Health Information and Quality Authority

An tÚdarás Um Fhaisnéis agus Cáilíocht Sláinte

Terms of Reference

Independent statutory review of the governance and oversight of processes within Children's Health Ireland (CHI) on the use of surgical implants / implantable medical devices, including a focus on the use of non-CE spring implants during spinal surgery in CHI at Temple Street

17 November 2023

Terms of Reference for the independent statutory review of the governance and oversight of processes within Children's Health Ireland (CHI) on the use of surgical implants / implantable medical devices, including a focus on the use of non-CE spring implants during spinal surgery in CHI at Temple Street

To be conducted under Section 8(1)(c) of the Health Act 2007 as amended, monitoring compliance with national standards.

Title

Independent statutory review of the governance and oversight of processes within Children's Health Ireland on the use of surgical implants / implantable medical devices, including a focus on the use of non-CE spring implants during spinal surgery in Children's Health Ireland at Temple Street.

Background

Children's Health Ireland ("CHI") provides health services for children and young people across Ireland. CHI is a statutory body established under the Children's Health Act 2018 with the stated object 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".[1] Its functions include the planning, conduct, development and provision of patient safety and quality specialist acute paediatric hospital services in Ireland. CHI operates four children's hospitals within the greater Dublin area, and manage all national paediatric services. The four children's hospitals are:

- CHI at Crumlin
- CHI at Temple Street
- CHI at Connolly, colocated with Connolly Hospital
- CHI at Tallaght, colocated with Tallaght University Hospital

CHI also contracts services from time to time to other healthcare providers.

The spinal surgery service in CHI at Temple Street came under scrutiny following the occurance of two serious incidents in July and September 2022. In September 2023, information emerged that non-CE-marked equipment[2] (in the form of metal springs)

[1] https://www.irishstatutebook.ie/eli/2018/act/27/enacted/en/html

[2] A medical device is used for a medical purpose and acts in a physical manner and not through pharmacological, immunological or metabolic means. Medical devices help patients and healthcare providers in the diagnosis, prevention, prediction, monitoring, prognosis or treatment of a disease,

may have been surgically implanted into a number of patients who underwent spinal surgery at that hospital. This led to significant concern among the families of the children impacted and caused significant public concern.

To date, three reports[3] have been published by CHI in relation to spinal surgery for patients with Spina Bifida in CHI at Temple Street. The scope of these reports relate to 16 cases over a time frame of 2018 to 2022. The reviews were undertaken due to the two serious incidents in July and September 2022 and due to concerns raised about spinal surgery outcomes in September to November 2022. The primary focus of these reports are on clinical outcomes of the affected patients.

In September 2023, the Health Service Executive (HSE) commissioned a new review of elements of the paediatric orthopaedic surgical service at CHI at Temple Street. This HSE commissioned review will be led by an external UK-based paediatric orthopaedic surgeon.

Further to these developments, on 4 October 2023, the Health Information and Quality Authority (HIQA) formally received a request from the Minister of Health, in accordance with HIQA's remit under Section 8(1)(c) of the Health Act 2007 as amended, to undertake a review into:

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

Objective

As part of this independent statutory review, HIQA will monitor compliance with the *National Standards for Safer Better Healthcare* in accordance with section 8(1)(c) the Health Act 2007 as amended and advise the Minister accordingly by reference to the two stated points in his letter dated 4 October 2023 and as detailed in the scope set out below. This review will aim to establish the end-to-end processes around the use of non-CE spring implants during spinal surgery in CHI at Temple Street. It will also assess the controls, oversight processes and governance arrangements in place

injury or disability. See https://www.hpra.ie/homepage/medical-devices/regulatory-information The legal definition of a medical device is set out in Article 2(1) of Regulation (EU) 2017/745 of the Europen Parliament and of the Council (2017) Official Journal of the European Union L117 p1 – 175. See https://eur-lex.europa.eu/legal-content/EN/TXT/PDF/?uri=CELEX:32017R0745 A CE Mark is a declaration that the product complies with the Essential Requirements of the relevant European Legislation. See articles 13 and 14 of Regulation (EU) 2017/745 above.

[3] Children's Health Ireland at Temple Street Spinal Surgery Programme for Patients with Spina Bifida External Quality Review and Programme Assessment (7 July 2023); Spines Clinical Review Report (May 2023); Children's Health Ireland Report on Spinal Surgery for Patients with Spina Bifida in Children's Health Ireland at Temple Street (8 August 2023).

within CHI across all hospital sites and services, on the use of surgical implants / implantable medical devices, including internal governance processes in meeting regulatory requirements.

The objective of the review will in the first instance be to seek to determine the relevant facts related to use of this equipment in a number of patients, to provide these facts to the Minister for Health and the public. The review will also work to determine the safety, quality and standards of services provided as it relates to the use of surgical implants / implantable medical devices across CHI in order to make recommendations that will eliminate or reduce potential serious risks to the health or welfare of service users and to improve the quality and safety of services in line with the *National Standards for Safer Better Healthcare.* This may include relevant publicly-provided services under contract to CHI, as they relate to sites where services under the scope of the review are provided on behalf of CHI.

Where HIQA identifies gaps in the service and or non-compliance with the *National Standards for Safer Better Healthcare*, it will make recommendations for improvement, which may have local or national applicability.

Recommendations for improvement will reflect current best practice and the future vision for services in line with standards, policy and legislation. The impacts on children and families affected will be considered in line with the scope of this review. It is HIQA's practice to engage with patients and families as part of its standard approach to monitoring against the *National Standards for Safer Better Healthcare*, and it is intended this will occur as part of this review.

These terms of reference have been developed having regard to the request from the Minister dated 4 October 2023. If, in the course of the review, it becomes apparent that there are reasonable grounds to believe that there are wider areas of concern or risks to children receiving services, HIQA may recommend that these terms be extended to include further evaluation or that a new body of work should be undertaken, as appropriate.

If, in the course of the review, potential opportunities for wider system learnings are identified, recommendations may be included aimed at implementing system-wide improvements at a local and or national level.

Scope

The scope of the review – as requested of HIQA by the Minister for Health - is to undertake a review, divided in two phases, as follows:

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

(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.

Governance

HIQA, in line with its functions under section 8(1)(c) of the Health Act 2007 as amended, will carry out this independent statutory review against relevant *National Standards for Safer Better Healthcare*.

In conducting the review, HIQA notes the provisions of section 8(2) of the Health Act 2007, as amended, which apply when it is conducting compliance monitoring pursuant to the Section 8(1)(c) of the Act.

The review will be carried out pursuant to Section 8(1)(c) of the the Health Act 2007 as amended. The review will be conducted by a review team appointed and authorised by HIQA in accordance with Part 9 of the Act. The team will carry out the review and may exercise all of the statutory powers[4] available to HIQA pursuant to the Health Act 2007 as amended. In addition, HIQA may engage the advice of specialist experts as it considers necessary in the undertaking of the review.

In the conduct of this work, HIQA will, where necessary, seek advice and expertise external to HIQA to fully inform the conduct and findings of our work. This may involve the provision of technical advice and support of a subject matter nature. It will also include assistance in the governance oversight element of the review, with external representation on the Programme Board (the oversight board for this review) to be inclusive of a surgeon nominee on behalf of the Royal College of Surgeons in Ireland and a service user representative.

Notwithstanding the input of external expertise to inform the review, the conduct and methodology of this review and its outputs remain the full responsibility of HIQA, and governance oversight and sign off will be provided by the Board of HIQA.

[4] Any powers under the Act may be used in the conduct of the review. This references particularly those powers set out in Part 9 of the Act, including rights of entry, rights to inspect premises, records and/or documents, rights to conduct interviews and rights to require explanations in relation to documents, records or other information.

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.

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