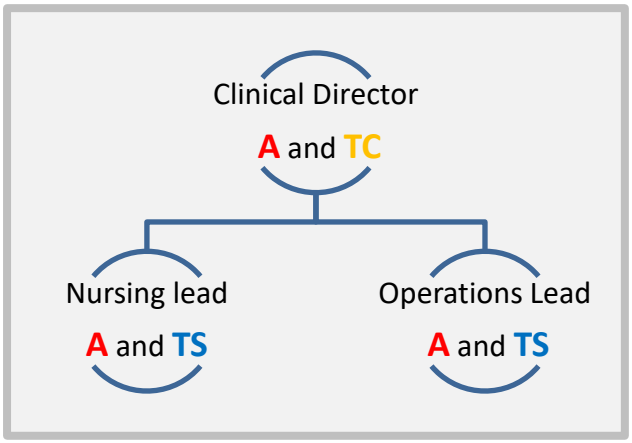


*Image source: CHI documentation provided to HIQA as part of this review (November, 2023)

CHI at Tallaght and CHI at Connolly Hospital Site Management

At CHI at Tallaght and CHI at Connolly (combined for the purposes of governance across the two separate hospital sites in southwest Dublin and west Dublin), the Clinical Director of Clinical Directorate **A** (who is based in CHI at Tallaght and CHI at Connolly) is supported in this combined site role by the Director of Nursing of Clinical Directorate **B** (based in CHI at Tallaght and CHI at Connolly) and Director of Operations of Clinical Directorate **B** (based in CHI at Tallaght and CHI at Connolly).

Clinical Directorate A Triumvirate Team

The Clinical Director (who is based in CHI at Tallaght and CHI at Connolly) with the Director of Nursing and Director of Operations (who are both based in CHI at Temple Street) are responsible for running their clinical directorate cross city, integrating services and moving towards a cross-city delivery model, in anticipation of each integrated service moving into the new National Children's Hospital.

Figure 12. Clinical Directorate B

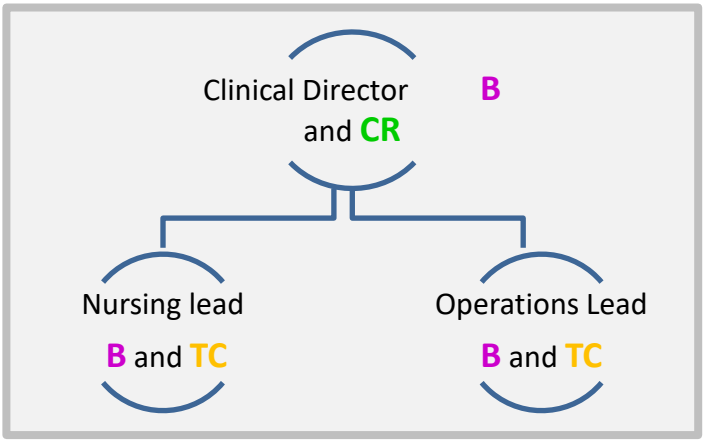


*Image source: CHI documentation provided to HIQA as part of this review (November, 2023)

CHI at Crumlin Hospital Site Management Team

At CHI at Crumlin, the Clinical Director of Clinical Directorate **B** (who is based in CHI at Crumlin) is supported in this hospital site role by the Director of Nursing of Clinical Directorate **C** (based in CHI at Crumlin) and Director of Operations of Clinical Directorate C (based in CHI at Crumlin).

Clinical Directorate B Triumvirate Team

The Clinical Director (who is based in CHI at Crumlin) with the Director of Nursing and Director of Operations (who are both based in CHI at Tallaght and CHI at Connolly) are responsible for running their clinical directorate cross city, integrating services and moving towards a cross-city delivery model, in anticipation of each integrated service moving into the new National Children's Hospital.

Figure 13. Clinical Directorate C

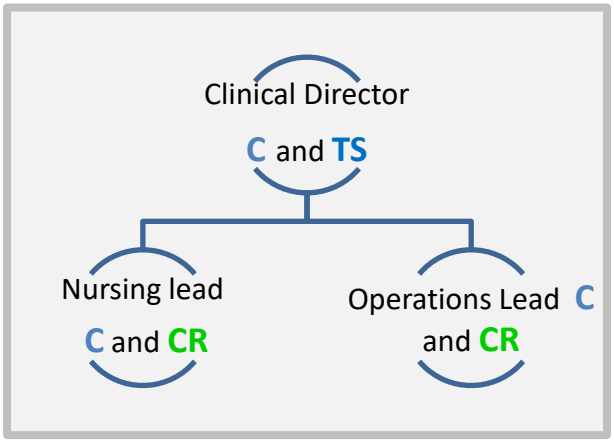


*Image source: CHI documentation provided to HIQA as part of this review (November, 2023)

CHI at Temple Street Hospital Site Management Team

At CHI at Temple Street, the Clinical Director of Clinical Directorate **C** (who is based in CHI at Temple Street) is supported in this hospital site role by the Director of Nursing of Clinical Directorate **A** (based in CHI at Temple Street) and Director of Operations of Clinical Directorate A (based in CHI at Temple Street).

Clinical Directorate C Triumvirate Team

The Clinical Director (who is based in CHI at Temple Street) with the Director of Nursing and Director of Operations (who are both based in CHI at Crumlin) are responsible for running their clinical directorate cross city, integrating services and moving towards a cross-city delivery model, in anticipation of each integrated service moving into the new National Children's Hospital.

Appendix F Further Information on CE marking and assessment of conformity

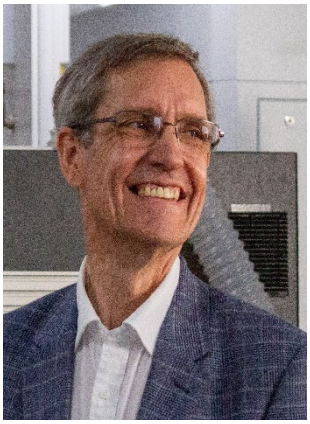
CE-marking and assessment of conformity

Many products require CE marking before they can be sold in the EU. CE marking indicates that a product has been assessed by the manufacturer and deemed to meet general safety and performance requirements which can cover amongst other things, safety, performance, technical, material and biological characteristics. It is required for products manufactured anywhere in the world that are then marketed in the EU.[36] A CE mark is a declaration that a product complies with the essential requirements of the relevant European legislation.[19] Once the device conforms with the relevant legislation, a manufacturer may place a CE mark on the device and accompanying materials.

CE marked surgical implants and implantable medical devices must undergo conformity assessment in order to demonstrate that they meet the requirements of the medical device regulatory framework. Conformity is assessed by a third party, known as a 'Notified Body'. The conformity assessment usually involves an audit of the manufacturer's quality system and a review of the technical documentation demonstrating how the device meets the safety and performance requirements of the Regulation. Part of the conformity process for such products involves assessing the implantable medical devices with the biological system of the human body and studying the interactions with living tissue that are exposed to the medical device when it comes in contact with the human body (known as biocompatibility).

Appendix G Membership of HIQA's Expert Advisory Group (EAG)

Name	**Role title and organisation**
Ruth Collins 	**Current position:** Immediate Past President and Director of the Association for Perioperative Practice (Afpp). North Yorkshire, UK. Clinical Director at Solasta Healthcare. With a distinguished career in healthcare and over 20 years' experience as a theatre nurse, Ruth is renowned for her unwavering commitment to maintaining high operating room standards and governance. In her previous role as a Nurse Development Lead, Ruth was responsible for coordinating education and training, practice development, clinical workforce, and governance. Although trained as an adult nurse, this role was in a paediatric setting, where she was responsible for nearly 500 nurses and was involved in the perioperative environment. Her expertise in perioperative practices has made her a respected leader in the field, where she actively champions initiatives aimed at enhancing patient safety and surgical outcomes. Ruth has played a pivotal role in shaping regulatory frameworks that govern surgical practices, ensuring that they align with best practices and evidence-based guidelines. Her reputation as a dedicated advocate for quality care is reflected in her collaborative work with healthcare professionals and regulatory bodies, striving to elevate the standards of perioperative services across the industry. Ruth's leadership at Solasta Healthcare and within Afpp underscores her passion for excellence in patient care and her commitment to fostering a culture of safety and accountability in the operating room environment.

Professor Aiden Devitt 	**Current position:** Consultant orthopaedic spinal surgeon in Galway University Hospitals. Aiden has served as national post-graduate programme director, RCSI representative specialist advisory committee and inter-collegiate examiner in trauma and orthopaedic surgery. He is current president of the Irish Orthopaedic Association.
Professor Richard Scott 	**Current position:** Director of Medical Physics and Bioengineering, University Hospitals Bristol and Weston, National Health Service Foundation Trust (NHS FT), England. Honorary Professor, School of Engineering & Physical sciences, Heriot Watt University, Edinburgh, UK. Richard is a Healthcare and Professions Council (HCPC) registered clinical scientist and Director of Medical Physics and Bioengineering at University Hospitals Bristol & Weston NHS FT. Additionally, Richard has been a Royal Academy of Engineering visiting professor in regulated medical technologies at Heriot Watt University, (HWU), helping develop "real world skills" in the field of healthcare technology design, adoption and management. Richard continues as an honorary professor at HWU, sharing his expertise in the application of international electromedical safety standards and medical device risk management processes with those involved in developing novel medical devices. An electronics engineer by background Richard has 40 years' experience as a practising clinical engineer, manager and leader in Medical Physics & Clinical Engineering, within the UK national health service. His areas of expertise involve medical device design, management and

	supporting clinical instrumentation, with research interests in respiratory mechanics and digital signal processing. Richard chairs IEC SC62A, the subcommittee responsible for common aspects of medical equipment, software, and systems standards within the IEC 60601 series of international standards. Currently Richard is playing a leading role in developing the 4th edition of IEC 60601-1.
Patrick Turner 	**Current position:** Decontamination Manager, Beaumont Hospital Dublin Patrick Turner has 35 years' experience in medical device decontamination. He holds a BSc in Sterile Services Technology/Management and a MSc in Healthcare Management. He is an Authorised Person for Decontamination, and a Certified Lead Auditor for EN ISO 13485.
Dr Niall MacAleenan (observer role on HIQA EAG) 	**Current position:** Director of Medical Devices, Health Products Regulatory Authority (HPRA), Dublin, Ireland.

Appendix H External membership of HIQA's Programme Board

Name	Role title and organisation
Professor Stephen Sheehan 	**Current position:** Clinical Director, Ireland East Hospital Group, Dublin 8. Perioperative Clinical Director at St Vincent's University Hospital (SVUH) for six years before transferring to Ireland East Hospital Group as Joint Group Clinical Director in 2021. Consultant Vascular Surgeon at SVUH, retired from clinical practice 2019. Chair Division of Surgery. Multiple roles in standards and training, data management, patient safety and management of adverse events. President Irish Vascular Society and Director Vascular Training Programme. Council member Union of European Medical Specialities and European Society of Vascular Surgery. Examiner General and Vascular Intercollegiate Boards and European Board of Vascular Surgery.
Tanya Ward 	**Current position:** Chief Executive of the Children's Rights Alliance. Tanya Ward is the CEO of Children's Rights Alliance and was previously the Deputy Director of the Irish Council for Civil Liberties. She has also worked with the City of Dublin ETB, the Curriculum Development Unit, Irish Centre for Migration Studies and the Irish Refugee Council. Tanya has an LLM in Human Rights from Queens University Belfast and several qualifications in business management from UCD, National College of Ireland and Common Purpose. She has also lectured widely in human rights including on the Masters Programme for the MPhil in Ethnic and Racial Studies in TCD and the Masters in Equality Studies in UCD.

	Tanya is a former Chair of the National Advisory Council for Children and Young People (2018-2022) and was elected Vice President of Eurochild in 2022. She is currently a member of the Programme Board on Senior Cycle Reform and has served on the McMahon Group on Review of the Protection Process (2014/2015) and the Boards of Mental Health Reform, the Law Centre for Children/Young People and Stand Up for Children. She has previously served as an Expert on HIQA's investigation on the management of child abuse allegations by Tusla and the Consultative Panel on the Governance of Charitable Organisations for the Charities Regulator. The Children's Rights Alliance has won several Good Governance Awards under her leadership. She is a previous Chair of the National Advisory Council for Children and Young People and is currently Vice President of Eurochild. She has served on a multitude of governance bodies representing children and young people's interests/rights.

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Glossary of terms and abbreviations used in the context of this report

Adverse event: An incident which results in harm, which may or may not be the result of an error.

Autoclave: is a machine that uses steam under pressure to kill harmful bacteria, viruses, fungi, and spores on items that are placed inside a pressure vessel.

Autonomy: Freedom to determine one's own actions and behaviour.

Best practice: Clinical, scientific or professional practices that are recognised by a majority of professionals in a particular field. These practices are typically evidence based and consensus-driven.

Category of incidents: Incidents are categorised as follows:

1. Category 1 Major/Extreme – Clinical and non-clinical Incidents rated as major or extreme as per the HSE's Risk Impact Table.
2. Category 2 Moderate – Clinical and non-clinical incidents rated as moderate as per the HSE's Risk Impact Table.
3. Category 3 Minor/Negligible – Clinical and non-clinical incidents rated as Minor or Negligible as per the HSE's Risk Impact Table

There is no specific definition for a 'serious incident'. Such incidents are considered category 1 incidents.

CE mark: 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 by the manufacturer 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.

Central Decontamination Unit: Central unit dedicated to the decontamination of reusable medical devices. Also referred to as Hospital Sterile Services Department (HSSD) or Central Hospital Sterile Services Department (CSSD).

Clinical directorates: The purpose of the clinical directorate model is to achieve the best clinical outcomes and experience for patients within the available resources through the involvement of clinicians in leadership positions, working closely with other key staff including management, nursing and health and social care professionals in a collaborative manner.

Clinical governance: An umbrella term which encompasses a range of activities in which health care staff should become involved in order to maintain and improve the

quality of care they provide to patients and to ensure full accountability of the system to patients.

Code of practice: A description of the values, principles and expected behaviours of individuals and teams working within a service.

Cohort: Any group of individuals affected by common diseases, environmental, temporal influences, treatments, or other traits.

Concern: A safety or quality issue regarding any aspect of service provision, raised by a service user, service provider, member of the workforce or general public.

Consent: Consent is the giving of permission or agreement for a treatment, investigation, receipt or use of a service or participation in research or teaching. Consent involves a process of communication about the proposed intervention in which the person has received sufficient information to enable them to understand the nature, potential risks and benefits of the proposed intervention. Seeking consent should usually occur as an on-going process rather than a one-off event.

Corporate governance: The system by which services direct and control their functions in order to achieve organisational objectives, manage their business processes, meet required standards of accountability, integrity and propriety and relate to external stakeholders.

Culture: The shared attitudes, beliefs and values that define a group or groups of people and shape and influence perceptions and behaviours.

Effective: A measure of the extent to which a specific intervention, procedure, treatment, or service, when delivered, does what it is intended to do for a specified population.

Evaluation: A formal process to determine the extent to which the planned or desired outcomes of an intervention are achieved.

Evidence: Data and information used to make decisions. Evidence can be derived from research, experiential learning, indicator data and evaluations.

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.

Governance: In healthcare, an integration of corporate and clinical governance; the systems, processes and behaviours by which services lead, direct and control their functions in order to achieve their objectives, including the quality and safety of services for service users. Good governance arrangements acknowledge the inter-

dependencies between organisational arrangements and clinical practice and integrate these to deliver high quality, safe and reliable care and support to all service users. As such, the term governance reflects structures, processes and activities required to both ensure and assure on the quality and safety of care from ward to board level within a healthcare service such as a hospital. See also **clinical governance** and **corporate governance** above.

Harm: Impairment of structure or function of the body and or any detrimental effect arising from this, including disease, injury, suffering, disability and death and which may be physical, social or psychological.

Health: The state of complete physical, mental and social wellbeing and not merely the absence of disease or infirmity.

Healthcare record: All information in both paper and electronic formats relating to the care of a person using a healthcare service.

Healthcare simulation: Simulation provides opportunities for standardised clinical experiences and offers a safe environment to learn and practice safely. Simulation is useful for learning as an individual or within a team and can be used for mastering practical or technical procedures and non-technical skills, such as communication and leadership. Simulation supports human factors approaches to improving the quality of care.

Health and social care professionals (HSCP): This collective term refers to dietitians, dispensing opticians, medical scientists, occupational therapists, optometrists, physiotherapists, podiatrists, radiographers, social workers and speech and language therapists.

Health Products Regulatory Authority (HPRA): The competent authority in Ireland for the regulation of medicines and devices for the benefit of people and animals.

Incidents: See entry for **category of incidents**

Informed consent: See entry on **consent**

Key performance indicators: See entry on **Monitoring and evaluation.**

Medical device: Any instrument, apparatus, appliance, software, implant, reagent, material or other article intended by the manufacturer to be used, alone or in combination, for human beings for one or more of the following specific medical purposes:

- diagnosis, prevention, monitoring, prediction, prognosis, treatment or alleviation of disease,

- diagnosis, monitoring, treatment, alleviation of, or compensation for, an injury or disability,
- investigation, replacement or modification of the anatomy or of a physiological or pathological process or state,
- providing information by means of in vitro examination of specimens derived from the human body, including organ, blood and tissue donations,
- and which does not achieve its principal intended action by pharmacological, immunological or metabolic means, in or on the human body, but which may be assisted in its function by such means. The following products shall also be deemed to be medical devices:
- devices for the control or support of conception;
- products specifically intended for the cleaning, disinfection or sterilisation of devices as referred to in Article 1(4) and of those referred to in the first paragraph of this point.

Some additional definitions related to medical devices and their use are:

- **Active medical device:** Means any device, the operation of which depends on a source of energy other than that generated by the human body for that purpose, or by gravity, and which acts by changing the density of or converting that energy. Devices intended to transmit energy, substances or other elements between an active device and the patient, without any significant change, shall not be deemed to be active devices.
- **Accessory to a medical device:** an article which, whilst not being itself a medical device, is intended by its manufacturer to be used together with one or several particular medical device(s) to specifically enable the medical device(s) to be used in accordance with its/their intended purpose(s) or to specifically and directly assist the medical functionality of the medical device(s) in terms of its/their intended purpose(s).
- **Implantable medical device:** any device, including those that are partially or wholly absorbed, which is intended:

    — to be totally introduced into the human body, or

    — to replace an epithelial surface or the surface of the eye,

    Any device intended to be partially introduced into the human body by clinical intervention and intended to remain in place after the procedure for at least 30 days shall also be deemed to be an implantable device.

- **Procedure pack:** means a combination of products packaged together and placed on the market with the purpose of being used for a specific medical purpose;
- **Surgical implant (implantable medical device):** any device, product or article implanted into the patient by a surgical intervention and intended to remain in place for a period of time.
- **[Medical Device] System:** means a combination of products, either packaged together or not, which are intended to be interconnected or combined to achieve a specific medical purpose.
- **In-house device:** a medical device which—
    - is manufactured and used only within a health institution,
    - complies with all of the conditions in Article 5(5) of the EU Regulation, and is not manufactured on an industrial scale.

Monitoring and evaluation: This refers to the systematic process of gathering information and tracking change over time. Monitoring provides a verification of progress towards achievement of objectives and goals. The evaluation process is used to determine the extent to which the planned or desired outcomes of an intervention are achieved. Records or activities can include:

- Audit: The assessment of performance against any standards and criteria (clinical and non-clinical) in a health or social care service
- Benchmarking: A continual process of measuring and comparing care and services with similar service providers

Multidisciplinary: An approach to the planning of treatment and the delivery of care for a service user by a team of healthcare professionals who work together to provide integrated care.

Novel: In medicine and biology, novel is used to refer to things that have never been seen before.

Passivation: A widely-used metal finishing process to prevent corrosion. In stainless steel, the passivation process or citric acid to remove free iron from the surface. The chemical treatment leads to a protective oxide layer, or passivation film, that is less likely to chemically react with air and cause corrosion. Passivated stainless steel resists rust.

Quaternary care: Anextension of tertiary care in reference to advanced levels of medicine which are highly specialised and not widely accessed, and usually only offered in a very limited number of national or international centres. Like tertiary

care, quaternary care also tends to have large catchment areas, often catering for individuals, not only countrywide but worldwide, particularly when providing care for very rare health conditions with small numbers of patients globally.

Serious incident: See entry for **category of incidents.**

Tertiary care: A level above secondary health care that has been defined as highly specialised medical care, usually provided over an extended period of time that involves advanced and complex diagnostics, procedures and treatments performed by medical specialists in state-of-the-art facilities. Tertiary care can be available either at a regional or national level, dependant on the size and resources available in the country

Risk: The likelihood of an adverse event or outcome. Risk means the combination of the probability of occurrence of harm and the severity of that harm.

Risk management: The systematic identification, evaluation and management of risk. It is a continual process with the aim of reducing risk to an organisation and individuals.

Service: Anywhere health or social care is provided. Examples include, but are not limited to: acute hospitals, community hospitals, district hospitals, health centres, dental clinics, general practice surgeries, homecare and so on.

Published by the Health Information and Quality Authority (HIQA).

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