

MINUTES OF THE BOARD MEETING OF THE HEALTH INFORMATION AND QUALITY AUTHORITY

31 October 4.30pm – 6pm Virtual

Present:

Name	Details	Initials
Pat O'Mahony	Chairperson	POM
Marion Meany	Board Member	MM
Martin Higgins	Board Member	MH
Lynsey Perdisatt	Board Member	LP
Paula Kilbane	Board Member	PK
Danny McConnell	Board Member	DMcC
Jim Kiely	Board Member	ЈК
Bernadette Costello	Board Member	BC
Caroline Spillane	Board Member	CS
Martin O'Halloran	Board Member	МОН

In Attendance:

Angela Fitzgerald	CEO	AF
Kathleen Lombard	Board Secretary and Chief Risk Officer	KL

Apologies:

Michael Rigby	Roard Mombor	MJR
Michael Rigby	Board Member	ЛГІЛ

1. Welcome and Quorum

The Chairperson welcomed the Board members to this additional meeting of the Board and introduced Dr Cliona Foley Nolan, who has been appointed to the Board by the Minister. The Chairperson advised that the purpose of the meeting is to consider the Minister's request to conduct an independent review of key processes relevant to concerns in relation to paediatric orthopaedic services in Children's Health Ireland at Temple Street.

A quorum was confirmed and the Board meeting was duly convened.

2. Declarations of Interest

No interests were declared in relation to the topic under discussion.

3. Children's Hospital Ireland – Section 8 review

Sean Egan (SE) Director of Healthcare, Aoife McCann (AMcC) Head of Legal, Gillian Hastings (GH) Statutory Investigations Co-ordinator and Emma Cook (EC) Acting Regional Manager, Healthcare joined the meeting for this item.

AF introduced the item and explained she had received a letter from the Minister requesting an independent review of:

- The end-to-end processes around the use of the non-CE spring implants during spinal surgery in Temple Street Children's Hospital and
- 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.

SE referred the Board to a number of documents circulated in advance of the meeting;

- Proposed Terms of Reference (ToR) for the Section 8 review
- The Quality Assurance Document (QAF) for undertaking Section 8(1)(c) reviews and Section 9 investigations and
- The proposed TOR for the Programme Board whose function will be to provide independent assurance to ensure that the review is carried out in line with its statutory remit, the project plan and the QAF.

SE presented to the Board the background and context leading to the Section 8 request.

Following the presentation, the Board had an in-depth discussion and SE clarified the following points arising:

- HIQA's review will focus on the end-to-end processes around the use of implantable devices whereas the HSE's commissioned review focusses on the clinical care provided by a consultant based at CHI at Temple Street
- HIQA will be cognisant of other external review work and will engage with the HSE where appropriate
- Procurement is one of the processes that is likely to be relevant
- Implications for other paediatric units will be considered where relevant and within the scope of the ToR
- Communication with the families of the patients is important it was confirmed that this has been initiated
- The impact of this project on the remainder of the Healthcare's Directorate business plan will be carefully managed and will be discussed at the next meeting of the Regulation Committee
- It is likely that the duration of the project will be 6 months at a minimum but will depend on what is discovered.

The Board considered that the proposed TOR are appropriate subject to minor amendments suggested during the discussion. JK proposed approval of the ToR and MH seconded the proposal. Accordingly the proposed TOR for the Section 8 Review of the processes around the use of the non-CE spring implants during spinal surgery and the use of surgical implants/implantable medical devices at CHI were approved. It was confirmed that the revised TOR with tracked changes will be circulated to the Board subsequent to the meeting.

4. Quality Assurance Framework (QAF) for undertaking the Review

SE referred the Board to the QAF document which sets out the process for undertaking Section 8 reviews and Section 9 statutory investigations. He advised that the QAF had recently been updated to reflect learning from previous investigations and reviews and is now before the Board for approval.

The Board considered the QAF document and indicated their agreement. POM proposed approval of the QAF for undertaking Section 8(1)(c) and Section 9 reviews and investigations and MOH seconded the proposal. Accordingly, the QAF as presented was approved.

5. Section 8 Programme Board ToR

SE referred the Board to the Terms of Reference (TOR) for the Programme Board which will be the assurance mechanism for ensuring that the work on the Section 8 Review is carried out in line with the legislation, the TOR for the review and the QAF.

The Board discussed the governance arrangements in detail and the following points were made:

- There are a number of management processes that will be subject to review such as procurement/decontamination/peri-operative processes and this will inform the choice of subject matter expert/s
- Ensuring conflicts of interests are effectively managed and
- Sourcing an independent service user representative.

SE confirmed that the observations of the Board will be reflected when finalising the membership of the Programme Board.

The Board considered the ToR for the Programme Board; CFN proposed approval of the ToR and CS seconded the proposal; **accordingly the TOR for the Programme Board as presented was approved.**

It was agreed that an update will be provided at the next Regulation Committee and reported through to the Board.

6. Committee membership

KL reminded the Board that at the September meeting of the Board, the Committee memberships were reviewed. It had been indicated that depending on the expertise of the incoming Board member that the Regulation Committee and the SIRT committee both needed an additional member. With the appointment of Cliona Foley Nolan to the Board, KL sought approval for her appointment to both Committees. The Board unanimously agreed the appointment and **accordingly CFN will become a member**

of Regulation Committee and the SIRT committee from this date for a period of three years.

7. Any other Business

POM thanked everyone for making themselves available at short notice for the meeting and for their contributions during the meeting. There being no further business, the meeting was closed.

Signed:

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Pat O'Mahony Chairperson

Kathleen Lombard Board Secretary

Actions arising from Board meeting on 31 October 2023

No	Action	Person Responsible	Time-frame
1	The revised TOR for the review with tracked changes to be circulated to the Board subsequent to the meeting.	SE	Within a week
2	Observations of the Board to be reflected when finalising the membership of the Programme Board.	SE	At appropriate time